Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nivolumab 240 mg/Relatlimab 80 mg
(Opdualag® 240 mg/80 mg)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 A

Anhang 4-G

Erstlinienbehandlung des fortgeschrittenen Melanoms mit Tumorzell-PD-L1-Expression < 1 % bei Erwachsenen und Jugendlichen

Ergänzende Analysen

Stand: 28.05.2026

Modul 4A – Anhang 4-G - Ergänzende Analysen der Studie RELATIVITY-047

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Anhang 4-G 1: Beobachtungsdauer auf Endpunktebene

Anhang 4-G 1.1: OS

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Table 3.2.1
Observation Period for Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187	Nivolumab N = 201
DURATION OF STUDY OBSERVATION (MONTHS)		
N	187	201
MEAN	42.39	36.37
MEDIAN	36.96	25.23
MIN, MAX	1.2, 87.3	0.3, 87.6
Q1, Q3	10.7, 79.7	9.1, 65.0
SD	32.022	30.469
OTHER STATISTICS		
>= 3 MONTHS (%)	173 (92.5)	182 (90.5)
>= 6 MONTHS (%)	159 (85.0)	162 (80.6)
>= 9 MONTHS (%)	147 (78.6)	151 (75.1)
>= 12 MONTHS (%)	136 (72.7)	133 (66.2)
>= 15 MONTHS (%)	129 (69.0)	121 (60.2)
>= 18 MONTHS (%)	119 (63.6)	113 (56.2)
>= 21 MONTHS (%)	110 (58.8)	108 (53.7)
>= 24 MONTHS (%)	104 (55.6)	103 (51.2)
>= 27 MONTHS (%)	101 (54.0)	96 (47.8)
>= 30 MONTHS (%)	99 (52.9)	91 (45.3)
>= 33 MONTHS (%)	97 (51.9)	89 (44.3)
>= 36 MONTHS (%)	94 (50.3)	87 (43.3)
>= 39 MONTHS (%)	90 (48.1)	86 (42.8)
>= 42 MONTHS (%)	89 (47.6)	85 (42.3)
>= 45 MONTHS (%)	88 (47.1)	81 (40.3)
>= 48 MONTHS (%)	88 (47.1)	77 (38.3)
>= 51 MONTHS (%)	86 (46.0)	73 (36.3)
>= 54 MONTHS (%)	85 (45.5)	71 (35.3)
>= 57 MONTHS (%)	83 (44.4)	68 (33.8)
>= 60 MONTHS (%)	76 (40.6)	58 (28.9)

NOV 2025 DBL.
The duration of observation for Overall Survival is the time from the randomization date to the last known alive date (for subjects who are alive) or death (for subjects who died).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-obs-ebr2586_b5.sas 11FEB2026:05:23:54

Anhang 4-G 1.2: EQ-5D-VAS

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Table 3.3.3
Observation Period for EQ-5D VAS
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187	Nivolumab N = 201
DURATION OF STUDY OBSERVATION (MONTHS)		
N	187	201
MEAN	36.89	29.32
MEDIAN	26.22	14.82
MIN, MAX	0.0, 86.4	0.0, 83.5
Q1, Q3	6.0, 70.3	4.4, 56.7
SD	31.790	28.986
OTHER STATISTICS		
>= 3 MONTHS (%)	157 (84.0)	161 (80.1)
>= 6 MONTHS (%)	142 (75.9)	143 (71.1)
>= 9 MONTHS (%)	131 (70.1)	123 (61.2)
>= 12 MONTHS (%)	119 (63.6)	109 (54.2)
>= 15 MONTHS (%)	108 (57.8)	100 (49.8)
>= 18 MONTHS (%)	100 (53.5)	97 (48.3)
>= 21 MONTHS (%)	99 (52.9)	90 (44.8)
>= 24 MONTHS (%)	96 (51.3)	84 (41.8)
>= 27 MONTHS (%)	93 (49.7)	79 (39.3)
>= 30 MONTHS (%)	91 (48.7)	76 (37.8)
>= 33 MONTHS (%)	88 (47.1)	72 (35.8)
>= 36 MONTHS (%)	84 (44.9)	72 (35.8)
>= 39 MONTHS (%)	82 (43.9)	72 (35.8)
>= 42 MONTHS (%)	81 (43.3)	65 (32.3)
>= 45 MONTHS (%)	80 (42.8)	63 (31.3)
>= 48 MONTHS (%)	78 (41.7)	58 (28.9)
>= 51 MONTHS (%)	74 (39.6)	56 (27.9)
>= 54 MONTHS (%)	70 (37.4)	54 (26.9)
>= 57 MONTHS (%)	68 (36.4)	50 (24.9)
>= 60 MONTHS (%)	63 (33.7)	45 (22.4)

NOV 2025 DBL.
The duration of observation for the EQ-5D VAS is the time from randomization date to the last timepoint when the EQ-5D VAS was completed.
The EQ-5D VAS is considered as completed if its value is non-missing.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-obs-ebr2586_b5.sas 11FEB2026:05:24:00

Anhang 4-G 1.3: FACT-M

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Table 3.3.1
Observation Period for FACT-M Overall Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187	Nivolumab N = 201
DURATION OF STUDY OBSERVATION (MONTHS)		
N	187	201
MEAN	19.89	18.58
MEDIAN	12.16	8.44
MIN, MAX	0.0, 83.7	0.0, 82.8
Q1, Q3	4.9, 29.1	3.8, 26.0
SD	20.633	20.994
OTHER STATISTICS		
>= 3 MONTHS (%)	155 (82.9)	159 (79.1)
>= 6 MONTHS (%)	130 (69.5)	131 (65.2)
>= 9 MONTHS (%)	104 (55.6)	98 (48.8)
>= 12 MONTHS (%)	94 (50.3)	83 (41.3)
>= 15 MONTHS (%)	80 (42.8)	76 (37.8)
>= 18 MONTHS (%)	69 (36.9)	72 (35.8)
>= 21 MONTHS (%)	65 (34.8)	64 (31.8)
>= 24 MONTHS (%)	57 (30.5)	55 (27.4)
>= 27 MONTHS (%)	53 (28.3)	49 (24.4)
>= 30 MONTHS (%)	45 (24.1)	47 (23.4)
>= 33 MONTHS (%)	41 (21.9)	40 (19.9)
>= 36 MONTHS (%)	35 (18.7)	38 (18.9)
>= 39 MONTHS (%)	29 (15.5)	37 (18.4)
>= 42 MONTHS (%)	26 (13.9)	29 (14.4)
>= 45 MONTHS (%)	23 (12.3)	26 (12.9)
>= 48 MONTHS (%)	22 (11.8)	20 (10.0)
>= 51 MONTHS (%)	20 (10.7)	20 (10.0)
>= 54 MONTHS (%)	19 (10.2)	18 (9.0)
>= 57 MONTHS (%)	16 (8.6)	17 (8.5)
>= 60 MONTHS (%)	14 (7.5)	14 (7.0)

NOV 2025 DBL.
The duration of observation for the FACT-M Overall Questionnaire is the time from randomization date to the last timepoint when the FACT-M Overall Questionnaire was completed.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-obs-ebr2586_b5.sas 11FEB2026:05:23:56

Anhang 4-G 1.4: UE

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Table 3.4.1
Observation Period for Adverse Events
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187	Nivolumab N = 201
DURATION OF STUDY OBSERVATION (MONTHS)		
N	187	201
MEAN	18.11	17.90
MEDIAN	7.95	8.31
MIN, MAX	1.2, 84.1	0.3, 83.5
Q1, Q3	5.2, 24.0	5.2, 23.1
SD	20.281	20.308
OTHER STATISTICS		
>= 3 MONTHS (%)	173 (92.5)	182 (90.5)
>= 6 MONTHS (%)	128 (68.4)	138 (68.7)
>= 9 MONTHS (%)	89 (47.6)	91 (45.3)
>= 12 MONTHS (%)	78 (41.7)	76 (37.8)
>= 15 MONTHS (%)	67 (35.8)	70 (34.8)
>= 18 MONTHS (%)	57 (30.5)	62 (30.8)
>= 21 MONTHS (%)	49 (26.2)	56 (27.9)
>= 24 MONTHS (%)	46 (24.6)	49 (24.4)
>= 27 MONTHS (%)	39 (20.9)	43 (21.4)
>= 30 MONTHS (%)	35 (18.7)	39 (19.4)
>= 33 MONTHS (%)	33 (17.6)	34 (16.9)
>= 36 MONTHS (%)	30 (16.0)	32 (15.9)
>= 39 MONTHS (%)	27 (14.4)	32 (15.9)
>= 42 MONTHS (%)	25 (13.4)	30 (14.9)
>= 45 MONTHS (%)	23 (12.3)	25 (12.4)
>= 48 MONTHS (%)	21 (11.2)	20 (10.0)
>= 51 MONTHS (%)	19 (10.2)	18 (9.0)
>= 54 MONTHS (%)	19 (10.2)	17 (8.5)
>= 57 MONTHS (%)	17 (9.1)	16 (8.0)
>= 60 MONTHS (%)	15 (8.0)	13 (6.5)

NOV 2025 DBL.
The duration of observation for the Adverse Events is the time from first dose date to 100 after last dose of study therapy, last known alive date or data cutoff date, whichever comes first.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-obs-ebr2586_b5.sas 11FEB2026:05:24:02

Anhang 4-G 2: Antineoplastische Folgetherapien: Jegliche systemische Folgetherapien

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Table 2.2.1
Full Subsequent Cancer Therapy Summary
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects (%)	
	BMS-986213 N = 187	Nivolumab N = 201
SUBJECTS WITH ANY SUBSEQUENT THERAPY (%) (1)	104 (55.6)	102 (50.7)
SUBJECTS WHO RECEIVED SUBSEQUENT RADIOTHERAPY (%)	27 (14.4)	24 (11.9)
SUBJECTS WHO RECEIVED SUBSEQUENT SURGERY (%)	16 (8.6)	18 (9.0)
SUBJECTS WHO RECEIVED SUBSEQUENT SYSTEMIC THERAPY (%)	89 (47.6)	92 (45.8)
SUBSEQUENT SYSTEMIC THERAPY		
PD1/CTLA4 INHIBITORS	41 (21.9)	43 (21.4)
AVELUMAB	0	1 (0.5)
BMS 986218	1 (0.5)	1 (0.5)
CEMIPLIMAB	0	1 (0.5)
DURVALUMAB	0	2 (1.0)
IPILIMUMAB	10 (5.3)	12 (6.0)
IPILIMUMAB;NIVOLUMAB	17 (9.1)	21 (10.4)
NIVOLUMAB	11 (5.9)	15 (7.5)
PEMBROLIZUMAB	6 (3.2)	6 (3.0)
PEMBROLIZUMAB;QUAVONLIMAB	1 (0.5)	0
PEMBROLIZUMAB;TALIMOGENE LAHERPAREPVEC	2 (1.1)	1 (0.5)
QUAVONLIMAB	1 (0.5)	0
TARGETED BRAF/MEK MONO AND COMBO	33 (17.6)	37 (18.4)
BINIMETINIB;BINIMETINIB;ENCORAFENIB	1 (0.5)	0
BINIMETINIB;ENCORAFENIB	13 (7.0)	16 (8.0)
COBIMETINIB;VEMURAFENIB	1 (0.5)	2 (1.0)
DABRAFENIB	1 (0.5)	0

NOV 2025 DBL.
(1) In this analysis, subsequent therapy is defined as therapy received after study treatment was discontinued (or after randomization date, if a subject was never treated). A subject may have received more than one subsequent treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ct-futherapy1-ebr2586_b5.sas 19FEB2026:07:05:03

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Table 2.2.1
Full Subsequent Cancer Therapy Summary
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects (%)	
	BMS-986213 N = 187	Nivolumab N = 201
DABRAFENIB MESILATE	1 (0.5)	0
DABRAFENIB MESILATE;TRAMETINIB DIMETHYL SULFOXIDE	2 (1.1)	1 (0.5)
DABRAFENIB;TRAMETINIB	17 (9.1)	24 (11.9)
TRAMETINIB DIMETHYL SULFOXIDE	1 (0.5)	1 (0.5)
VEMURAFENIB	0	1 (0.5)
OTHER	36 (19.3)	47 (23.4)
ANTINEOPLASTIC AGENTS	4 (2.1)	1 (0.5)
AZACITIDINE	0	1 (0.5)
CARBOPLATIN	0	1 (0.5)
CARBOPLATIN;DACARBAZINE	0	1 (0.5)
CARBOPLATIN;PACLITAXEL	5 (2.7)	7 (3.5)
CERALASERTIB	0	1 (0.5)
CISPLATIN;DACARBAZINE	1 (0.5)	1 (0.5)
CISPLATIN;DACARBAZINE;VINBLASTINE	0	1 (0.5)
COMBINATIONS OF ANTINEOPLASTIC AGENTS	1 (0.5)	4 (2.0)
CV 8102	0	1 (0.5)
DACARBAZINE	9 (4.8)	14 (7.0)
DACARBAZINE CITRATE	1 (0.5)	1 (0.5)
DACARBAZINE;DOXORUBICIN	0	1 (0.5)
DENOSUMAB	1 (0.5)	0
ENTRECTINIB	1 (0.5)	0
FOTEMUSTINE	0	1 (0.5)
IMATINIB	2 (1.1)	0
INVESTIGATIONAL ANTINEOPLASTIC DRUGS	10 (5.3)	11 (5.5)

NOV 2025 DBL.
(1) In this analysis, subsequent therapy is defined as therapy received after study treatment was discontinued (or after randomization date, if a subject was never treated). A subject may have received more than one subsequent treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ct-futherapy1-ebr2586_b5.sas 19FEB2026:07:05:03

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Table 2.2.1
Full Subsequent Cancer Therapy Summary
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects (%)	
	BMS-986213 N = 187	Nivolumab N = 201
INVESTIGATIONAL DRUG	0	1 (0.5)
LOMUSTINE;TEMOZOLOMIDE;VINCRISTINE	1 (0.5)	0
MEDI 1191	0	1 (0.5)
MELANOMA VACCINE	1 (0.5)	1 (0.5)
NEMVALEUKIN ALFA	1 (0.5)	0
OTHER ANTINEOPLASTIC AGENTS	1 (0.5)	2 (1.0)
PACLITAXEL	1 (0.5)	4 (2.0)
TALIMOGENE LAHERPAREPVEC	2 (1.1)	2 (1.0)
TEMOZOLOMIDE	2 (1.1)	4 (2.0)
TUMOR-INFILTRATING LYMPHOCYTES	0	1 (0.5)
VINBLASTINE	1 (0.5)	1 (0.5)

NOV 2025 DBL.
(1) In this analysis, subsequent therapy is defined as therapy received after study treatment was discontinued (or after randomization date, if a subject was never treated). A subject may have received more than one subsequent treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ct-futherapy1-ebr2586_b5.sas 19FEB2026:07:05:03

Anhang 4-G 3: Rücklaufquoten für alle Fragebögen

Anhang 4-G 3.1: EQ-5D-VAS

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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
NUMBER OF SUBJECTS WITH BASELINE AND >=1 POST BASELINE VALUE (b)	174/187 (93.0)	183/201 (91.0)	357/388 (92.0)
NUMBER OF SUBJECTS WITHOUT BASELINE VALUE (b)	6/187 (3.2)	5/201 (2.5)	11/388 (2.8)
NUMBER OF SUBJECTS WITHOUT POST BASELINE VALUE (b)	7/187 (3.7)	13/201 (6.5)	20/388 (5.2)
TIMEPOINT			
WEEK 1 (BASELINE)	181/187 (96.8)	196/201 (97.5)	377/388 (97.2)
ON-STUDY			
WEEK 4	159/175 (90.9)	165/184 (89.7)	324/359 (90.3)
WEEK 8	144/156 (92.3)	149/168 (88.7)	293/324 (90.4)
WEEK 12	131/137 (95.6)	136/149 (91.3)	267/286 (93.4)
WEEK 16	111/115 (96.5)	128/131 (97.7)	239/246 (97.2)

NOV 2025 DBL.
The EQ-5D VAS is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:12

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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 20	97/103 (94.2)	107/112 (95.5)	204/215 (94.9)
WEEK 24	91/ 94 (96.8)	91/100 (91.0)	182/194 (93.8)
WEEK 28	79/ 88 (89.8)	86/ 92 (93.5)	165/180 (91.7)
WEEK 32	75/ 85 (88.2)	84/ 86 (97.7)	159/171 (93.0)
WEEK 36	79/ 84 (94.0)	73/ 79 (92.4)	152/163 (93.3)
WEEK 40	74/ 78 (94.9)	74/ 76 (97.4)	148/154 (96.1)
WEEK 44	70/ 73 (95.9)	70/ 74 (94.6)	140/147 (95.2)
WEEK 48	66/ 72 (91.7)	68/ 72 (94.4)	134/144 (93.1)
WEEK 52	65/ 68 (95.6)	63/ 70 (90.0)	128/138 (92.8)
WEEK 56	59/ 63 (93.7)	60/ 67 (89.6)	119/130 (91.5)
WEEK 60	56/ 61 (91.8)	62/ 65 (95.4)	118/126 (93.7)
WEEK 64	58/ 60 (96.7)	60/ 63 (95.2)	118/123 (95.9)
WEEK 68	56/ 57 (98.2)	53/ 61 (86.9)	109/118 (92.4)
WEEK 72	49/ 54 (90.7)	56/ 59 (94.9)	105/113 (92.9)
WEEK 76	51/ 54 (94.4)	50/ 57 (87.7)	101/111 (91.0)
WEEK 80	45/ 49 (91.8)	49/ 56 (87.5)	94/105 (89.5)
WEEK 84	44/ 48 (91.7)	51/ 56 (91.1)	95/104 (91.3)
WEEK 88	40/ 47 (85.1)	48/ 52 (92.3)	88/ 99 (88.9)
WEEK 92	43/ 46 (93.5)	45/ 50 (90.0)	88/ 96 (91.7)
WEEK 96	42/ 45 (93.3)	45/ 49 (91.8)	87/ 94 (92.6)

NOV 2025 DBL.
The EQ-5D VAS is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:12

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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 100	40/ 42 (95.2)	40/ 44 (90.9)	80/ 86 (93.0)
WEEK 104	34/ 39 (87.2)	40/ 43 (93.0)	74/ 82 (90.2)
WEEK 108	34/ 38 (89.5)	42/ 43 (97.7)	76/ 81 (93.8)
WEEK 112	32/ 36 (88.9)	38/ 41 (92.7)	70/ 77 (90.9)
WEEK 116	34/ 36 (94.4)	39/ 40 (97.5)	73/ 76 (96.1)
WEEK 120	32/ 35 (91.4)	39/ 39 (100.0)	71/ 74 (95.9)
WEEK 124	34/ 35 (97.1)	35/ 37 (94.6)	69/ 72 (95.8)
WEEK 128	31/ 33 (93.9)	35/ 37 (94.6)	66/ 70 (94.3)
WEEK 132	32/ 33 (97.0)	31/ 34 (91.2)	63/ 67 (94.0)
WEEK 136	32/ 32 (100.0)	31/ 34 (91.2)	63/ 66 (95.5)
WEEK 140	28/ 30 (93.3)	29/ 33 (87.9)	57/ 63 (90.5)
WEEK 144	28/ 30 (93.3)	30/ 32 (93.8)	58/ 62 (93.5)
WEEK 148	26/ 29 (89.7)	28/ 32 (87.5)	54/ 61 (88.5)
WEEK 152	26/ 28 (92.9)	28/ 32 (87.5)	54/ 60 (90.0)
WEEK 156	26/ 27 (96.3)	27/ 32 (84.4)	53/ 59 (89.8)
WEEK 160	24/ 26 (92.3)	28/ 31 (90.3)	52/ 57 (91.2)
WEEK 164	24/ 26 (92.3)	29/ 31 (93.5)	53/ 57 (93.0)
WEEK 168	21/ 26 (80.8)	31/ 31 (100.0)	52/ 57 (91.2)
WEEK 172	22/ 25 (88.0)	29/ 30 (96.7)	51/ 55 (92.7)
WEEK 176	21/ 25 (84.0)	27/ 29 (93.1)	48/ 54 (88.9)

NOV 2025 DBL.
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(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 180	22/ 23 (95.7)	28/ 29 (96.6)	50/ 52 (96.2)
WEEK 184	22/ 23 (95.7)	24/ 24 (100.0)	46/ 47 (97.9)
WEEK 188	22/ 23 (95.7)	22/ 23 (95.7)	44/ 46 (95.7)
WEEK 192	22/ 23 (95.7)	20/ 23 (87.0)	42/ 46 (91.3)
WEEK 196	19/ 21 (90.5)	18/ 20 (90.0)	37/ 41 (90.2)
WEEK 200	17/ 19 (89.5)	19/ 20 (95.0)	36/ 39 (92.3)
WEEK 204	19/ 19 (100.0)	16/ 19 (84.2)	35/ 38 (92.1)
WEEK 208	18/ 19 (94.7)	18/ 18 (100.0)	36/ 37 (97.3)
WEEK 212	19/ 19 (100.0)	17/ 18 (94.4)	36/ 37 (97.3)
WEEK 216	17/ 19 (89.5)	18/ 18 (100.0)	35/ 37 (94.6)
WEEK 220	17/ 19 (89.5)	16/ 17 (94.1)	33/ 36 (91.7)
WEEK 224	17/ 18 (94.4)	16/ 17 (94.1)	33/ 35 (94.3)
WEEK 228	16/ 18 (88.9)	16/ 17 (94.1)	32/ 35 (91.4)
WEEK 232	16/ 17 (94.1)	15/ 16 (93.8)	31/ 33 (93.9)
WEEK 236	15/ 17 (88.2)	16/ 16 (100.0)	31/ 33 (93.9)
WEEK 240	14/ 17 (82.4)	14/ 16 (87.5)	28/ 33 (84.8)
WEEK 244	16/ 17 (94.1)	14/ 16 (87.5)	30/ 33 (90.9)
WEEK 248	12/ 17 (70.6)	14/ 15 (93.3)	26/ 32 (81.3)
WEEK 252	15/ 17 (88.2)	11/ 14 (78.6)	26/ 31 (83.9)
WEEK 256	15/ 16 (93.8)	13/ 14 (92.9)	28/ 30 (93.3)

NOV 2025 DBL.
The EQ-5D VAS is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:12

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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 260	14/ 16 (87.5)	12/ 14 (85.7)	26/ 30 (86.7)
WEEK 264	11/ 13 (84.6)	12/ 12 (100.0)	23/ 25 (92.0)
WEEK 268	9/ 13 (69.2)	11/ 12 (91.7)	20/ 25 (80.0)
WEEK 272	11/ 13 (84.6)	11/ 11 (100.0)	22/ 24 (91.7)
WEEK 276	11/ 13 (84.6)	11/ 11 (100.0)	22/ 24 (91.7)
WEEK 280	12/ 13 (92.3)	9/ 11 (81.8)	21/ 24 (87.5)
WEEK 284	11/ 12 (91.7)	8/ 11 (72.7)	19/ 23 (82.6)
WEEK 288	10/ 12 (83.3)	7/ 9 (77.8)	17/ 21 (81.0)
WEEK 292	10/ 12 (83.3)	7/ 8 (87.5)	17/ 20 (85.0)
WEEK 296	9/ 11 (81.8)	8/ 8 (100.0)	17/ 19 (89.5)
WEEK 300	6/ 11 (54.5)	8/ 8 (100.0)	14/ 19 (73.7)
WEEK 304	6/ 6 (100.0)	7/ 7 (100.0)	13/ 13 (100.0)
WEEK 308	4/ 4 (100.0)	7/ 7 (100.0)	11/ 11 (100.0)
WEEK 312	4/ 4 (100.0)	6/ 7 (85.7)	10/ 11 (90.9)
WEEK 316	4/ 4 (100.0)	7/ 7 (100.0)	11/ 11 (100.0)
WEEK 320	3/ 4 (75.0)	7/ 7 (100.0)	10/ 11 (90.9)
WEEK 324	3/ 4 (75.0)	7/ 7 (100.0)	10/ 11 (90.9)
WEEK 328	4/ 4 (100.0)	7/ 7 (100.0)	11/ 11 (100.0)
WEEK 332	4/ 4 (100.0)	6/ 7 (85.7)	10/ 11 (90.9)
WEEK 336	4/ 4 (100.0)	6/ 7 (85.7)	10/ 11 (90.9)

NOV 2025 DBL.
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(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
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Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 340	4/ 4 (100.0)	5/ 7 (71.4)	9/ 11 (81.8)
WEEK 344	4/ 4 (100.0)	5/ 6 (83.3)	9/ 10 (90.0)
WEEK 348	3/ 3 (100.0)	4/ 5 (80.0)	7/ 8 (87.5)
WEEK 352	3/ 3 (100.0)	3/ 5 (60.0)	6/ 8 (75.0)
WEEK 356	3/ 3 (100.0)	2/ 3 (66.7)	5/ 6 (83.3)
WEEK 360	2/ 2 (100.0)	1/ 1 (100.0)	3/ 3 (100.0)
WEEK 364	1/ 2 (50.0)	0/ 1	1/ 3 (33.3)
FOLLOW-UP			
FOLLOW-UP 1	122/171 (71.3)	131/189 (69.3)	253/360 (70.3)
FOLLOW-UP 2	94/141 (66.7)	94/153 (61.4)	188/294 (63.9)
SURVIVAL FOLLOW-UP			
SURVIVAL FOLLOW-UP 1	83/127 (65.4)	77/128 (60.2)	160/255 (62.7)
SURVIVAL FOLLOW-UP 2	70/112 (62.5)	55/111 (49.5)	125/223 (56.1)
SURVIVAL FOLLOW-UP 3	61/ 96 (63.5)	57/ 94 (60.6)	118/190 (62.1)
SURVIVAL FOLLOW-UP 4	63/ 90 (70.0)	46/ 89 (51.7)	109/179 (60.9)
SURVIVAL FOLLOW-UP 5	56/ 86 (65.1)	47/ 81 (58.0)	103/167 (61.7)
SURVIVAL FOLLOW-UP 6	51/ 77 (66.2)	43/ 73 (58.9)	94/150 (62.7)
SURVIVAL FOLLOW-UP 7	53/ 72 (73.6)	43/ 70 (61.4)	96/142 (67.6)

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(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:12

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Table 11.8
EQ-5D VAS Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
SURVIVAL FOLLOW-UP 8	50/ 71 (70.4)	35/ 63 (55.6)	85/134 (63.4)
SURVIVAL FOLLOW-UP 9	49/ 70 (70.0)	32/ 60 (53.3)	81/130 (62.3)
SURVIVAL FOLLOW-UP 10	44/ 68 (64.7)	25/ 57 (43.9)	69/125 (55.2)
SURVIVAL FOLLOW-UP 11	40/ 66 (60.6)	26/ 53 (49.1)	66/119 (55.5)
SURVIVAL FOLLOW-UP 12	36/ 59 (61.0)	25/ 49 (51.0)	61/108 (56.5)
SURVIVAL FOLLOW-UP 13	39/ 57 (68.4)	17/ 44 (38.6)	56/101 (55.4)
SURVIVAL FOLLOW-UP 14	35/ 55 (63.6)	19/ 36 (52.8)	54/ 91 (59.3)
SURVIVAL FOLLOW-UP 15	34/ 53 (64.2)	16/ 32 (50.0)	50/ 85 (58.8)
SURVIVAL FOLLOW-UP 16	31/ 47 (66.0)	18/ 31 (58.1)	49/ 78 (62.8)
SURVIVAL FOLLOW-UP 17	27/ 46 (58.7)	19/ 30 (63.3)	46/ 76 (60.5)
SURVIVAL FOLLOW-UP 18	26/ 41 (63.4)	15/ 26 (57.7)	41/ 67 (61.2)
SURVIVAL FOLLOW-UP 19	21/ 38 (55.3)	10/ 23 (43.5)	31/ 61 (50.8)
SURVIVAL FOLLOW-UP 20	22/ 35 (62.9)	13/ 20 (65.0)	35/ 55 (63.6)
SURVIVAL FOLLOW-UP 21	19/ 31 (61.3)	11/ 18 (61.1)	30/ 49 (61.2)
SURVIVAL FOLLOW-UP 22	17/ 29 (58.6)	7/ 18 (38.9)	24/ 47 (51.1)
SURVIVAL FOLLOW-UP 23	17/ 28 (60.7)	8/ 15 (53.3)	25/ 43 (58.1)
SURVIVAL FOLLOW-UP 24	14/ 25 (56.0)	6/ 11 (54.5)	20/ 36 (55.6)
SURVIVAL FOLLOW-UP 25	10/ 20 (50.0)	3/ 5 (60.0)	13/ 25 (52.0)
SURVIVAL FOLLOW-UP 26	5/ 13 (38.5)	1/ 3 (33.3)	6/ 16 (37.5)
SURVIVAL FOLLOW-UP 27	1/ 4 (25.0)	N.A.	1/ 4 (25.0)

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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
NUMBER OF SUBJECTS WITH BASELINE AND >=1 POST BASELINE VALUE	174/187 (93.0)	183/201 (91.0)	357/388 (92.0)
NUMBER OF SUBJECTS WITHOUT BASELINE VALUE	6/187 (3.2)	5/201 (2.5)	11/388 (2.8)
NUMBER OF SUBJECTS WITHOUT POST BASELINE VALUE	7/187 (3.7)	13/201 (6.5)	20/388 (5.2)
TIMEPOINT			
WEEK 1 (BASELINE)	181/187 (96.8)	196/201 (97.5)	377/388 (97.2)
ON-STUDY			
WEEK 4	159/187 (85.0)	165/201 (82.1)	324/388 (83.5)
WEEK 8	144/187 (77.0)	149/201 (74.1)	293/388 (75.5)
WEEK 12	131/187 (70.1)	136/201 (67.7)	267/388 (68.8)
WEEK 16	111/187 (59.4)	128/201 (63.7)	239/388 (61.6)

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Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 20	97/187 (51.9)	107/201 (53.2)	204/388 (52.6)
WEEK 24	91/187 (48.7)	91/201 (45.3)	182/388 (46.9)
WEEK 28	79/187 (42.2)	86/201 (42.8)	165/388 (42.5)
WEEK 32	75/187 (40.1)	84/201 (41.8)	159/388 (41.0)
WEEK 36	79/187 (42.2)	73/201 (36.3)	152/388 (39.2)
WEEK 40	74/187 (39.6)	74/201 (36.8)	148/388 (38.1)
WEEK 44	70/187 (37.4)	70/201 (34.8)	140/388 (36.1)
WEEK 48	66/187 (35.3)	68/201 (33.8)	134/388 (34.5)
WEEK 52	65/187 (34.8)	63/201 (31.3)	128/388 (33.0)
WEEK 56	59/187 (31.6)	60/201 (29.9)	119/388 (30.7)
WEEK 60	56/187 (29.9)	62/201 (30.8)	118/388 (30.4)
WEEK 64	58/187 (31.0)	60/201 (29.9)	118/388 (30.4)
WEEK 68	56/187 (29.9)	53/201 (26.4)	109/388 (28.1)
WEEK 72	49/187 (26.2)	56/201 (27.9)	105/388 (27.1)
WEEK 76	51/187 (27.3)	50/201 (24.9)	101/388 (26.0)
WEEK 80	45/187 (24.1)	49/201 (24.4)	94/388 (24.2)
WEEK 84	44/187 (23.5)	51/201 (25.4)	95/388 (24.5)
WEEK 88	40/187 (21.4)	48/201 (23.9)	88/388 (22.7)
WEEK 92	43/187 (23.0)	45/201 (22.4)	88/388 (22.7)
WEEK 96	42/187 (22.5)	45/201 (22.4)	87/388 (22.4)

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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 100	40/187 (21.4)	40/201 (19.9)	80/388 (20.6)
WEEK 104	34/187 (18.2)	40/201 (19.9)	74/388 (19.1)
WEEK 108	34/187 (18.2)	42/201 (20.9)	76/388 (19.6)
WEEK 112	32/187 (17.1)	38/201 (18.9)	70/388 (18.0)
WEEK 116	34/187 (18.2)	39/201 (19.4)	73/388 (18.8)
WEEK 120	32/187 (17.1)	39/201 (19.4)	71/388 (18.3)
WEEK 124	34/187 (18.2)	35/201 (17.4)	69/388 (17.8)
WEEK 128	31/187 (16.6)	35/201 (17.4)	66/388 (17.0)
WEEK 132	32/187 (17.1)	31/201 (15.4)	63/388 (16.2)
WEEK 136	32/187 (17.1)	31/201 (15.4)	63/388 (16.2)
WEEK 140	28/187 (15.0)	29/201 (14.4)	57/388 (14.7)
WEEK 144	28/187 (15.0)	30/201 (14.9)	58/388 (14.9)
WEEK 148	26/187 (13.9)	28/201 (13.9)	54/388 (13.9)
WEEK 152	26/187 (13.9)	28/201 (13.9)	54/388 (13.9)
WEEK 156	26/187 (13.9)	27/201 (13.4)	53/388 (13.7)
WEEK 160	24/187 (12.8)	28/201 (13.9)	52/388 (13.4)
WEEK 164	24/187 (12.8)	29/201 (14.4)	53/388 (13.7)
WEEK 168	21/187 (11.2)	31/201 (15.4)	52/388 (13.4)
WEEK 172	22/187 (11.8)	29/201 (14.4)	51/388 (13.1)
WEEK 176	21/187 (11.2)	27/201 (13.4)	48/388 (12.4)

NOV 2025 DBL.
The EQ-5D VAS is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 180	22/187 (11.8)	28/201 (13.9)	50/388 (12.9)
WEEK 184	22/187 (11.8)	24/201 (11.9)	46/388 (11.9)
WEEK 188	22/187 (11.8)	22/201 (10.9)	44/388 (11.3)
WEEK 192	22/187 (11.8)	20/201 (10.0)	42/388 (10.8)
WEEK 196	19/187 (10.2)	18/201 (9.0)	37/388 (9.5)
WEEK 200	17/187 (9.1)	19/201 (9.5)	36/388 (9.3)
WEEK 204	19/187 (10.2)	16/201 (8.0)	35/388 (9.0)
WEEK 208	18/187 (9.6)	18/201 (9.0)	36/388 (9.3)
WEEK 212	19/187 (10.2)	17/201 (8.5)	36/388 (9.3)
WEEK 216	17/187 (9.1)	18/201 (9.0)	35/388 (9.0)
WEEK 220	17/187 (9.1)	16/201 (8.0)	33/388 (8.5)
WEEK 224	17/187 (9.1)	16/201 (8.0)	33/388 (8.5)
WEEK 228	16/187 (8.6)	16/201 (8.0)	32/388 (8.2)
WEEK 232	16/187 (8.6)	15/201 (7.5)	31/388 (8.0)
WEEK 236	15/187 (8.0)	16/201 (8.0)	31/388 (8.0)
WEEK 240	14/187 (7.5)	14/201 (7.0)	28/388 (7.2)
WEEK 244	16/187 (8.6)	14/201 (7.0)	30/388 (7.7)
WEEK 248	12/187 (6.4)	14/201 (7.0)	26/388 (6.7)
WEEK 252	15/187 (8.0)	11/201 (5.5)	26/388 (6.7)
WEEK 256	15/187 (8.0)	13/201 (6.5)	28/388 (7.2)

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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 260	14/187 (7.5)	12/201 (6.0)	26/388 (6.7)
WEEK 264	11/187 (5.9)	12/201 (6.0)	23/388 (5.9)
WEEK 268	9/187 (4.8)	11/201 (5.5)	20/388 (5.2)
WEEK 272	11/187 (5.9)	11/201 (5.5)	22/388 (5.7)
WEEK 276	11/187 (5.9)	11/201 (5.5)	22/388 (5.7)
WEEK 280	12/187 (6.4)	9/201 (4.5)	21/388 (5.4)
WEEK 284	11/187 (5.9)	8/201 (4.0)	19/388 (4.9)
WEEK 288	10/187 (5.3)	7/201 (3.5)	17/388 (4.4)
WEEK 292	10/187 (5.3)	7/201 (3.5)	17/388 (4.4)
WEEK 296	9/187 (4.8)	8/201 (4.0)	17/388 (4.4)
WEEK 300	6/187 (3.2)	8/201 (4.0)	14/388 (3.6)
WEEK 304	6/187 (3.2)	7/201 (3.5)	13/388 (3.4)
WEEK 308	4/187 (2.1)	7/201 (3.5)	11/388 (2.8)
WEEK 312	4/187 (2.1)	6/201 (3.0)	10/388 (2.6)
WEEK 316	4/187 (2.1)	7/201 (3.5)	11/388 (2.8)
WEEK 320	3/187 (1.6)	7/201 (3.5)	10/388 (2.6)
WEEK 324	3/187 (1.6)	7/201 (3.5)	10/388 (2.6)
WEEK 328	4/187 (2.1)	7/201 (3.5)	11/388 (2.8)
WEEK 332	4/187 (2.1)	6/201 (3.0)	10/388 (2.6)
WEEK 336	4/187 (2.1)	6/201 (3.0)	10/388 (2.6)

NOV 2025 DBL.
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Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 340	4/187 (2.1)	5/201 (2.5)	9/388 (2.3)
WEEK 344	4/187 (2.1)	5/201 (2.5)	9/388 (2.3)
WEEK 348	3/187 (1.6)	4/201 (2.0)	7/388 (1.8)
WEEK 352	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 356	3/187 (1.6)	2/201 (1.0)	5/388 (1.3)
WEEK 360	2/187 (1.1)	1/201 (0.5)	3/388 (0.8)
WEEK 364	1/187 (0.5)	0/201	1/388 (0.3)
FOLLOW-UP			
FOLLOW-UP 1	122/187 (65.2)	131/201 (65.2)	253/388 (65.2)
FOLLOW-UP 2	94/187 (50.3)	94/201 (46.8)	188/388 (48.5)
SURVIVAL FOLLOW-UP			
SURVIVAL FOLLOW-UP 1	83/187 (44.4)	77/201 (38.3)	160/388 (41.2)
SURVIVAL FOLLOW-UP 2	70/187 (37.4)	55/201 (27.4)	125/388 (32.2)
SURVIVAL FOLLOW-UP 3	61/187 (32.6)	57/201 (28.4)	118/388 (30.4)
SURVIVAL FOLLOW-UP 4	63/187 (33.7)	46/201 (22.9)	109/388 (28.1)
SURVIVAL FOLLOW-UP 5	56/187 (29.9)	47/201 (23.4)	103/388 (26.5)
SURVIVAL FOLLOW-UP 6	51/187 (27.3)	43/201 (21.4)	94/388 (24.2)
SURVIVAL FOLLOW-UP 7	53/187 (28.3)	43/201 (21.4)	96/388 (24.7)

NOV 2025 DBL.
The EQ-5D VAS is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:07:51

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Table 11.7
EQ-5D VAS Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
SURVIVAL FOLLOW-UP 8	50/187 (26.7)	35/201 (17.4)	85/388 (21.9)
SURVIVAL FOLLOW-UP 9	49/187 (26.2)	32/201 (15.9)	81/388 (20.9)
SURVIVAL FOLLOW-UP 10	44/187 (23.5)	25/201 (12.4)	69/388 (17.8)
SURVIVAL FOLLOW-UP 11	40/187 (21.4)	26/201 (12.9)	66/388 (17.0)
SURVIVAL FOLLOW-UP 12	36/187 (19.3)	25/201 (12.4)	61/388 (15.7)
SURVIVAL FOLLOW-UP 13	39/187 (20.9)	17/201 (8.5)	56/388 (14.4)
SURVIVAL FOLLOW-UP 14	35/187 (18.7)	19/201 (9.5)	54/388 (13.9)
SURVIVAL FOLLOW-UP 15	34/187 (18.2)	16/201 (8.0)	50/388 (12.9)
SURVIVAL FOLLOW-UP 16	31/187 (16.6)	18/201 (9.0)	49/388 (12.6)
SURVIVAL FOLLOW-UP 17	27/187 (14.4)	19/201 (9.5)	46/388 (11.9)
SURVIVAL FOLLOW-UP 18	26/187 (13.9)	15/201 (7.5)	41/388 (10.6)
SURVIVAL FOLLOW-UP 19	21/187 (11.2)	10/201 (5.0)	31/388 (8.0)
SURVIVAL FOLLOW-UP 20	22/187 (11.8)	13/201 (6.5)	35/388 (9.0)
SURVIVAL FOLLOW-UP 21	19/187 (10.2)	11/201 (5.5)	30/388 (7.7)
SURVIVAL FOLLOW-UP 22	17/187 (9.1)	7/201 (3.5)	24/388 (6.2)
SURVIVAL FOLLOW-UP 23	17/187 (9.1)	8/201 (4.0)	25/388 (6.4)
SURVIVAL FOLLOW-UP 24	14/187 (7.5)	6/201 (3.0)	20/388 (5.2)
SURVIVAL FOLLOW-UP 25	10/187 (5.3)	3/201 (1.5)	13/388 (3.4)
SURVIVAL FOLLOW-UP 26	5/187 (2.7)	1/201 (0.5)	6/388 (1.5)
SURVIVAL FOLLOW-UP 27	1/187 (0.5)	0/201	1/388 (0.3)

NOV 2025 DBL.
The EQ-5D VAS is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:07:51

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
NUMBER OF SUBJECTS WITH BASELINE AND >=1 POST BASELINE VALUE (b)	173/187 (92.5)	182/201 (90.5)	355/388 (91.5)
NUMBER OF SUBJECTS WITHOUT BASELINE VALUE (b)	7/187 (3.7)	7/201 (3.5)	14/388 (3.6)
NUMBER OF SUBJECTS WITHOUT POST BASELINE VALUE (b)	7/187 (3.7)	13/201 (6.5)	20/388 (5.2)
TIMEPOINT			
WEEK 1 (BASELINE)	180/187 (96.3)	194/201 (96.5)	374/388 (96.4)
ON-STUDY			
WEEK 4	158/175 (90.3)	164/184 (89.1)	322/359 (89.7)
WEEK 8	144/156 (92.3)	153/168 (91.1)	297/324 (91.7)
WEEK 12	130/137 (94.9)	135/149 (90.6)	265/286 (92.7)
WEEK 16	111/115 (96.5)	126/131 (96.2)	237/246 (96.3)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 20	94/103 (91.3)	104/112 (92.9)	198/215 (92.1)
WEEK 24	90/ 94 (95.7)	89/100 (89.0)	179/194 (92.3)
WEEK 28	79/ 88 (89.8)	86/ 92 (93.5)	165/180 (91.7)
WEEK 32	75/ 85 (88.2)	83/ 86 (96.5)	158/171 (92.4)
WEEK 36	79/ 84 (94.0)	74/ 79 (93.7)	153/163 (93.9)
WEEK 40	73/ 78 (93.6)	74/ 76 (97.4)	147/154 (95.5)
WEEK 44	70/ 73 (95.9)	69/ 74 (93.2)	139/147 (94.6)
WEEK 48	66/ 72 (91.7)	70/ 72 (97.2)	136/144 (94.4)
WEEK 52	64/ 68 (94.1)	62/ 70 (88.6)	126/138 (91.3)
WEEK 56	58/ 63 (92.1)	59/ 67 (88.1)	117/130 (90.0)
WEEK 60	55/ 61 (90.2)	62/ 65 (95.4)	117/126 (92.9)
WEEK 64	57/ 60 (95.0)	59/ 63 (93.7)	116/123 (94.3)
WEEK 68	56/ 57 (98.2)	54/ 61 (88.5)	110/118 (93.2)
WEEK 72	49/ 54 (90.7)	56/ 59 (94.9)	105/113 (92.9)
WEEK 76	50/ 54 (92.6)	51/ 57 (89.5)	101/111 (91.0)
WEEK 80	45/ 49 (91.8)	49/ 56 (87.5)	94/105 (89.5)
WEEK 84	44/ 48 (91.7)	52/ 56 (92.9)	96/104 (92.3)
WEEK 88	41/ 47 (87.2)	49/ 52 (94.2)	90/ 99 (90.9)
WEEK 92	43/ 46 (93.5)	46/ 50 (92.0)	89/ 96 (92.7)
WEEK 96	40/ 45 (88.9)	46/ 49 (93.9)	86/ 94 (91.5)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 100	41/ 42 (97.6)	38/ 44 (86.4)	79/ 86 (91.9)
WEEK 104	34/ 39 (87.2)	40/ 43 (93.0)	74/ 82 (90.2)
WEEK 108	34/ 38 (89.5)	42/ 43 (97.7)	76/ 81 (93.8)
WEEK 112	31/ 36 (86.1)	38/ 41 (92.7)	69/ 77 (89.6)
WEEK 116	34/ 36 (94.4)	39/ 40 (97.5)	73/ 76 (96.1)
WEEK 120	32/ 35 (91.4)	39/ 39 (100.0)	71/ 74 (95.9)
WEEK 124	33/ 35 (94.3)	34/ 37 (91.9)	67/ 72 (93.1)
WEEK 128	31/ 33 (93.9)	35/ 37 (94.6)	66/ 70 (94.3)
WEEK 132	32/ 33 (97.0)	32/ 34 (94.1)	64/ 67 (95.5)
WEEK 136	32/ 32 (100.0)	31/ 34 (91.2)	63/ 66 (95.5)
WEEK 140	28/ 30 (93.3)	28/ 33 (84.8)	56/ 63 (88.9)
WEEK 144	27/ 30 (90.0)	30/ 32 (93.8)	57/ 62 (91.9)
WEEK 148	28/ 29 (96.6)	28/ 32 (87.5)	56/ 61 (91.8)
WEEK 152	25/ 28 (89.3)	28/ 32 (87.5)	53/ 60 (88.3)
WEEK 156	26/ 27 (96.3)	28/ 32 (87.5)	54/ 59 (91.5)
WEEK 160	24/ 26 (92.3)	28/ 31 (90.3)	52/ 57 (91.2)
WEEK 164	24/ 26 (92.3)	28/ 31 (90.3)	52/ 57 (91.2)
WEEK 168	22/ 26 (84.6)	29/ 31 (93.5)	51/ 57 (89.5)
WEEK 172	22/ 25 (88.0)	29/ 30 (96.7)	51/ 55 (92.7)
WEEK 176	21/ 25 (84.0)	26/ 29 (89.7)	47/ 54 (87.0)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 180	22/ 23 (95.7)	28/ 29 (96.6)	50/ 52 (96.2)
WEEK 184	22/ 23 (95.7)	23/ 24 (95.8)	45/ 47 (95.7)
WEEK 188	22/ 23 (95.7)	21/ 23 (91.3)	43/ 46 (93.5)
WEEK 192	22/ 23 (95.7)	22/ 23 (95.7)	44/ 46 (95.7)
WEEK 196	19/ 21 (90.5)	18/ 20 (90.0)	37/ 41 (90.2)
WEEK 200	17/ 19 (89.5)	19/ 20 (95.0)	36/ 39 (92.3)
WEEK 204	19/ 19 (100.0)	17/ 19 (89.5)	36/ 38 (94.7)
WEEK 208	18/ 19 (94.7)	18/ 18 (100.0)	36/ 37 (97.3)
WEEK 212	19/ 19 (100.0)	17/ 18 (94.4)	36/ 37 (97.3)
WEEK 216	18/ 19 (94.7)	18/ 18 (100.0)	36/ 37 (97.3)
WEEK 220	17/ 19 (89.5)	16/ 17 (94.1)	33/ 36 (91.7)
WEEK 224	17/ 18 (94.4)	16/ 17 (94.1)	33/ 35 (94.3)
WEEK 228	15/ 18 (83.3)	16/ 17 (94.1)	31/ 35 (88.6)
WEEK 232	16/ 17 (94.1)	15/ 16 (93.8)	31/ 33 (93.9)
WEEK 236	15/ 17 (88.2)	16/ 16 (100.0)	31/ 33 (93.9)
WEEK 240	14/ 17 (82.4)	14/ 16 (87.5)	28/ 33 (84.8)
WEEK 244	16/ 17 (94.1)	14/ 16 (87.5)	30/ 33 (90.9)
WEEK 248	12/ 17 (70.6)	14/ 15 (93.3)	26/ 32 (81.3)
WEEK 252	15/ 17 (88.2)	11/ 14 (78.6)	26/ 31 (83.9)
WEEK 256	15/ 16 (93.8)	13/ 14 (92.9)	28/ 30 (93.3)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 260	14/ 16 (87.5)	13/ 14 (92.9)	27/ 30 (90.0)
WEEK 264	11/ 13 (84.6)	11/ 12 (91.7)	22/ 25 (88.0)
WEEK 268	9/ 13 (69.2)	12/ 12 (100.0)	21/ 25 (84.0)
WEEK 272	11/ 13 (84.6)	11/ 11 (100.0)	22/ 24 (91.7)
WEEK 276	11/ 13 (84.6)	10/ 11 (90.9)	21/ 24 (87.5)
WEEK 280	12/ 13 (92.3)	9/ 11 (81.8)	21/ 24 (87.5)
WEEK 284	11/ 12 (91.7)	8/ 11 (72.7)	19/ 23 (82.6)
WEEK 288	10/ 12 (83.3)	7/ 9 (77.8)	17/ 21 (81.0)
WEEK 292	10/ 12 (83.3)	7/ 8 (87.5)	17/ 20 (85.0)
WEEK 296	9/ 11 (81.8)	8/ 8 (100.0)	17/ 19 (89.5)
WEEK 300	6/ 11 (54.5)	8/ 8 (100.0)	14/ 19 (73.7)
WEEK 304	6/ 6 (100.0)	7/ 7 (100.0)	13/ 13 (100.0)
WEEK 308	4/ 4 (100.0)	7/ 7 (100.0)	11/ 11 (100.0)
WEEK 312	4/ 4 (100.0)	6/ 7 (85.7)	10/ 11 (90.9)
WEEK 316	4/ 4 (100.0)	7/ 7 (100.0)	11/ 11 (100.0)
WEEK 320	3/ 4 (75.0)	7/ 7 (100.0)	10/ 11 (90.9)
WEEK 324	3/ 4 (75.0)	7/ 7 (100.0)	10/ 11 (90.9)
WEEK 328	4/ 4 (100.0)	7/ 7 (100.0)	11/ 11 (100.0)
WEEK 332	3/ 4 (75.0)	6/ 7 (85.7)	9/ 11 (81.8)
WEEK 336	4/ 4 (100.0)	6/ 7 (85.7)	10/ 11 (90.9)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 340	4/ 4 (100.0)	5/ 7 (71.4)	9/ 11 (81.8)
WEEK 344	4/ 4 (100.0)	5/ 6 (83.3)	9/ 10 (90.0)
WEEK 348	3/ 3 (100.0)	4/ 5 (80.0)	7/ 8 (87.5)
WEEK 352	3/ 3 (100.0)	3/ 5 (60.0)	6/ 8 (75.0)
WEEK 356	3/ 3 (100.0)	3/ 3 (100.0)	6/ 6 (100.0)
WEEK 360	2/ 2 (100.0)	1/ 1 (100.0)	3/ 3 (100.0)
WEEK 364	1/ 2 (50.0)	0/ 1	1/ 3 (33.3)
FOLLOW-UP			
FOLLOW-UP 1	119/171 (69.6)	126/189 (66.7)	245/360 (68.1)
FOLLOW-UP 2	82/141 (58.2)	84/153 (54.9)	166/294 (56.5)
SURVIVAL FOLLOW-UP			
SURVIVAL FOLLOW-UP 1	15/127 (11.8)	14/128 (10.9)	29/255 (11.4)
SURVIVAL FOLLOW-UP 2	10/112 (8.9)	8/111 (7.2)	18/223 (8.1)
SURVIVAL FOLLOW-UP 3	10/ 96 (10.4)	7/ 94 (7.4)	17/190 (8.9)
SURVIVAL FOLLOW-UP 4	13/ 90 (14.4)	5/ 89 (5.6)	18/179 (10.1)
SURVIVAL FOLLOW-UP 5	8/ 86 (9.3)	5/ 81 (6.2)	13/167 (7.8)
SURVIVAL FOLLOW-UP 6	9/ 77 (11.7)	5/ 73 (6.8)	14/150 (9.3)
SURVIVAL FOLLOW-UP 7	10/ 72 (13.9)	5/ 70 (7.1)	15/142 (10.6)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.2
FACT-M Overall Questionnaire Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
SURVIVAL FOLLOW-UP 8	7/ 71 (9.9)	3/ 63 (4.8)	10/134 (7.5)
SURVIVAL FOLLOW-UP 9	7/ 70 (10.0)	5/ 60 (8.3)	12/130 (9.2)
SURVIVAL FOLLOW-UP 10	5/ 68 (7.4)	4/ 57 (7.0)	9/125 (7.2)
SURVIVAL FOLLOW-UP 11	3/ 66 (4.5)	3/ 53 (5.7)	6/119 (5.0)
SURVIVAL FOLLOW-UP 12	1/ 59 (1.7)	3/ 49 (6.1)	4/108 (3.7)
SURVIVAL FOLLOW-UP 13	1/ 57 (1.8)	0/ 44	1/101 (1.0)
SURVIVAL FOLLOW-UP 14	0/ 55	0/ 36	0/ 91
SURVIVAL FOLLOW-UP 15	0/ 53	0/ 32	0/ 85
SURVIVAL FOLLOW-UP 16	0/ 47	1/ 31 (3.2)	1/ 78 (1.3)
SURVIVAL FOLLOW-UP 17	0/ 46	0/ 30	0/ 76
SURVIVAL FOLLOW-UP 18	0/ 41	0/ 26	0/ 67
SURVIVAL FOLLOW-UP 19	0/ 38	0/ 23	0/ 61
SURVIVAL FOLLOW-UP 20	0/ 35	0/ 20	0/ 55
SURVIVAL FOLLOW-UP 21	0/ 31	0/ 18	0/ 49
SURVIVAL FOLLOW-UP 22	0/ 29	0/ 18	0/ 47
SURVIVAL FOLLOW-UP 23	0/ 28	0/ 15	0/ 43
SURVIVAL FOLLOW-UP 24	0/ 25	0/ 11	0/ 36
SURVIVAL FOLLOW-UP 25	0/ 20	0/ 5	0/ 25
SURVIVAL FOLLOW-UP 26	0/ 13	0/ 3	0/ 16
SURVIVAL FOLLOW-UP 27	0/ 4	N.A.	0/ 4

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:06:06

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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
NUMBER OF SUBJECTS WITH BASELINE AND >=1 POST BASELINE VALUE	173/187 (92.5)	182/201 (90.5)	355/388 (91.5)
NUMBER OF SUBJECTS WITHOUT BASELINE VALUE	7/187 (3.7)	7/201 (3.5)	14/388 (3.6)
NUMBER OF SUBJECTS WITHOUT POST BASELINE VALUE	7/187 (3.7)	13/201 (6.5)	20/388 (5.2)
TIMEPOINT			
WEEK 1 (BASELINE)	180/187 (96.3)	194/201 (96.5)	374/388 (96.4)
ON-STUDY			
WEEK 4	158/187 (84.5)	164/201 (81.6)	322/388 (83.0)
WEEK 8	144/187 (77.0)	153/201 (76.1)	297/388 (76.5)
WEEK 12	130/187 (69.5)	135/201 (67.2)	265/388 (68.3)
WEEK 16	111/187 (59.4)	126/201 (62.7)	237/388 (61.1)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:05:46

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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 20	94/187 (50.3)	104/201 (51.7)	198/388 (51.0)
WEEK 24	90/187 (48.1)	89/201 (44.3)	179/388 (46.1)
WEEK 28	79/187 (42.2)	86/201 (42.8)	165/388 (42.5)
WEEK 32	75/187 (40.1)	83/201 (41.3)	158/388 (40.7)
WEEK 36	79/187 (42.2)	74/201 (36.8)	153/388 (39.4)
WEEK 40	73/187 (39.0)	74/201 (36.8)	147/388 (37.9)
WEEK 44	70/187 (37.4)	69/201 (34.3)	139/388 (35.8)
WEEK 48	66/187 (35.3)	70/201 (34.8)	136/388 (35.1)
WEEK 52	64/187 (34.2)	62/201 (30.8)	126/388 (32.5)
WEEK 56	58/187 (31.0)	59/201 (29.4)	117/388 (30.2)
WEEK 60	55/187 (29.4)	62/201 (30.8)	117/388 (30.2)
WEEK 64	57/187 (30.5)	59/201 (29.4)	116/388 (29.9)
WEEK 68	56/187 (29.9)	54/201 (26.9)	110/388 (28.4)
WEEK 72	49/187 (26.2)	56/201 (27.9)	105/388 (27.1)
WEEK 76	50/187 (26.7)	51/201 (25.4)	101/388 (26.0)
WEEK 80	45/187 (24.1)	49/201 (24.4)	94/388 (24.2)
WEEK 84	44/187 (23.5)	52/201 (25.9)	96/388 (24.7)
WEEK 88	41/187 (21.9)	49/201 (24.4)	90/388 (23.2)
WEEK 92	43/187 (23.0)	46/201 (22.9)	89/388 (22.9)
WEEK 96	40/187 (21.4)	46/201 (22.9)	86/388 (22.2)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:05:46

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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 100	41/187 (21.9)	38/201 (18.9)	79/388 (20.4)
WEEK 104	34/187 (18.2)	40/201 (19.9)	74/388 (19.1)
WEEK 108	34/187 (18.2)	42/201 (20.9)	76/388 (19.6)
WEEK 112	31/187 (16.6)	38/201 (18.9)	69/388 (17.8)
WEEK 116	34/187 (18.2)	39/201 (19.4)	73/388 (18.8)
WEEK 120	32/187 (17.1)	39/201 (19.4)	71/388 (18.3)
WEEK 124	33/187 (17.6)	34/201 (16.9)	67/388 (17.3)
WEEK 128	31/187 (16.6)	35/201 (17.4)	66/388 (17.0)
WEEK 132	32/187 (17.1)	32/201 (15.9)	64/388 (16.5)
WEEK 136	32/187 (17.1)	31/201 (15.4)	63/388 (16.2)
WEEK 140	28/187 (15.0)	28/201 (13.9)	56/388 (14.4)
WEEK 144	27/187 (14.4)	30/201 (14.9)	57/388 (14.7)
WEEK 148	28/187 (15.0)	28/201 (13.9)	56/388 (14.4)
WEEK 152	25/187 (13.4)	28/201 (13.9)	53/388 (13.7)
WEEK 156	26/187 (13.9)	28/201 (13.9)	54/388 (13.9)
WEEK 160	24/187 (12.8)	28/201 (13.9)	52/388 (13.4)
WEEK 164	24/187 (12.8)	28/201 (13.9)	52/388 (13.4)
WEEK 168	22/187 (11.8)	29/201 (14.4)	51/388 (13.1)
WEEK 172	22/187 (11.8)	29/201 (14.4)	51/388 (13.1)
WEEK 176	21/187 (11.2)	26/201 (12.9)	47/388 (12.1)

NOV 2025 DBL.
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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 180	22/187 (11.8)	28/201 (13.9)	50/388 (12.9)
WEEK 184	22/187 (11.8)	23/201 (11.4)	45/388 (11.6)
WEEK 188	22/187 (11.8)	21/201 (10.4)	43/388 (11.1)
WEEK 192	22/187 (11.8)	22/201 (10.9)	44/388 (11.3)
WEEK 196	19/187 (10.2)	18/201 (9.0)	37/388 (9.5)
WEEK 200	17/187 (9.1)	19/201 (9.5)	36/388 (9.3)
WEEK 204	19/187 (10.2)	17/201 (8.5)	36/388 (9.3)
WEEK 208	18/187 (9.6)	18/201 (9.0)	36/388 (9.3)
WEEK 212	19/187 (10.2)	17/201 (8.5)	36/388 (9.3)
WEEK 216	18/187 (9.6)	18/201 (9.0)	36/388 (9.3)
WEEK 220	17/187 (9.1)	16/201 (8.0)	33/388 (8.5)
WEEK 224	17/187 (9.1)	16/201 (8.0)	33/388 (8.5)
WEEK 228	15/187 (8.0)	16/201 (8.0)	31/388 (8.0)
WEEK 232	16/187 (8.6)	15/201 (7.5)	31/388 (8.0)
WEEK 236	15/187 (8.0)	16/201 (8.0)	31/388 (8.0)
WEEK 240	14/187 (7.5)	14/201 (7.0)	28/388 (7.2)
WEEK 244	16/187 (8.6)	14/201 (7.0)	30/388 (7.7)
WEEK 248	12/187 (6.4)	14/201 (7.0)	26/388 (6.7)
WEEK 252	15/187 (8.0)	11/201 (5.5)	26/388 (6.7)
WEEK 256	15/187 (8.0)	13/201 (6.5)	28/388 (7.2)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
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Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:05:46

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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 260	14/187 (7.5)	13/201 (6.5)	27/388 (7.0)
WEEK 264	11/187 (5.9)	11/201 (5.5)	22/388 (5.7)
WEEK 268	9/187 (4.8)	12/201 (6.0)	21/388 (5.4)
WEEK 272	11/187 (5.9)	11/201 (5.5)	22/388 (5.7)
WEEK 276	11/187 (5.9)	10/201 (5.0)	21/388 (5.4)
WEEK 280	12/187 (6.4)	9/201 (4.5)	21/388 (5.4)
WEEK 284	11/187 (5.9)	8/201 (4.0)	19/388 (4.9)
WEEK 288	10/187 (5.3)	7/201 (3.5)	17/388 (4.4)
WEEK 292	10/187 (5.3)	7/201 (3.5)	17/388 (4.4)
WEEK 296	9/187 (4.8)	8/201 (4.0)	17/388 (4.4)
WEEK 300	6/187 (3.2)	8/201 (4.0)	14/388 (3.6)
WEEK 304	6/187 (3.2)	7/201 (3.5)	13/388 (3.4)
WEEK 308	4/187 (2.1)	7/201 (3.5)	11/388 (2.8)
WEEK 312	4/187 (2.1)	6/201 (3.0)	10/388 (2.6)
WEEK 316	4/187 (2.1)	7/201 (3.5)	11/388 (2.8)
WEEK 320	3/187 (1.6)	7/201 (3.5)	10/388 (2.6)
WEEK 324	3/187 (1.6)	7/201 (3.5)	10/388 (2.6)
WEEK 328	4/187 (2.1)	7/201 (3.5)	11/388 (2.8)
WEEK 332	3/187 (1.6)	6/201 (3.0)	9/388 (2.3)
WEEK 336	4/187 (2.1)	6/201 (3.0)	10/388 (2.6)

NOV 2025 DBL.
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Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:05:46

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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 340	4/187 (2.1)	5/201 (2.5)	9/388 (2.3)
WEEK 344	4/187 (2.1)	5/201 (2.5)	9/388 (2.3)
WEEK 348	3/187 (1.6)	4/201 (2.0)	7/388 (1.8)
WEEK 352	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 356	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 360	2/187 (1.1)	1/201 (0.5)	3/388 (0.8)
WEEK 364	1/187 (0.5)	0/201	1/388 (0.3)
FOLLOW-UP			
FOLLOW-UP 1	119/187 (63.6)	126/201 (62.7)	245/388 (63.1)
FOLLOW-UP 2	82/187 (43.9)	84/201 (41.8)	166/388 (42.8)
SURVIVAL FOLLOW-UP			
SURVIVAL FOLLOW-UP 1	15/187 (8.0)	14/201 (7.0)	29/388 (7.5)
SURVIVAL FOLLOW-UP 2	10/187 (5.3)	8/201 (4.0)	18/388 (4.6)
SURVIVAL FOLLOW-UP 3	10/187 (5.3)	7/201 (3.5)	17/388 (4.4)
SURVIVAL FOLLOW-UP 4	13/187 (7.0)	5/201 (2.5)	18/388 (4.6)
SURVIVAL FOLLOW-UP 5	8/187 (4.3)	5/201 (2.5)	13/388 (3.4)
SURVIVAL FOLLOW-UP 6	9/187 (4.8)	5/201 (2.5)	14/388 (3.6)
SURVIVAL FOLLOW-UP 7	10/187 (5.3)	5/201 (2.5)	15/388 (3.9)

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:05:46

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Table 11.1
FACT-M Overall Questionnaire Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
SURVIVAL FOLLOW-UP 8	7/187 (3.7)	3/201 (1.5)	10/388 (2.6)
SURVIVAL FOLLOW-UP 9	7/187 (3.7)	5/201 (2.5)	12/388 (3.1)
SURVIVAL FOLLOW-UP 10	5/187 (2.7)	4/201 (2.0)	9/388 (2.3)
SURVIVAL FOLLOW-UP 11	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
SURVIVAL FOLLOW-UP 12	1/187 (0.5)	3/201 (1.5)	4/388 (1.0)
SURVIVAL FOLLOW-UP 13	1/187 (0.5)	0/201	1/388 (0.3)
SURVIVAL FOLLOW-UP 14	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 15	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 16	0/187	1/201 (0.5)	1/388 (0.3)
SURVIVAL FOLLOW-UP 17	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 18	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 19	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 20	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 21	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 22	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 23	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 24	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 25	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 26	0/187	0/201	0/388
SURVIVAL FOLLOW-UP 27	0/187	0/201	0/388

NOV 2025 DBL.
The FACT-M overall questionnaire is considered as completed if all the subscales are non-missing (after imputation).
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Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:05:46

Anhang 4-G 3.3: WPAI:GH

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Table 11.11
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
NUMBER OF SUBJECTS WITH BASELINE AND >=1 POST BASELINE VALUE (b)	47/187 (25.1)	49/201 (24.4)	96/388 (24.7)
NUMBER OF SUBJECTS WITHOUT BASELINE VALUE (b)	135/187 (72.2)	145/201 (72.1)	280/388 (72.2)
NUMBER OF SUBJECTS WITHOUT POST BASELINE VALUE (b)	124/187 (66.3)	136/201 (67.7)	260/388 (67.0)
TIMEPOINT			
WEEK 1 (BASELINE)	52/187 (27.8)	56/201 (27.9)	108/388 (27.8)
ON-STUDY			
WEEK 4	41/175 (23.4)	47/184 (25.5)	88/359 (24.5)
WEEK 8	35/156 (22.4)	42/168 (25.0)	77/324 (23.8)
WEEK 12	32/137 (23.4)	38/149 (25.5)	70/286 (24.5)
WEEK 16	28/115 (24.3)	35/131 (26.7)	63/246 (25.6)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:09:14

Table 11.11
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 20	29/103 (28.2)	30/111 (27.0)	59/214 (27.6)
WEEK 24	25/ 94 (26.6)	27/100 (27.0)	52/194 (26.8)
WEEK 28	23/ 88 (26.1)	30/ 92 (32.6)	53/180 (29.4)
WEEK 32	22/ 85 (25.9)	27/ 86 (31.4)	49/171 (28.7)
WEEK 36	23/ 84 (27.4)	27/ 79 (34.2)	50/163 (30.7)
WEEK 40	27/ 78 (34.6)	28/ 76 (36.8)	55/154 (35.7)
WEEK 44	25/ 73 (34.2)	23/ 74 (31.1)	48/147 (32.7)
WEEK 48	26/ 72 (36.1)	21/ 72 (29.2)	47/144 (32.6)
WEEK 52	23/ 68 (33.8)	18/ 70 (25.7)	41/138 (29.7)
WEEK 56	20/ 63 (31.7)	15/ 67 (22.4)	35/130 (26.9)
WEEK 60	21/ 61 (34.4)	15/ 65 (23.1)	36/126 (28.6)
WEEK 64	18/ 59 (30.5)	15/ 63 (23.8)	33/122 (27.0)
WEEK 68	19/ 57 (33.3)	14/ 61 (23.0)	33/118 (28.0)
WEEK 72	18/ 54 (33.3)	14/ 59 (23.7)	32/113 (28.3)
WEEK 76	18/ 54 (33.3)	12/ 57 (21.1)	30/111 (27.0)
WEEK 80	15/ 49 (30.6)	12/ 56 (21.4)	27/105 (25.7)
WEEK 84	14/ 48 (29.2)	10/ 56 (17.9)	24/104 (23.1)
WEEK 88	13/ 47 (27.7)	10/ 52 (19.2)	23/ 99 (23.2)
WEEK 92	15/ 46 (32.6)	10/ 50 (20.0)	25/ 96 (26.0)
WEEK 96	14/ 45 (31.1)	9/ 48 (18.8)	23/ 93 (24.7)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
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Table 11.11
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 100	14/ 42 (33.3)	7/ 44 (15.9)	21/ 86 (24.4)
WEEK 104	13/ 39 (33.3)	8/ 43 (18.6)	21/ 82 (25.6)
WEEK 108	14/ 38 (36.8)	7/ 43 (16.3)	21/ 81 (25.9)
WEEK 112	11/ 36 (30.6)	8/ 41 (19.5)	19/ 77 (24.7)
WEEK 116	12/ 36 (33.3)	7/ 40 (17.5)	19/ 76 (25.0)
WEEK 120	12/ 35 (34.3)	7/ 38 (18.4)	19/ 73 (26.0)
WEEK 124	12/ 35 (34.3)	7/ 37 (18.9)	19/ 72 (26.4)
WEEK 128	8/ 33 (24.2)	7/ 36 (19.4)	15/ 69 (21.7)
WEEK 132	8/ 33 (24.2)	7/ 34 (20.6)	15/ 67 (22.4)
WEEK 136	8/ 32 (25.0)	7/ 34 (20.6)	15/ 66 (22.7)
WEEK 140	8/ 30 (26.7)	6/ 33 (18.2)	14/ 63 (22.2)
WEEK 144	9/ 30 (30.0)	7/ 32 (21.9)	16/ 62 (25.8)
WEEK 148	10/ 29 (34.5)	8/ 32 (25.0)	18/ 61 (29.5)
WEEK 152	9/ 28 (32.1)	6/ 32 (18.8)	15/ 60 (25.0)
WEEK 156	7/ 27 (25.9)	9/ 32 (28.1)	16/ 59 (27.1)
WEEK 160	7/ 26 (26.9)	7/ 31 (22.6)	14/ 57 (24.6)
WEEK 164	7/ 26 (26.9)	7/ 31 (22.6)	14/ 57 (24.6)
WEEK 168	6/ 26 (23.1)	6/ 31 (19.4)	12/ 57 (21.1)
WEEK 172	6/ 25 (24.0)	7/ 30 (23.3)	13/ 55 (23.6)
WEEK 176	6/ 25 (24.0)	6/ 29 (20.7)	12/ 54 (22.2)

NOV 2025 DBL.
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(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
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Table 11.11
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 180	5/ 23 (21.7)	9/ 29 (31.0)	14/ 52 (26.9)
WEEK 184	5/ 23 (21.7)	7/ 24 (29.2)	12/ 47 (25.5)
WEEK 188	5/ 23 (21.7)	7/ 23 (30.4)	12/ 46 (26.1)
WEEK 192	6/ 23 (26.1)	7/ 23 (30.4)	13/ 46 (28.3)
WEEK 196	6/ 21 (28.6)	6/ 20 (30.0)	12/ 41 (29.3)
WEEK 200	5/ 19 (26.3)	6/ 20 (30.0)	11/ 39 (28.2)
WEEK 204	6/ 19 (31.6)	6/ 19 (31.6)	12/ 38 (31.6)
WEEK 208	5/ 19 (26.3)	6/ 18 (33.3)	11/ 37 (29.7)
WEEK 212	7/ 19 (36.8)	5/ 18 (27.8)	12/ 37 (32.4)
WEEK 216	5/ 19 (26.3)	7/ 18 (38.9)	12/ 37 (32.4)
WEEK 220	5/ 19 (26.3)	6/ 17 (35.3)	11/ 36 (30.6)
WEEK 224	5/ 18 (27.8)	4/ 17 (23.5)	9/ 35 (25.7)
WEEK 228	4/ 18 (22.2)	5/ 17 (29.4)	9/ 35 (25.7)
WEEK 232	5/ 17 (29.4)	5/ 16 (31.3)	10/ 33 (30.3)
WEEK 236	3/ 17 (17.6)	5/ 16 (31.3)	8/ 33 (24.2)
WEEK 240	4/ 17 (23.5)	4/ 16 (25.0)	8/ 33 (24.2)
WEEK 244	5/ 17 (29.4)	4/ 16 (25.0)	9/ 33 (27.3)
WEEK 248	4/ 17 (23.5)	4/ 15 (26.7)	8/ 32 (25.0)
WEEK 252	4/ 17 (23.5)	4/ 14 (28.6)	8/ 31 (25.8)
WEEK 256	5/ 16 (31.3)	5/ 14 (35.7)	10/ 30 (33.3)

NOV 2025 DBL.
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(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
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Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:09:14

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Table 11.11
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 260	5/ 16 (31.3)	4/ 14 (28.6)	9/ 30 (30.0)
WEEK 264	4/ 13 (30.8)	2/ 12 (16.7)	6/ 25 (24.0)
WEEK 268	3/ 13 (23.1)	3/ 12 (25.0)	6/ 25 (24.0)
WEEK 272	3/ 13 (23.1)	3/ 11 (27.3)	6/ 24 (25.0)
WEEK 276	3/ 13 (23.1)	3/ 11 (27.3)	6/ 24 (25.0)
WEEK 280	4/ 13 (30.8)	2/ 11 (18.2)	6/ 24 (25.0)
WEEK 284	3/ 12 (25.0)	3/ 11 (27.3)	6/ 23 (26.1)
WEEK 288	3/ 12 (25.0)	2/ 9 (22.2)	5/ 21 (23.8)
WEEK 292	3/ 12 (25.0)	3/ 8 (37.5)	6/ 20 (30.0)
WEEK 296	2/ 11 (18.2)	3/ 8 (37.5)	5/ 19 (26.3)
WEEK 300	2/ 11 (18.2)	3/ 8 (37.5)	5/ 19 (26.3)
WEEK 304	2/ 6 (33.3)	3/ 7 (42.9)	5/ 13 (38.5)
WEEK 308	2/ 4 (50.0)	3/ 7 (42.9)	5/ 11 (45.5)
WEEK 312	2/ 4 (50.0)	3/ 7 (42.9)	5/ 11 (45.5)
WEEK 316	2/ 4 (50.0)	2/ 7 (28.6)	4/ 11 (36.4)
WEEK 320	1/ 4 (25.0)	3/ 7 (42.9)	4/ 11 (36.4)
WEEK 324	2/ 4 (50.0)	3/ 7 (42.9)	5/ 11 (45.5)
WEEK 328	2/ 4 (50.0)	1/ 7 (14.3)	3/ 11 (27.3)
WEEK 332	2/ 4 (50.0)	1/ 7 (14.3)	3/ 11 (27.3)
WEEK 336	1/ 4 (25.0)	1/ 7 (14.3)	2/ 11 (18.2)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:09:14

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Table 11.11
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Expected to Complete the Questionnaire
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Expected to Complete the Questionnaire (a)		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 340	1/ 4 (25.0)	1/ 7 (14.3)	2/ 11 (18.2)
WEEK 344	2/ 4 (50.0)	1/ 6 (16.7)	3/ 10 (30.0)
WEEK 348	1/ 3 (33.3)	1/ 5 (20.0)	2/ 8 (25.0)
WEEK 352	1/ 3 (33.3)	1/ 5 (20.0)	2/ 8 (25.0)
WEEK 356	1/ 3 (33.3)	1/ 3 (33.3)	2/ 6 (33.3)
WEEK 360	0/ 2	0/ 1	0/ 3
WEEK 364	0/ 2	0/ 1	0/ 3
FOLLOW-UP			
FOLLOW-UP 1	26/171 (15.2)	26/189 (13.8)	52/360 (14.4)
FOLLOW-UP 2	19/141 (13.5)	16/153 (10.5)	35/294 (11.9)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
(a) Subjects who were on-treatment/in follow-up at the respective on-treatment/follow-up assessment timepoint.
(b) Calculated using randomized subjects as a denominator.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:09:14

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Table 11.10
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
NUMBER OF SUBJECTS WITH BASELINE AND >=1 POST BASELINE VALUE	47/187 (25.1)	49/201 (24.4)	96/388 (24.7)
NUMBER OF SUBJECTS WITHOUT BASELINE VALUE	135/187 (72.2)	145/201 (72.1)	280/388 (72.2)
NUMBER OF SUBJECTS WITHOUT POST BASELINE VALUE	124/187 (66.3)	136/201 (67.7)	260/388 (67.0)
TIMEPOINT			
WEEK 1 (BASELINE)	52/187 (27.8)	56/201 (27.9)	108/388 (27.8)
ON-STUDY			
WEEK 4	41/187 (21.9)	47/201 (23.4)	88/388 (22.7)
WEEK 8	35/187 (18.7)	42/201 (20.9)	77/388 (19.8)
WEEK 12	32/187 (17.1)	38/201 (18.9)	70/388 (18.0)
WEEK 16	28/187 (15.0)	35/201 (17.4)	63/388 (16.2)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:54

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Table 11.10
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 20	29/187 (15.5)	30/201 (14.9)	59/388 (15.2)
WEEK 24	25/187 (13.4)	27/201 (13.4)	52/388 (13.4)
WEEK 28	23/187 (12.3)	30/201 (14.9)	53/388 (13.7)
WEEK 32	22/187 (11.8)	27/201 (13.4)	49/388 (12.6)
WEEK 36	23/187 (12.3)	27/201 (13.4)	50/388 (12.9)
WEEK 40	27/187 (14.4)	28/201 (13.9)	55/388 (14.2)
WEEK 44	25/187 (13.4)	23/201 (11.4)	48/388 (12.4)
WEEK 48	26/187 (13.9)	21/201 (10.4)	47/388 (12.1)
WEEK 52	23/187 (12.3)	18/201 (9.0)	41/388 (10.6)
WEEK 56	20/187 (10.7)	15/201 (7.5)	35/388 (9.0)
WEEK 60	21/187 (11.2)	15/201 (7.5)	36/388 (9.3)
WEEK 64	18/187 (9.6)	15/201 (7.5)	33/388 (8.5)
WEEK 68	19/187 (10.2)	14/201 (7.0)	33/388 (8.5)
WEEK 72	18/187 (9.6)	14/201 (7.0)	32/388 (8.2)
WEEK 76	18/187 (9.6)	12/201 (6.0)	30/388 (7.7)
WEEK 80	15/187 (8.0)	12/201 (6.0)	27/388 (7.0)
WEEK 84	14/187 (7.5)	10/201 (5.0)	24/388 (6.2)
WEEK 88	13/187 (7.0)	10/201 (5.0)	23/388 (5.9)
WEEK 92	15/187 (8.0)	10/201 (5.0)	25/388 (6.4)
WEEK 96	14/187 (7.5)	9/201 (4.5)	23/388 (5.9)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:54

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Table 11.10
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 100	14/187 (7.5)	7/201 (3.5)	21/388 (5.4)
WEEK 104	13/187 (7.0)	8/201 (4.0)	21/388 (5.4)
WEEK 108	14/187 (7.5)	7/201 (3.5)	21/388 (5.4)
WEEK 112	11/187 (5.9)	8/201 (4.0)	19/388 (4.9)
WEEK 116	12/187 (6.4)	7/201 (3.5)	19/388 (4.9)
WEEK 120	12/187 (6.4)	7/201 (3.5)	19/388 (4.9)
WEEK 124	12/187 (6.4)	7/201 (3.5)	19/388 (4.9)
WEEK 128	8/187 (4.3)	7/201 (3.5)	15/388 (3.9)
WEEK 132	8/187 (4.3)	7/201 (3.5)	15/388 (3.9)
WEEK 136	8/187 (4.3)	7/201 (3.5)	15/388 (3.9)
WEEK 140	8/187 (4.3)	6/201 (3.0)	14/388 (3.6)
WEEK 144	9/187 (4.8)	7/201 (3.5)	16/388 (4.1)
WEEK 148	10/187 (5.3)	8/201 (4.0)	18/388 (4.6)
WEEK 152	9/187 (4.8)	6/201 (3.0)	15/388 (3.9)
WEEK 156	7/187 (3.7)	9/201 (4.5)	16/388 (4.1)
WEEK 160	7/187 (3.7)	7/201 (3.5)	14/388 (3.6)
WEEK 164	7/187 (3.7)	7/201 (3.5)	14/388 (3.6)
WEEK 168	6/187 (3.2)	6/201 (3.0)	12/388 (3.1)
WEEK 172	6/187 (3.2)	7/201 (3.5)	13/388 (3.4)
WEEK 176	6/187 (3.2)	6/201 (3.0)	12/388 (3.1)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:54

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Table 11.10
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 180	5/187 (2.7)	9/201 (4.5)	14/388 (3.6)
WEEK 184	5/187 (2.7)	7/201 (3.5)	12/388 (3.1)
WEEK 188	5/187 (2.7)	7/201 (3.5)	12/388 (3.1)
WEEK 192	6/187 (3.2)	7/201 (3.5)	13/388 (3.4)
WEEK 196	6/187 (3.2)	6/201 (3.0)	12/388 (3.1)
WEEK 200	5/187 (2.7)	6/201 (3.0)	11/388 (2.8)
WEEK 204	6/187 (3.2)	6/201 (3.0)	12/388 (3.1)
WEEK 208	5/187 (2.7)	6/201 (3.0)	11/388 (2.8)
WEEK 212	7/187 (3.7)	5/201 (2.5)	12/388 (3.1)
WEEK 216	5/187 (2.7)	7/201 (3.5)	12/388 (3.1)
WEEK 220	5/187 (2.7)	6/201 (3.0)	11/388 (2.8)
WEEK 224	5/187 (2.7)	4/201 (2.0)	9/388 (2.3)
WEEK 228	4/187 (2.1)	5/201 (2.5)	9/388 (2.3)
WEEK 232	5/187 (2.7)	5/201 (2.5)	10/388 (2.6)
WEEK 236	3/187 (1.6)	5/201 (2.5)	8/388 (2.1)
WEEK 240	4/187 (2.1)	4/201 (2.0)	8/388 (2.1)
WEEK 244	5/187 (2.7)	4/201 (2.0)	9/388 (2.3)
WEEK 248	4/187 (2.1)	4/201 (2.0)	8/388 (2.1)
WEEK 252	4/187 (2.1)	4/201 (2.0)	8/388 (2.1)
WEEK 256	5/187 (2.7)	5/201 (2.5)	10/388 (2.6)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:54

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Table 11.10
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 260	5/187 (2.7)	4/201 (2.0)	9/388 (2.3)
WEEK 264	4/187 (2.1)	2/201 (1.0)	6/388 (1.5)
WEEK 268	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 272	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 276	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 280	4/187 (2.1)	2/201 (1.0)	6/388 (1.5)
WEEK 284	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 288	3/187 (1.6)	2/201 (1.0)	5/388 (1.3)
WEEK 292	3/187 (1.6)	3/201 (1.5)	6/388 (1.5)
WEEK 296	2/187 (1.1)	3/201 (1.5)	5/388 (1.3)
WEEK 300	2/187 (1.1)	3/201 (1.5)	5/388 (1.3)
WEEK 304	2/187 (1.1)	3/201 (1.5)	5/388 (1.3)
WEEK 308	2/187 (1.1)	3/201 (1.5)	5/388 (1.3)
WEEK 312	2/187 (1.1)	3/201 (1.5)	5/388 (1.3)
WEEK 316	2/187 (1.1)	2/201 (1.0)	4/388 (1.0)
WEEK 320	1/187 (0.5)	3/201 (1.5)	4/388 (1.0)
WEEK 324	2/187 (1.1)	3/201 (1.5)	5/388 (1.3)
WEEK 328	2/187 (1.1)	1/201 (0.5)	3/388 (0.8)
WEEK 332	2/187 (1.1)	1/201 (0.5)	3/388 (0.8)
WEEK 336	1/187 (0.5)	1/201 (0.5)	2/388 (0.5)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:54

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Table 11.10
WPAI:GH Activity Impairment Item Completion Rates Out of Subjects Randomized
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	Number of Subjects Who Completed the Questionnaire/ Number of Subjects Randomized		
Completion Rate (%)	BMS-986213 N = 187	Nivolumab N = 201	Total N = 388
WEEK 340	1/187 (0.5)	1/201 (0.5)	2/388 (0.5)
WEEK 344	2/187 (1.1)	1/201 (0.5)	3/388 (0.8)
WEEK 348	1/187 (0.5)	1/201 (0.5)	2/388 (0.5)
WEEK 352	1/187 (0.5)	1/201 (0.5)	2/388 (0.5)
WEEK 356	1/187 (0.5)	1/201 (0.5)	2/388 (0.5)
WEEK 360	0/187	0/201	0/388
WEEK 364	0/187	0/201	0/388
FOLLOW-UP			
FOLLOW-UP 1	26/187 (13.9)	26/201 (12.9)	52/388 (13.4)
FOLLOW-UP 2	19/187 (10.2)	16/201 (8.0)	35/388 (9.0)

NOV 2025 DBL.
The WPAI:GH Activity Impairment Item is considered as completed if its value is non-missing.
Program Path: /pic/projects2/blinded/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-comp-ebr2586_b5.sas 20FEB2026:10:08:54

Anhang 4-G 4: MMRM-Analysen zu EQ-5D-VAS und FACT-M

Anhang 4-G 4.1: EQ-5D-VAS

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Table 12.2
EQ-5D VAS Mixed Model Repeated Measures Analysis
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187			Nivolumab N = 201			BMS-986213 vs. Nivolumab	
EQ-5D-3L Domain	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)(3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)(3)	Difference in Mean Change (95% CI) P-value (3)	SMD as Hedges' g (95% CI)
VAS	169	76.6 (20.2)	-0.40 (-2.59, 1.79)	178	76.9 (21.1)	-0.55 (-2.68, 1.58)	0.15 (-2.89, 3.20) 0.9206	0.01 (-0.20, 0.22)

NOV 2025 DBL. NE = Not estimable. SMD = standardized mean difference. SD = standard deviation.
(1) N is the number of subjects with non-missing baseline and at least one on-treatment assessment.
(2) A positive change from baseline characterizes an improvement.
(3) Estimates based on an MMRM with change from baseline as dependent variable. Treatment, visit, the treatment*visit interaction, and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since Unstructured covariance did not converge, the model was fit using Compound Symmetry covariance.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-mmrm-ebr2586_b5.sas 13FEB2026:10:03:00

Anhang 4-G 4.2: FACT-M

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Table 12.1
FACT-M Mixed Model Repeated Measures Analysis
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187			Nivolumab N = 201			BMS-986213 vs. Nivolumab	
FACT-M Domain	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)(3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)(3)	Difference in Mean Change (95% CI) P-value (3)	SMD as Hedges' g (95% CI)
FACT-M TOTAL SCORE	167	132.9 (25.3)	-1.89 (-4.50, 0.72)	177	134.4 (22.7)	0.67 (-1.85, 3.20)	-2.56 (-6.18, 1.05) 0.1638	-0.15 (-0.36, 0.06)
FACT-G TOTAL SCORE	167	80.9 (17.1)	-2.25 (-4.15, -0.35)	177	81.3 (15.4)	0.28 (-1.56, 2.12)	-2.53 (-5.17, 0.11) 0.0602	-0.20 (-0.41, 0.01)
PWB (PHYSICAL WELL-BEING)	167	23.1 (5.2)	-1.11 (-1.72, -0.51)	179	23.6 (5.1)	-1.36 (-1.94, -0.78)	0.25 (-0.58, 1.08) 0.5554	0.06 (-0.15, 0.27)
SWB (SOCIAL WELL-BEING)	169	21.9 (5.7)	-1.84 (-2.50, -1.17)	178	22.0 (5.4)	0.30 (-0.34, 0.94)	-2.13 (-3.05, -1.21) <0.0001	-0.49 (-0.70, -0.27)
EWB (EMOTIONAL WELL-BEING)	168	17.3 (4.4)	1.23 (0.71, 1.74)	178	17.4 (4.4)	1.49 (0.99, 1.99)	-0.26 (-0.97, 0.45) 0.4748	-0.08 (-0.29, 0.13)
FWB (FUNCTIONAL WELL-BEING)	169	18.6 (6.5)	-0.66 (-1.40, 0.08)	177	18.2 (6.5)	-0.15 (-0.87, 0.58)	-0.51 (-1.55, 0.52) 0.3302	-0.10 (-0.32, 0.11)

NOV 2025 DBL. NE = Not estimable. SMD = standardized mean difference. SD = standard deviation.
(1) N is the number of subjects with non-missing baseline and at least one on-treatment assessment.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
(3) Estimates based on an MMRM with change from baseline as dependent variable. Treatment, visit, the treatment*visit interaction, and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since Unstructured covariance did not converge for any scale, all models were fit using Compound Symmetry covariance.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-mmrm-ebr2586_b5.sas 13FEB2026:10:03:29

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Table 12.1
FACT-M Mixed Model Repeated Measures Analysis
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187			Nivolumab N = 201			BMS-986213 vs. Nivolumab	
FACT-M Domain	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)(3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)(3)	Difference in Mean Change (95% CI) P-value (3)	SMD as Hedges' g (95% CI)
FACT-M MELANOMA SUBSCALE	169	52.0 (9.7)	0.19 (-0.74, 1.13)	182	53.2 (8.9)	0.36 (-0.53, 1.24)	-0.16 (-1.44, 1.12) 0.8017	-0.03 (-0.24, 0.18)
FACT-M MSS (MELANOMA SURGERY SCALE)	161	24.4 (7.3)	1.18 (0.48, 1.88)	178	25.4 (6.3)	1.20 (0.54, 1.86)	-0.02 (-0.98, 0.93) 0.9653	0.00 (-0.22, 0.21)
GP5 ITEM	154	0.2 (0.6)	0.52 (0.40, 0.64)	167	0.3 (0.9)	0.36 (0.25, 0.48)	0.15 (-0.01, 0.32) 0.0712	0.20 (-0.02, 0.42)

NOV 2025 DBL. NE = Not estimable. SMD = standardized mean difference. SD = standard deviation.
(1) N is the number of subjects with non-missing baseline and at least one on-treatment assessment.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
(3) Estimates based on an MMRM with change from baseline as dependent variable. Treatment, visit, the treatment*visit interaction, and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since Unstructured covariance did not converge for any scale, all models were fit using Compound Symmetry covariance.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-sy-mmrm-ebr2586_b5.sas 13FEB2026:10:03:29

Anhang 4-G 5: Verlaufsdarstellungen zum FACT-M (einschließlich aller Skalen)

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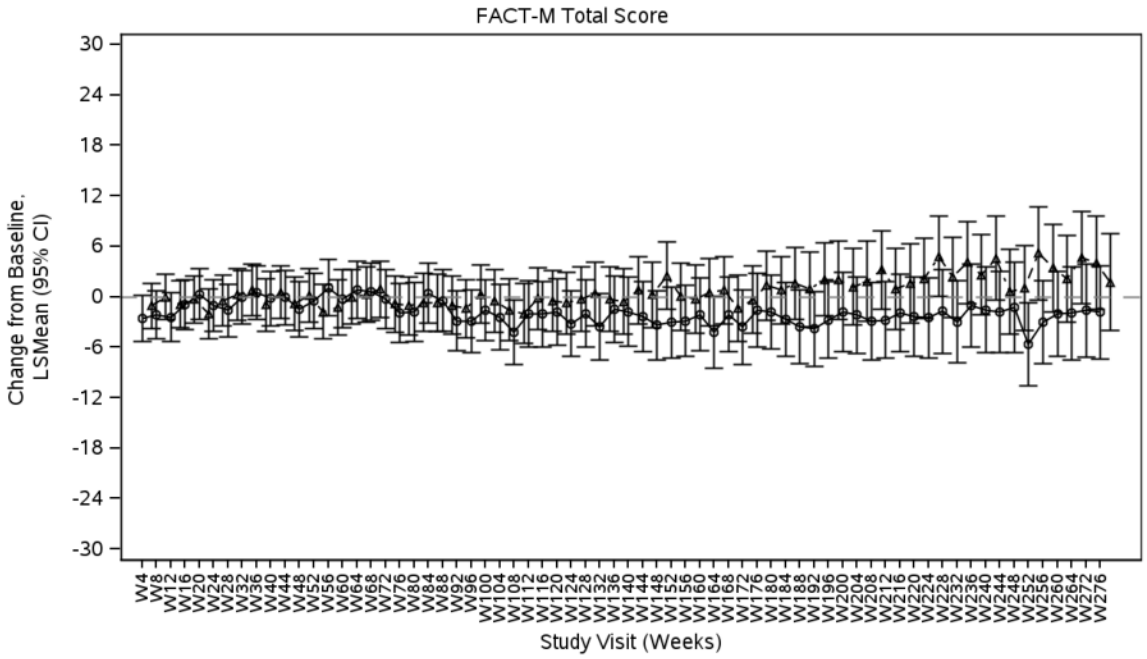
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

153	125	89	74	74	66	61	52	53	47	42	42	39	32	32	31	30	26	26	24	23	20	21	21	19	19	19	17	15	15	16	15	14	11
137	104	85	71	68	62	55	54	47	44	39	38	32	30	30	29	30	25	23	22	20	21	21	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

159	129	101	82	71	66	60	59	52	48	49	44	36	40	37	32	31	27	27	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
149	122	86	81	71	67	56	57	53	47	47	44	38	37	37	33	30	29	27	27	28	25	22	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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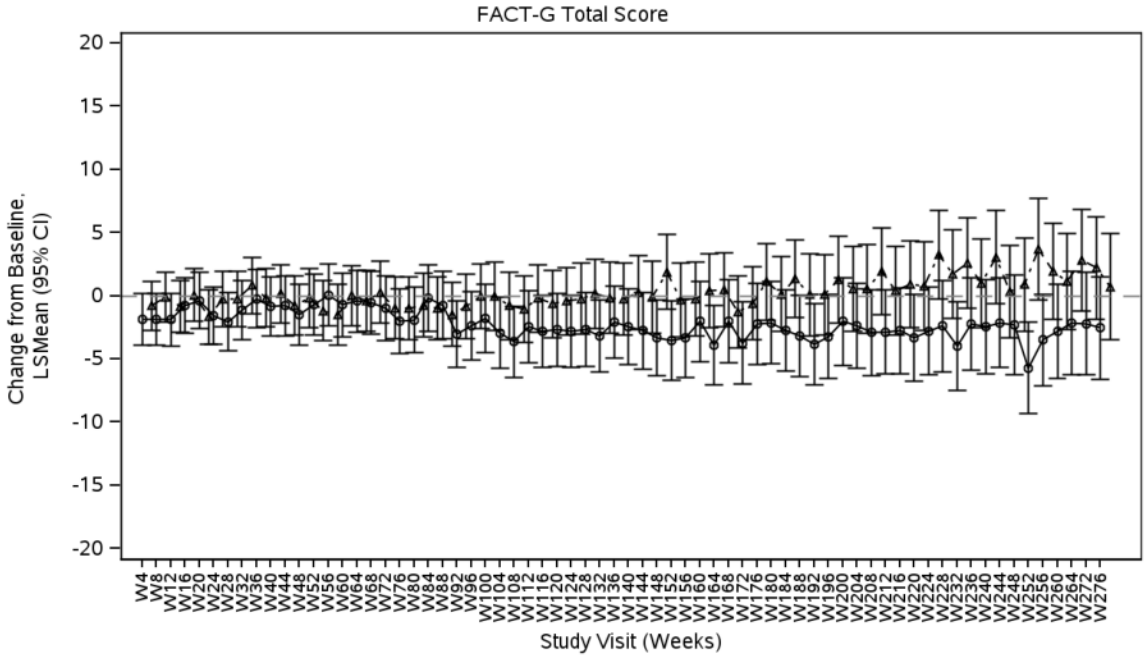
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

153	125	89	74	74	66	61	52	53	47	42	42	39	32	32	31	30	26	26	24	23	20	21	21	19	19	19	17	15	15	16	15	14	11
137	104	85	71	68	62	55	54	47	44	39	38	33	30	30	29	30	25	23	22	20	21	21	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

160	129	101	82	71	66	60	59	52	48	49	44	36	40	37	32	31	27	27	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
150	122	86	81	71	67	57	57	53	47	47	44	38	37	37	33	30	29	27	27	29	25	23	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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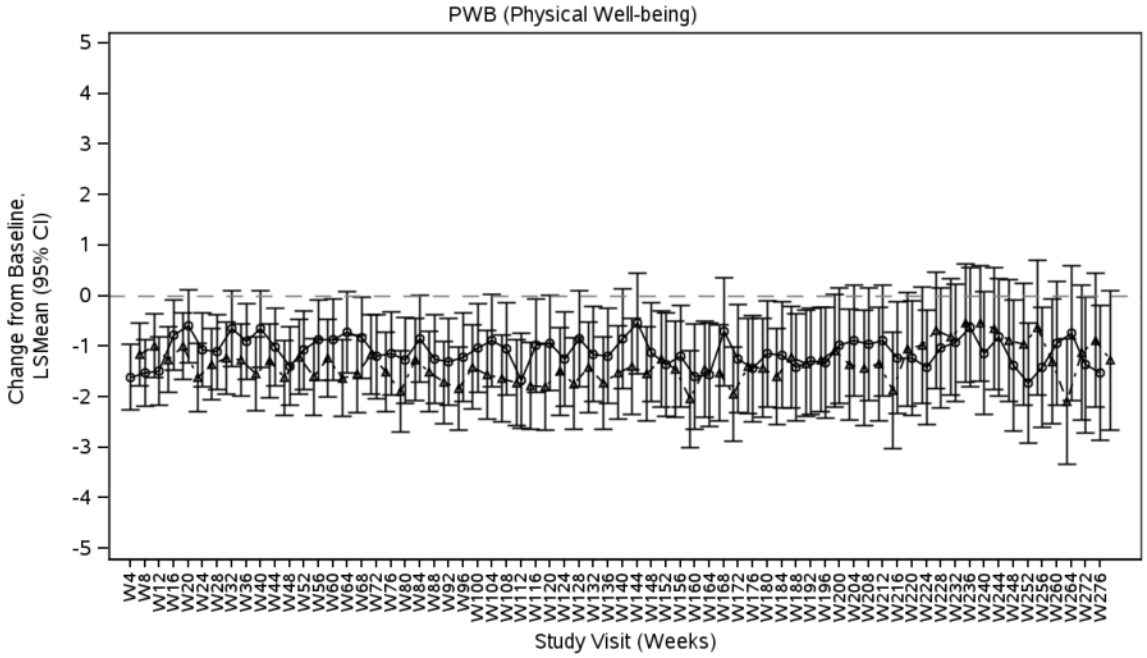
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

153	125	89	74	74	66	61	52	53	48	42	42	39	32	32	31	30	26	26	24	23	20	21	21	19	19	19	17	15	15	16	15	14	11
137	104	85	71	68	62	55	55	47	44	39	39	33	30	30	29	30	25	23	22	20	21	21	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

164	130	104	83	72	67	60	60	53	49	50	44	36	40	37	32	31	27	27	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
151	122	86	81	73	68	58	58	54	47	47	44	38	37	37	33	30	29	27	27	29	25	23	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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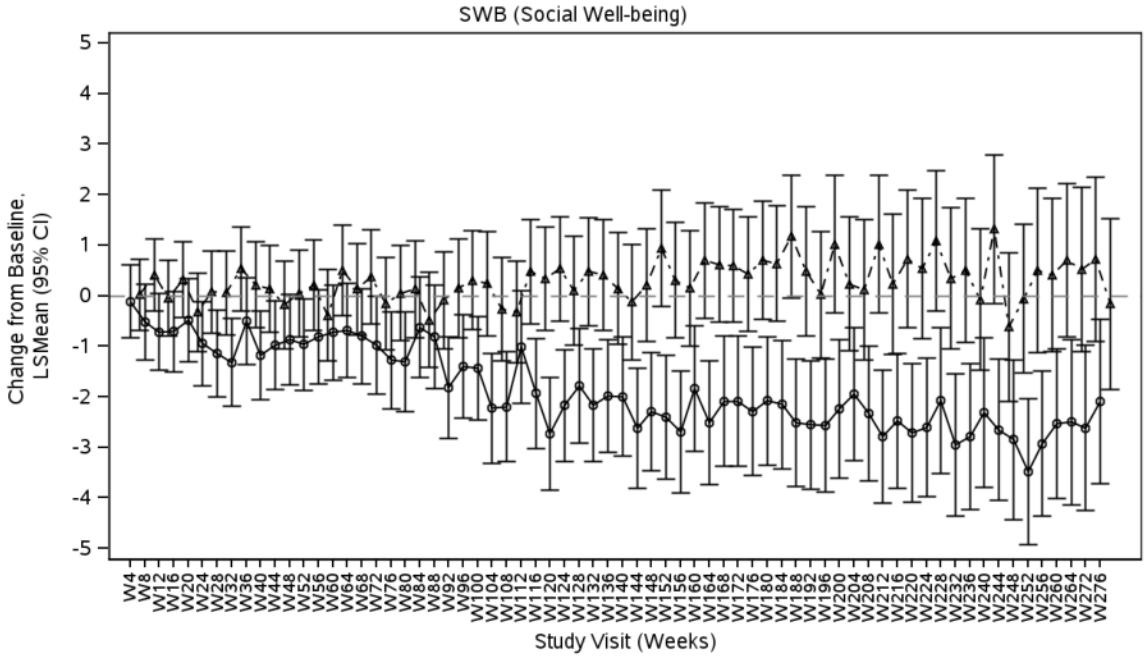
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

155	127	90	74	74	66	61	52	53	48	42	42	39	32	32	31	30	26	26	24	23	20	21	21	19	19	19	17	15	15	16	15	14	11
139	106	85	71	68	62	55	55	47	44	39	39	33	30	30	29	30	25	23	22	20	21	21	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

162	130	103	83	72	67	60	60	53	49	50	44	36	40	37	32	31	27	27	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
152	122	87	81	73	68	58	58	54	47	47	44	38	37	37	33	30	29	27	27	29	25	23	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
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Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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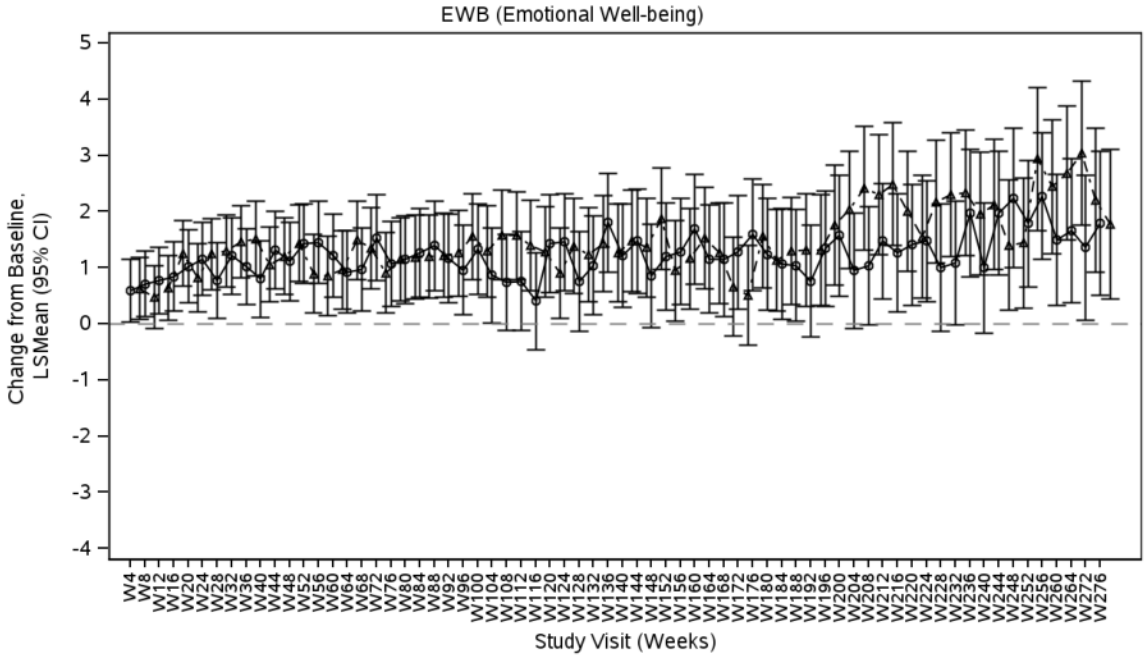
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

154	126	89	74	74	66	61	52	53	47	42	42	39	32	32	31	30	26	26	24	23	20	21	21	19	19	19	17	15	15	16	15	14	11
138	105	86	71	68	62	55	54	47	44	39	39	33	30	30	29	30	25	23	22	20	21	21	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

162	130	103	83	72	67	60	60	53	49	50	44	37	40	37	32	31	27	27	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
152	122	87	81	72	68	58	59	54	47	47	44	38	37	37	33	30	29	27	27	29	25	23	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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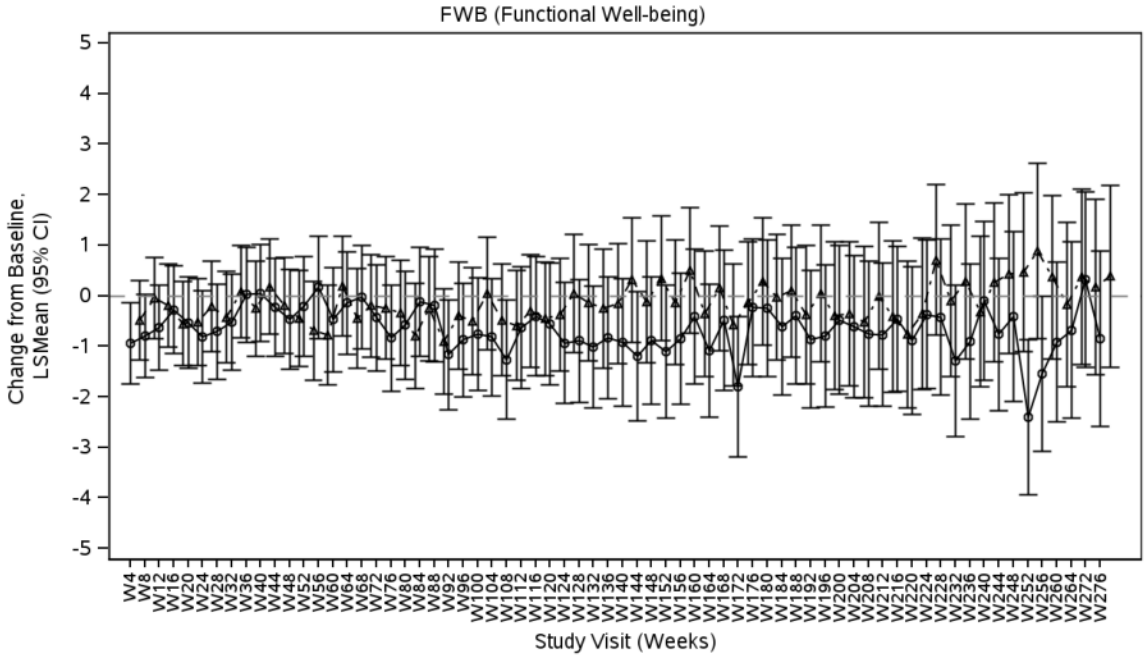
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

155 127 90 74 74 66 61 52 53 47 42 42 39 32 32 31 30 26 26 24 23 20 21 21 19 19 19 17 15 15 16 15 14 11

139 106 86 71 68 62 55 54 47 44 39 38 33 30 30 29 30 25 23 22 20 21 21 21 17 18 18 17 16 14 12 15 11 11

Nivolumab

161 129 102 82 71 66 60 59 52 48 49 44 37 40 37 32 31 27 27 27 27 28 27 20 17 16 16 16 16 16 14 11 13 11

150 122 87 81 71 67 57 58 53 47 47 44 38 37 37 33 30 29 27 27 29 25 23 21 18 17 17 16 15 14 14 13 11 10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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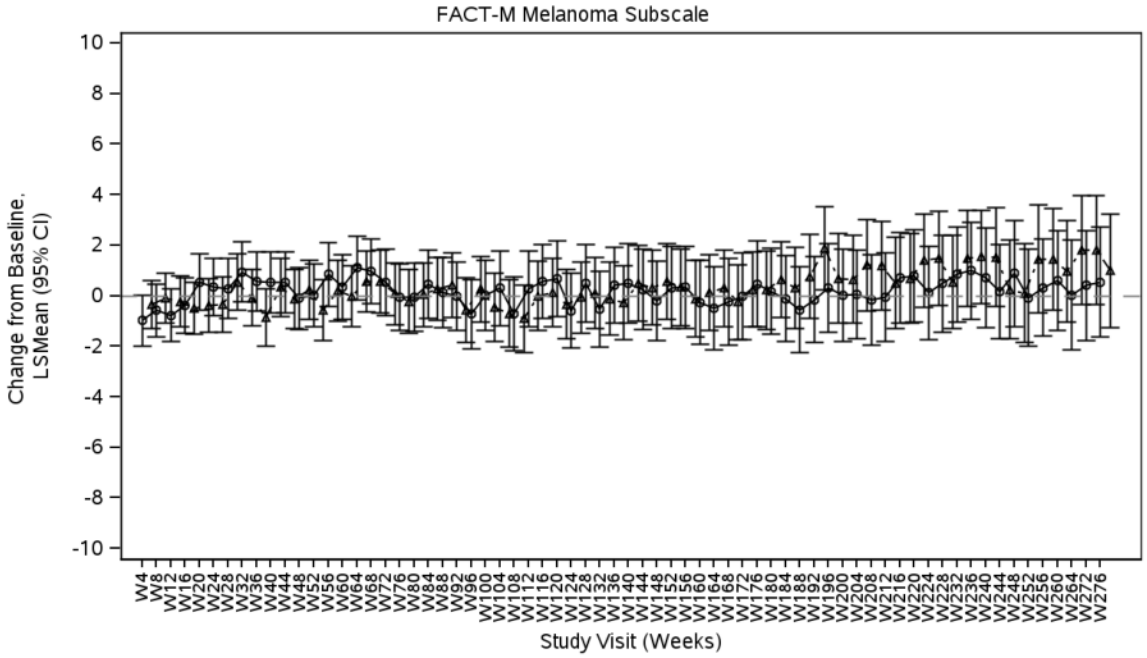
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

156	127	90	75	76	66	61	53	53	49	42	42	39	32	32	31	30	26	26	24	23	20	21	21	19	19	19	17	15	15	16	15	14	11
139	107	87	72	69	62	56	55	48	44	39	39	32	30	30	29	30	25	23	22	20	21	21	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

166	133	106	85	74	69	62	62	54	51	52	46	39	42	39	34	32	28	28	28	28	29	28	21	18	17	17	16	16	16	14	11	13	11
154	124	90	83	75	70	59	60	56	49	49	46	40	38	39	35	31	30	28	28	29	26	23	22	19	18	18	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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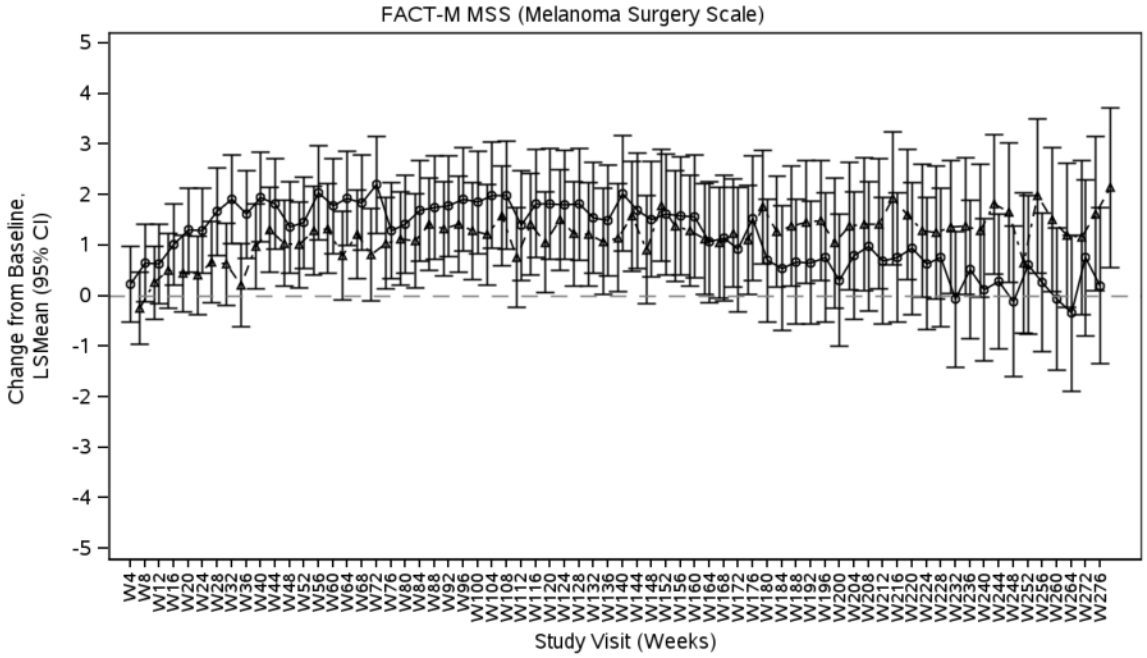
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

143	122	87	72	71	62	59	50	50	47	40	40	38	31	31	30	29	25	25	23	22	20	21	20	18	19	19	17	15	15	16	15	14	11
128	99	83	68	65	59	53	53	46	43	37	37	33	29	29	28	29	25	22	21	20	20	20	21	17	18	18	17	16	14	12	15	11	11

Nivolumab

162	127	103	82	71	66	59	59	51	49	49	43	37	38	36	32	31	27	26	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
150	121	87	79	72	67	57	58	53	46	46	42	37	36	36	33	29	29	27	27	29	25	21	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

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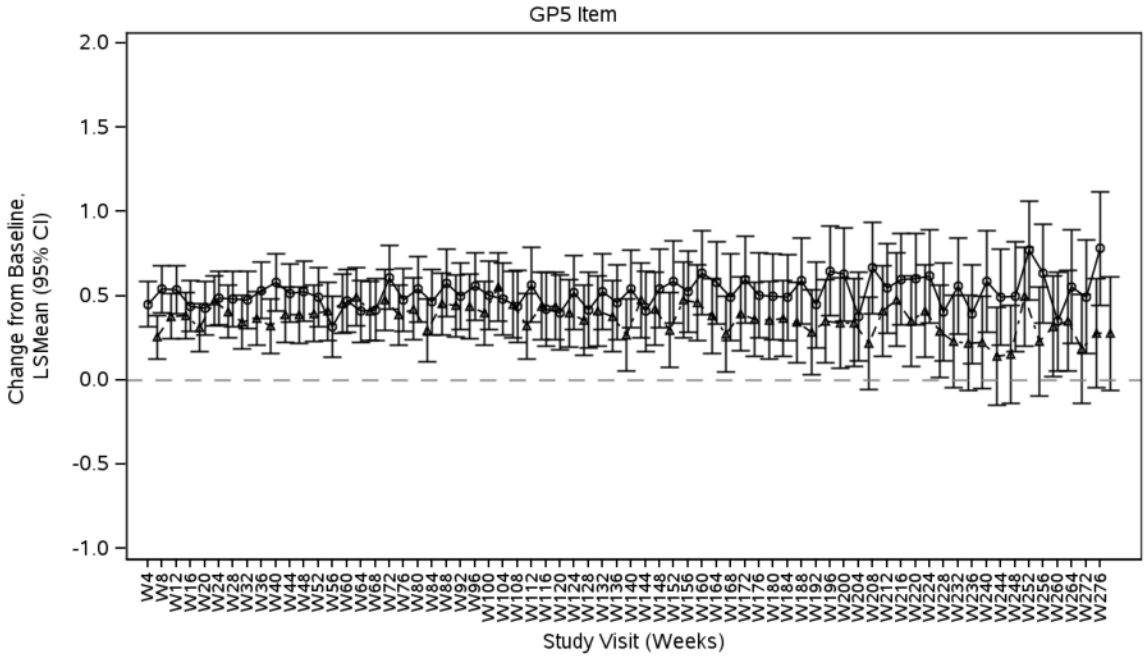
Figure 12.1
Plot of Mixed Model Repeated Measures Analysis of FACT-M by Timepoint - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects with Measurement at Timepoint

BMS-986213

140	118	84	69	69	61	58	48	51	46	41	40	37	31	30	29	28	25	25	23	22	19	20	20	18	18	18	17	14	14	15	14	14	10
128	99	81	66	64	57	52	52	45	42	38	38	31	28	28	27	28	23	22	21	19	20	20	20	16	17	17	16	15	13	11	14	10	10

Nivolumab

155	124	99	78	70	64	57	58	51	48	49	43	35	40	37	32	31	27	27	27	27	28	27	20	17	16	16	16	16	16	14	11	13	11
144	113	81	77	70	65	54	57	52	46	46	43	38	37	37	33	30	29	27	27	29	25	23	21	18	17	17	16	15	14	14	13	11	10

NOV 2025 DBL.
N = number of randomized subjects with non-missing baseline and Week t assessment timepoint.
(2) Negative change characterizes an improvement for GP5, positive change - for other scales.
MMRM with change from baseline as dependent variable. Treatment, visit, treatment*visit,
and the baseline PRO score were included as fixed effects.
Visit was specified as a repeated effect to model within-subject correlations.
Since UN did not converge for any scale, all models were fit using a CS covariance structure.
Only the on-treatment visits with 10 subjects or more in each treatment group were included.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-mmrm-ebr2586_b5.sas 13FEB2026:07:00:09

Anhang 4-G 6: Auswertungen der UE auf Ebene der SOC und PT

Anhang 4-G 6.1.1: Jegliche UE auf Ebene der SOC und PT

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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	187	185 (98.9)	0.49 (0.39, 0.59)	201	195 (97.0)	0.69 (0.53, 0.92)	1.34 (1.09, 1.64)	0.0048*
GASTROINTESTINAL DISORDERS	187	118 (63.1)	5.42 (3.68, 7.23)	201	105 (52.2)	11.17 (6.47, 15.90)	1.37 (1.05, 1.78)	0.0198*
DIARRHOEA	187	52 (27.8)	44.35 (21.45, N.A.)	201	47 (23.4)	N.A. (42.48, N.A.)	1.23 (0.83, 1.83)	0.3011
NAUSEA	187	42 (22.5)	N.A. (33.77, N.A.)	201	43 (21.4)	N.A.	1.04 (0.68, 1.59)	0.8705
ABDOMINAL PAIN	187	21 (11.2)	N.A.	201	16 (8.0)	N.A.	1.44 (0.75, 2.76)	0.2676
VOMITING	187	20 (10.7)	N.A.	201	15 (7.5)	N.A.	1.44 (0.74, 2.81)	0.2837
CONSTIPATION	187	19 (10.2)	N.A.	201	15 (7.5)	N.A.	1.36 (0.69, 2.68)	0.3692
DRY MOUTH	187	15 (8.0)	N.A.	201	10 (5.0)	N.A.	1.58 (0.71, 3.52)	0.2595

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-taesocpthr-ebr2586_b5.sas 13FEB2026:10:03:46

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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
ABDOMINAL PAIN UPPER	187	11 (5.9)	N.A.	201	8 (4.0)	N.A.	1.46 (0.59, 3.64)	0.4100
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	187	116 (62.0)	5.13 (3.68, 8.31)	201	103 (51.2)	8.21 (5.55, 22.44)	1.32 (1.02, 1.73)	0.0370*
FATIGUE	187	60 (32.1)	45.01 (22.51, N.A.)	201	40 (19.9)	N.A.	1.72 (1.16, 2.57)	0.0069*
PYREXIA	187	29 (15.5)	N.A.	201	28 (13.9)	N.A.	1.13 (0.67, 1.91)	0.6357
ASTHENIA	187	28 (15.0)	N.A.	201	23 (11.4)	N.A.	1.27 (0.73, 2.21)	0.3882
OEDEMA PERIPHERAL	187	16 (8.6)	N.A.	201	8 (4.0)	N.A.	2.16 (0.92, 5.04)	0.0688
INFLUENZA LIKE ILLNESS	187	12 (6.4)	N.A.	201	9 (4.5)	N.A.	1.43 (0.60, 3.41)	0.4103
PAIN	187	7 (3.7)	N.A.	201	10 (5.0)	N.A.	0.73 (0.28, 1.92)	0.5197

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-taesocpthr-ebr2586_b5.sas 13FEB2026:10:03:46

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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	187	99 (52.9)	8.21 (5.75, 17.38)	201	83 (41.3)	18.30 (13.34, 29.14)	1.38 (1.03, 1.84)	0.0315*
ARTHRALGIA	187	49 (26.2)	49.74 (28.65, N.A.)	201	34 (16.9)	N.A. (34.73, N.A.)	1.65 (1.06, 2.55)	0.0244*
BACK PAIN	187	23 (12.3)	N.A.	201	20 (10.0)	N.A.	1.25 (0.69, 2.28)	0.4627
MYALGIA	187	16 (8.6)	N.A.	201	18 (9.0)	N.A.	0.96 (0.49, 1.89)	0.9081
PAIN IN EXTREMITY	187	16 (8.6)	N.A.	201	9 (4.5)	N.A.	1.94 (0.86, 4.40)	0.1040
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	187	99 (52.9)	6.70 (5.36, 10.05)	201	93 (46.3)	12.32 (6.60, 17.08)	1.28 (0.97, 1.71)	0.0823
PRURITUS	187	53 (28.3)	N.A. (20.21, N.A.)	201	33 (16.4)	N.A.	1.93 (1.25, 2.98)	0.0026*
RASH	187	32 (17.1)	N.A.	201	29 (14.4)	N.A. (60.32, N.A.)	1.20 (0.73, 1.99)	0.4710

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

System Organ Class (%) Preferred Term (%)	BMS-986213 N	BMS-986213 Subjects with Event n (%)	BMS-986213 KME [95% CI] (mon) (1)	Nivolumab N	Nivolumab Subjects with Event n (%)	Nivolumab KME [95% CI] (mon) (1)	BMS-986213 vs. Nivolumab HR [95% CI] (2)	BMS-986213 vs. Nivolumab P-value (3)
VITILIGO	187	26 (13.9)	N.A.	201	20 (10.0)	N.A.	1.41 (0.79, 2.53)	0.2423
ERYTHEMA	187	5 (2.7)	N.A.	201	11 (5.5)	N.A.	0.46 (0.16, 1.33)	0.1402
INFECTIONS AND INFESTATIONS	187	97 (51.9)	9.30 (7.39, 12.85)	201	83 (41.3)	16.39 (13.70, 27.43)	1.44 (1.07, 1.94)	0.0144*
URINARY TRACT INFECTION	187	19 (10.2)	N.A.	201	21 (10.4)	N.A.	0.96 (0.51, 1.78)	0.8863
COVID-19	187	17 (9.1)	N.A. (40.77, N.A.)	201	16 (8.0)	N.A. (58.87, N.A.)	1.23 (0.62, 2.43)	0.5577
UPPER RESPIRATORY TRACT INFECTION	187	12 (6.4)	N.A. (76.16, N.A.)	201	6 (3.0)	N.A.	2.17 (0.81, 5.78)	0.1139
INFLUENZA	187	11 (5.9)	N.A.	201	4 (2.0)	N.A.	3.03 (0.96, 9.53)	0.0458*
NASOPHARYNGITIS	187	11 (5.9)	N.A.	201	11 (5.5)	N.A.	1.07 (0.47, 2.48)	0.8669

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
INVESTIGATIONS	187	87 (46.5)	16.20 (8.77, 22.31)	201	89 (44.3)	15.41 (10.22, 63.97)	1.04 (0.77, 1.40)	0.7991
ALANINE AMINOTRANSFERASE INCREASED	187	20 (10.7)	N.A.	201	20 (10.0)	N.A.	1.08 (0.58, 2.00)	0.8184
ASPARTATE AMINOTRANSFERASE INCREASED	187	19 (10.2)	N.A.	201	18 (9.0)	N.A.	1.12 (0.59, 2.14)	0.7244
WEIGHT DECREASED	187	17 (9.1)	N.A.	201	12 (6.0)	N.A.	1.53 (0.73, 3.21)	0.2552
TROPONIN INCREASED	187	15 (8.0)	N.A.	201	13 (6.5)	N.A.	1.21 (0.58, 2.55)	0.6080
BLOOD ALKALINE PHOSPHATASE INCREASED	187	13 (7.0)	N.A. (60.45, N.A.)	201	11 (5.5)	N.A.	1.26 (0.56, 2.81)	0.5707
GAMMA-GLUTAMYLTRANSFERASE INCREASED	187	11 (5.9)	N.A.	201	11 (5.5)	N.A.	1.05 (0.45, 2.42)	0.9131
BLOOD CREATININE INCREASED	187	10 (5.3)	N.A.	201	9 (4.5)	N.A.	1.20 (0.49, 2.95)	0.6939

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
BLOOD LACTATE DEHYDROGENASE INCREASED	187	6 (3.2)	N.A.	201	12 (6.0)	N.A.	0.53 (0.20, 1.42)	0.2004
LIPASE INCREASED	187	5 (2.7)	N.A.	201	10 (5.0)	N.A.	0.53 (0.18, 1.55)	0.2392
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	187	79 (42.2)	18.33 (9.99, 39.56)	201	68 (33.8)	44.98 (17.15, N.A.)	1.30 (0.94, 1.80)	0.1131
COUGH	187	29 (15.5)	N.A.	201	27 (13.4)	N.A.	1.16 (0.69, 1.96)	0.5823
DYSPNOEA	187	19 (10.2)	N.A.	201	14 (7.0)	N.A.	1.43 (0.72, 2.86)	0.3049
PNEUMONITIS	187	13 (7.0)	N.A. (70.21, N.A.)	201	7 (3.5)	N.A.	1.97 (0.79, 4.94)	0.1400
NERVOUS SYSTEM DISORDERS	187	76 (40.6)	16.85 (11.07, N.A.)	201	65 (32.3)	47.34 (26.64, N.A.)	1.38 (0.99, 1.92)	0.0560
HEADACHE	187	39 (20.9)	N.A. (59.43, N.A.)	201	33 (16.4)	N.A.	1.35 (0.85, 2.14)	0.2077

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
DIZZINESS	187	7 (3.7)	N.A.	201	14 (7.0)	N.A.	0.53 (0.22, 1.32)	0.1667
METABOLISM AND NUTRITION DISORDERS	187	64 (34.2)	32.46 (15.41, N.A.)	201	68 (33.8)	46.19 (22.34, N.A.)	1.05 (0.74, 1.47)	0.7966
DECREASED APPETITE	187	30 (16.0)	N.A.	201	17 (8.5)	N.A.	1.95 (1.07, 3.53)	0.0253*
HYPOKALAEMIA	187	12 (6.4)	N.A.	201	6 (3.0)	N.A.	2.18 (0.82, 5.80)	0.1110
HYPERGLYCAEMIA	187	10 (5.3)	N.A.	201	22 (10.9)	N.A.	0.47 (0.22, 1.00)	0.0456*
BLOOD AND LYMPHATIC SYSTEM DISORDERS	187	57 (30.5)	N.A. (24.74, N.A.)	201	46 (22.9)	N.A. (46.65, N.A.)	1.46 (0.99, 2.15)	0.0567
ANAEMIA	187	42 (22.5)	N.A.	201	31 (15.4)	N.A.	1.54 (0.97, 2.45)	0.0675
ENDOCRINE DISORDERS	187	54 (28.9)	N.A. (43.86, N.A.)	201	38 (18.9)	N.A.	1.54 (1.01, 2.33)	0.0408*

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
HYPOTHYROIDISM	187	34 (18.2)	N.A.	201	28 (13.9)	N.A.	1.30 (0.79, 2.14)	0.3065
HYPERTHYROIDISM	187	16 (8.6)	N.A.	201	15 (7.5)	N.A.	1.12 (0.55, 2.26)	0.7567
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	187	49 (26.2)	N.A.	201	62 (30.8)	47.90 (36.24, N.A.)	0.86 (0.59, 1.25)	0.4246
MALIGNANT NEOPLASM PROGRESSION	187	22 (11.8)	N.A.	201	38 (18.9)	N.A.	0.61 (0.36, 1.03)	0.0601
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	187	34 (18.2)	71.75 (59.04, N.A.)	201	29 (14.4)	N.A. (72.21, N.A.)	1.36 (0.82, 2.24)	0.2279
INFUSION RELATED REACTION	187	13 (7.0)	N.A.	201	5 (2.5)	N.A.	2.81 (1.00, 7.89)	0.0401*
EYE DISORDERS	187	33 (17.6)	N.A.	201	19 (9.5)	N.A.	1.97 (1.12, 3.47)	0.0161*
VISION BLURRED	187	10 (5.3)	N.A.	201	3 (1.5)	N.A.	3.61 (0.99, 13.12)	0.0370*

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
RENAL AND URINARY DISORDERS	187	30 (16.0)	N.A. (40.05, N.A.)	201	26 (12.9)	N.A.	1.22 (0.72, 2.07)	0.4530
VASCULAR DISORDERS	187	29 (15.5)	N.A. (66.04, N.A.)	201	22 (10.9)	N.A.	1.55 (0.89, 2.70)	0.1188
HYPERTENSION	187	11 (5.9)	N.A. (66.04, N.A.)	201	8 (4.0)	N.A.	1.57 (0.63, 3.91)	0.3271
CARDIAC DISORDERS	187	22 (11.8)	N.A.	201	29 (14.4)	N.A.	0.79 (0.45, 1.37)	0.4020
PSYCHIATRIC DISORDERS	187	22 (11.8)	N.A.	201	17 (8.5)	N.A.	1.38 (0.73, 2.60)	0.3133
ANXIETY	187	10 (5.3)	N.A.	201	5 (2.5)	N.A.	2.10 (0.72, 6.13)	0.1673
HEPATOBILIARY DISORDERS	187	18 (9.6)	N.A. (61.57, N.A.)	201	14 (7.0)	N.A.	1.34 (0.66, 2.69)	0.4137
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	187	13 (7.0)	N.A.	201	8 (4.0)	N.A.	1.75 (0.72, 4.22)	0.2085

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.1
Frequent Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
EAR AND LABYRINTH DISORDERS	187	11 (5.9)	N.A.	201	8 (4.0)	N.A.	1.51 (0.61, 3.75)	0.3742

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events are those that occurred in >=10 subjects or >=10% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Anhang 4-G 6.1.2: Schwere UE (CTCAE-Grad ≥ 3) auf Ebene der SOC und PT

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Table 16.2
Frequent CTCAE Grade 3-4-5 Adverse Events : Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	187	104 (55.6)	12.62 (8.21, 20.86)	201	116 (57.7)	10.81 (8.34, 17.64)	1.00 (0.77, 1.30)	0.9920
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	187	26 (13.9)	N.A. (70.77, N.A.)	201	48 (23.9)	N.A. (47.90, N.A.)	0.57 (0.35, 0.92)	0.0197*
MALIGNANT NEOPLASM PROGRESSION	187	21 (11.2)	N.A.	201	37 (18.4)	N.A.	0.60 (0.35, 1.02)	0.0573
INFECTIONS AND INFESTATIONS	187	25 (13.4)	N.A.	201	17 (8.5)	N.A.	1.57 (0.85, 2.91)	0.1464
INVESTIGATIONS	187	18 (9.6)	N.A.	201	15 (7.5)	N.A.	1.28 (0.65, 2.54)	0.4757
GASTROINTESTINAL DISORDERS	187	15 (8.0)	N.A.	201	16 (8.0)	N.A.	1.00 (0.50, 2.03)	0.9953
METABOLISM AND NUTRITION DISORDERS	187	14 (7.5)	N.A. (69.13, N.A.)	201	17 (8.5)	N.A.	0.85 (0.42, 1.73)	0.6619
BLOOD AND LYMPHATIC SYSTEM DISORDERS	187	13 (7.0)	N.A.	201	11 (5.5)	N.A.	1.28 (0.57, 2.85)	0.5510

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events with CTCAE Grade 3-4-5 are those that occurred in >=10 subjects or >=5% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 16.2
Frequent CTCAE Grade 3-4-5 Adverse Events : Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
ANAEMIA	187	10 (5.3)	N.A.	201	7 (3.5)	N.A.	1.53 (0.58, 4.01)	0.3866
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	187	12 (6.4)	N.A.	201	12 (6.0)	N.A.	1.04 (0.47, 2.32)	0.9175
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	187	11 (5.9)	N.A. (69.29, N.A.)	201	5 (2.5)	N.A.	2.36 (0.82, 6.78)	0.1016
HEPATOBILIARY DISORDERS	187	10 (5.3)	N.A.	201	2 (1.0)	N.A.	5.33 (1.17, 24.32)	0.0155*
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	187	4 (2.1)	N.A.	201	14 (7.0)	N.A.	0.30 (0.10, 0.91)	0.0244*

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Adverse Events with CTCAE Grade 3-4-5 are those that occurred in >=10 subjects or >=5% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Anhang 4-G 6.1.3: SUE auf Ebene der SOC und PT

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Table 16.3
Frequent Serious Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	N	Subjects with Event n (%)	KME [95% CI] (mon) (1)	HR [95% CI] (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	187	94 (50.3)	18.07 (10.15, 26.45)	201	101 (50.2)	15.84 (9.89, 32.69)	1.04 (0.79, 1.38)	0.7682
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	187	31 (16.6)	N.A. (70.77, N.A.)	201	47 (23.4)	N.A. (47.90, N.A.)	0.71 (0.45, 1.11)	0.1332
MALIGNANT NEOPLASM PROGRESSION	187	21 (11.2)	N.A.	201	36 (17.9)	N.A.	0.62 (0.36, 1.05)	0.0744
INFECTIONS AND INFESTATIONS	187	23 (12.3)	N.A.	201	16 (8.0)	N.A.	1.51 (0.80, 2.87)	0.1993
GASTROINTESTINAL DISORDERS	187	17 (9.1)	N.A.	201	12 (6.0)	N.A.	1.51 (0.72, 3.16)	0.2716
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	187	12 (6.4)	N.A.	201	11 (5.5)	N.A.	1.15 (0.51, 2.61)	0.7366
CARDIAC DISORDERS	187	8 (4.3)	N.A.	201	11 (5.5)	N.A.	0.79 (0.32, 1.95)	0.6034

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Serious Adverse Events are those that occurred in >=10 subjects or >=5% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-taesocpthr-ebr2586_b5.sas 13FEB2026:10:03:50

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Table 16.3
Frequent Serious Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

System Organ Class (%) Preferred Term (%)	BMS-986213 N	BMS-986213 Subjects with Event n (%)	BMS-986213 KME [95% CI] (mon) (1)	Nivolumab N	Nivolumab Subjects with Event n (%)	Nivolumab KME [95% CI] (mon) (1)	BMS-986213 vs. Nivolumab HR [95% CI] (2)	BMS-986213 vs. Nivolumab P-value (3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	187	5 (2.7)	N.A.	201	12 (6.0)	N.A.	0.44 (0.16, 1.25)	0.1144

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model.
(3) Unstratified log-rank test.. P-values <0.05 are indicated by 1 asterisk.
Frequent Serious Adverse Events are those that occurred in >=10 subjects or >=5% of subjects in one arm.
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-taesocpthr-ebr2586_b5.sas 13FEB2026:10:03:50

Anhang 4-G 6.1.4: Zum Therapieabbruch führende UE auf Ebene der SOC und PT

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Table 18.1
Adverse Events Leading to Discontinuation of Study Treatment
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187			Nivolumab N = 201		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	48 (25.7)	27 (14.4)	2 (1.1)	43 (21.4)	18 (9.0)	3 (1.5)
Respiratory, thoracic and mediastinal disorders	7 (3.7)	1 (0.5)	1 (0.5)	7 (3.5)	3 (1.5)	1 (0.5)
Pneumonitis	4 (2.1)	1 (0.5)	0	1 (0.5)	0	0
Dyspnoea exertional	1 (0.5)	0	0	0	0	0
Pleural effusion	1 (0.5)	0	0	2 (1.0)	1 (0.5)	0
Pulmonary oedema	1 (0.5)	0	1 (0.5)	0	0	0
Immune-mediated lung disease	0	0	0	1 (0.5)	1 (0.5)	0
Increased bronchial secretion	0	0	0	1 (0.5)	0	0
Respiratory failure	0	0	0	2 (1.0)	1 (0.5)	1 (0.5)
Gastrointestinal disorders	6 (3.2)	4 (2.1)	0	4 (2.0)	2 (1.0)	0
Colitis	2 (1.1)	2 (1.1)	0	0	0	0
Diarrhoea	2 (1.1)	1 (0.5)	0	0	0	0
Enteritis	1 (0.5)	0	0	0	0	0
Gastritis	1 (0.5)	1 (0.5)	0	0	0	0
Abdominal pain	0	0	0	1 (0.5)	1 (0.5)	0
Ascites	0	0	0	1 (0.5)	0	0
Pancreatic failure	0	0	0	1 (0.5)	1 (0.5)	0
Pancreatitis	0	0	0	1 (0.5)	0	0
Hepatobiliary disorders	5 (2.7)	5 (2.7)	0	4 (2.0)	1 (0.5)	0
Drug-induced liver injury	2 (1.1)	2 (1.1)	0	0	0	0
Autoimmune hepatitis	1 (0.5)	1 (0.5)	0	1 (0.5)	0	0
Hepatic artery aneurysm	1 (0.5)	1 (0.5)	0	0	0	0

NOV 2025 DBL. Based on events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 28.0; CTC Version: 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-aeltdcat-ebr2586_b5.sas 12FEB2026:12:02:10

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Table 18.1
Adverse Events Leading to Discontinuation of Study Treatment
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

System Organ Class (%) Preferred Term (%)	BMS-986213 N = 187 Any Grade	Grade 3-4	Grade 5	Nivolumab N = 201 Any Grade	Grade 3-4	Grade 5
Hepatitis	1 (0.5)	1 (0.5)	0	0	0	0
Hepatotoxicity	0	0	0	1 (0.5)	0	0
Hyperbilirubinaemia	0	0	0	1 (0.5)	0	0
Immune-mediated hepatitis	0	0	0	1 (0.5)	1 (0.5)	0
Investigations	5 (2.7)	2 (1.1)	0	2 (1.0)	0	0
Troponin increased	2 (1.1)	0	0	0	0	0
Alanine aminotransferase increased	1 (0.5)	1 (0.5)	0	0	0	0
Blood alkaline phosphatase increased	1 (0.5)	0	0	0	0	0
Electrocardiogram QT prolonged	1 (0.5)	0	0	0	0	0
Gamma-glutamyltransferase increased	1 (0.5)	1 (0.5)	0	0	0	0
Troponin T increased	0	0	0	1 (0.5)	0	0
Weight decreased	0	0	0	1 (0.5)	0	0
Infections and infestations	4 (2.1)	4 (2.1)	0	3 (1.5)	2 (1.0)	0
COVID-19 pneumonia	1 (0.5)	1 (0.5)	0	0	0	0
Encephalitis	1 (0.5)	1 (0.5)	0	0	0	0
Sepsis	1 (0.5)	1 (0.5)	0	0	0	0
Septic shock	1 (0.5)	1 (0.5)	0	0	0	0
Atypical pneumonia	0	0	0	1 (0.5)	1 (0.5)	0
COVID-19	0	0	0	1 (0.5)	0	0
Pneumonia	0	0	0	1 (0.5)	1 (0.5)	0
Musculoskeletal and connective tissue disorders	4 (2.1)	2 (1.1)	0	5 (2.5)	0	0

NOV 2025 DBL. Based on events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 28.0; CTC Version: 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-aeltdcat-ebr2586_b5.sas 12FEB2026:12:02:10

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Table 18.1
Adverse Events Leading to Discontinuation of Study Treatment
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

System Organ Class (%) Preferred Term (%)	BMS-986213 N = 187			Nivolumab N = 201		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Myositis	2 (1.1)	1 (0.5)	0	0	0	0
Bursitis	1 (0.5)	1 (0.5)	0	0	0	0
Polymyalgia rheumatica	1 (0.5)	0	0	1 (0.5)	0	0
Arthralgia	0	0	0	4 (2.0)	0	0
Myalgia	0	0	0	1 (0.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (2.1)	1 (0.5)	1 (0.5)	8 (4.0)	6 (3.0)	1 (0.5)
Malignant neoplasm progression	2 (1.1)	1 (0.5)	1 (0.5)	7 (3.5)	6 (3.0)	1 (0.5)
Breast cancer	1 (0.5)	0	0	0	0	0
Metastases to central nervous system	1 (0.5)	0	0	0	0	0
Clear cell sarcoma of soft tissue	0	0	0	1 (0.5)	0	0
Blood and lymphatic system disorders	3 (1.6)	2 (1.1)	0	2 (1.0)	2 (1.0)	0
Anaemia	1 (0.5)	1 (0.5)	0	1 (0.5)	0	0
Haemolytic anaemia	1 (0.5)	1 (0.5)	0	0	0	0
Lymphadenopathy	1 (0.5)	0	0	0	0	0
Febrile neutropenia	0	0	0	1 (0.5)	1 (0.5)	0
Lymphopenia	0	0	0	1 (0.5)	1 (0.5)	0
Cardiac disorders	3 (1.6)	1 (0.5)	0	4 (2.0)	1 (0.5)	1 (0.5)
Myocarditis	3 (1.6)	1 (0.5)	0	1 (0.5)	0	0
Cardiac failure	0	0	0	1 (0.5)	1 (0.5)	0
Myocardial infarction	0	0	0	2 (1.0)	0	1 (0.5)
Endocrine disorders	2 (1.1)	0	0	0	0	0
Hypothyroidism	1 (0.5)	0	0	0	0	0

NOV 2025 DBL. Based on events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 28.0; CTC Version: 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-aeltdcat-ebr2586_b5.sas 12FEB2026:12:02:10

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Table 18.1
Adverse Events Leading to Discontinuation of Study Treatment
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

System Organ Class (%) Preferred Term (%)	BMS-986213 N = 187 Any Grade	Grade 3-4	Grade 5	Nivolumab N = 201 Any Grade	Grade 3-4	Grade 5
Lymphocytic hypophysitis	1 (0.5)	0	0	0	0	0
General disorders and administration site conditions	2 (1.1)	0	0	2 (1.0)	1 (0.5)	0
Inflammation	1 (0.5)	0	0	0	0	0
Oedema peripheral	1 (0.5)	0	0	1 (0.5)	0	0
Mucosal inflammation	0	0	0	1 (0.5)	1 (0.5)	0
Injury, poisoning and procedural complications	2 (1.1)	2 (1.1)	0	0	0	0
Hip fracture	1 (0.5)	1 (0.5)	0	0	0	0
Infusion related reaction	1 (0.5)	1 (0.5)	0	0	0	0
Metabolism and nutrition disorders	2 (1.1)	1 (0.5)	0	0	0	0
Hyperuricaemia	1 (0.5)	0	0	0	0	0
Hypocalcaemia	1 (0.5)	0	0	0	0	0
Metabolic acidosis	1 (0.5)	1 (0.5)	0	0	0	0
Renal and urinary disorders	2 (1.1)	1 (0.5)	0	2 (1.0)	0	0
Choluria	1 (0.5)	0	0	0	0	0
Renal failure	1 (0.5)	1 (0.5)	0	1 (0.5)	0	0
Nephropathy	0	0	0	1 (0.5)	0	0
Nervous system disorders	1 (0.5)	1 (0.5)	0	0	0	0
Optic neuritis	1 (0.5)	1 (0.5)	0	0	0	0
Skin and subcutaneous tissue disorders	1 (0.5)	0	0	2 (1.0)	1 (0.5)	0
Rash	1 (0.5)	0	0	0	0	0
Lichen planus	0	0	0	1 (0.5)	1 (0.5)	0

NOV 2025 DBL. Based on events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 28.0; CTC Version: 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-aeltdcat-ebr2586_b5.sas 12FEB2026:12:02:10

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Table 18.1
Adverse Events Leading to Discontinuation of Study Treatment
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213 N = 187			Nivolumab N = 201		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Pemphigoid	0	0	0	1 (0.5)	0	0
Eye disorders	0	0	0	2 (1.0)	1 (0.5)	0
Autoimmune uveitis	0	0	0	1 (0.5)	1 (0.5)	0
Uveitis	0	0	0	1 (0.5)	0	0
Immune system disorders	0	0	0	1 (0.5)	0	0
Sarcoidosis	0	0	0	1 (0.5)	0	0

NOV 2025 DBL. Based on events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 28.0; CTC Version: 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-aeltdcat-ebr2586_b5.sas 12FEB2026:12:02:10

Anhang 4-G 7: Vollständige Darstellung der Subgruppenanalysen

Anhang 4-G 7.1: OS

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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	104 (55.6)	38.28 (22.97, 81.08)	201	135 (67.2)	25.40 (18.04, 42.41)	0.75 (0.58, 0.97) 0.0262	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.9633
LAG-3 >= 1%	118	63 (53.4)	43.01 (21.75, N.A.)	120	77 (64.2)	37.03 (18.73, 53.09)	0.75 (0.54, 1.04) 0.0866	
LAG-3 < 1%	69	41 (59.4)	29.60 (16.95, 81.08)	81	58 (71.6)	21.98 (14.26, 31.93)	0.76 (0.51, 1.14) 0.1858	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-ossubra-ebr2586_b5.sas 13FEB2026:10:01:53

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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.7050
LAG-3 >= 5%	35	15 (42.9)	N.A. (21.75, N.A.)	40	23 (57.5)	51.22 (18.04, N.A.)	0.66 (0.34, 1.27) 0.2081	
LAG-3 < 5%	152	89 (58.6)	34.04 (20.37, 64.46)	161	112 (69.6)	23.95 (16.16, 32.00)	0.76 (0.58, 1.01) 0.0554	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-ossubra-ebr2586_b5.sas 13FEB2026:10:01:53

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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.9543
BRAF MUTANT	77	39 (50.6)	76.06 (34.14, N.A.)	75	44 (58.7)	46.69 (22.60, 79.47)	0.76 (0.50, 1.17) 0.2179	
BRAF WILDTYPE	110	65 (59.1)	21.75 (17.08, 64.46)	126	91 (72.2)	21.98 (13.83, 28.48)	0.77 (0.56, 1.05) 0.1011	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-ossubra-ebr2586_b5.sas 13FEB2026:10:01:53

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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.8345
M0/M1ANY[0]	123	60 (48.8)	81.08 (36.96, N.A.)	125	73 (58.4)	50.53 (32.00, 65.45)	0.77 (0.55, 1.08) 0.1294	
M1ANY[1]	64	44 (68.8)	10.84 (6.87, 21.29)	76	62 (81.6)	9.79 (7.06, 17.28)	0.76 (0.52, 1.12) 0.1707	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-ossubra-ebr2586_b5.sas 13FEB2026:10:01:53

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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.9733
M0	21	12 (57.1)	55.82 (14.52, N.A.)	10	7 (70.0)	45.22 (9.13, N.A.)	0.79 (0.31, 2.01) 0.6179	
M1A	42	21 (50.0)	N.A. (21.75, N.A.)	56	35 (62.5)	50.53 (24.41, 70.11)	0.79 (0.46, 1.36) 0.3990	
M1B	40	22 (55.0)	58.64 (24.31, N.A.)	46	31 (67.4)	23.95 (14.26, 54.24)	0.65 (0.37, 1.12) 0.1188	
M1C	80	48 (60.0)	18.83 (14.03, 64.49)	81	57 (70.4)	17.28 (9.79, 31.93)	0.76 (0.52, 1.12) 0.1642	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ef-ossubra-ebr2586_b5.sas 13FEB2026:10:01:53

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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.8534
STAGE III	21	12 (57.1)	55.82 (14.52, N.A.)	10	7 (70.0)	45.22 (9.13, N.A.)	0.79 (0.31, 2.01) 0.6179	
STAGE IV	166	92 (55.4)	37.06 (21.75, N.A.)	190	127 (66.8)	25.23 (18.04, 42.41)	0.75 (0.58, 0.98) 0.0377	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.0527
CUTANEOUS ACRAL	23	19 (82.6)	12.62 (3.94, 21.09)	26	21 (80.8)	13.34 (9.92, 24.87)	1.27 (0.68, 2.37) 0.4467	
CUTANEOUS NON-ACRAL	122	62 (50.8)	64.49 (30.82, N.A.)	139	87 (62.6)	35.45 (23.95, 53.09)	0.72 (0.52, 1.00) 0.0470	
MUCOSAL	17	12 (70.6)	18.23 (6.80, 57.10)	20	14 (70.0)	21.63 (5.59, N.A.)	1.13 (0.52, 2.45) 0.7575	
OTHER	25	11 (44.0)	N.A. (19.25, N.A.)	16	13 (81.3)	15.95 (2.96, 28.06)	0.33 (0.14, 0.76) 0.0066	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.7379
<= ULN	120	59 (49.2)	81.08 (36.96, N.A.)	121	71 (58.7)	50.53 (32.00, 65.45)	0.77 (0.55, 1.09) 0.1462	
> ULN	66	44 (66.7)	13.86 (9.17, 34.04)	80	64 (80.0)	11.30 (7.72, 17.28)	0.75 (0.51, 1.10) 0.1356	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.6020
<= 2 X ULN	168	88 (52.4)	57.10 (29.60, N.A.)	181	118 (65.2)	31.93 (22.60, 49.54)	0.72 (0.55, 0.95) 0.0190	
> 2 X ULN	18	15 (83.3)	3.55 (2.20, 13.86)	20	17 (85.0)	8.18 (2.43, 19.09)	0.97 (0.48, 1.95) 0.9114	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.8147
< QUARTILE 1	35	13 (37.1)	N.A. (76.06, N.A.)	43	20 (46.5)	79.47 (46.69, N.A.)	0.70 (0.35, 1.41) 0.3181	
QUARTILE 1 TO < QUARTILE 3	84	48 (57.1)	30.82 (21.09, N.A.)	89	60 (67.4)	25.23 (15.21, 49.91)	0.79 (0.54, 1.16) 0.2348	
>= QUARTILE 3	46	31 (67.4)	17.23 (9.63, 34.20)	44	35 (79.5)	7.20 (4.01, 18.73)	0.68 (0.42, 1.11) 0.1194	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.4411
0	121	57 (47.1)	N.A. (43.01, N.A.)	136	83 (61.0)	40.54 (24.87, 59.07)	0.67 (0.48, 0.94) 0.0189	
1	66	47 (71.2)	15.87 (10.18, 22.97)	65	52 (80.0)	12.25 (8.54, 21.98)	0.83 (0.56, 1.24) 0.3701	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.2574
CURRENT/FORMER	63	31 (49.2)	81.08 (24.31, N.A.)	76	50 (65.8)	27.33 (15.80, 55.49)	0.64 (0.41, 1.00) 0.0473	
NEVER SMOKED	116	70 (60.3)	24.48 (17.87, 57.10)	121	81 (66.9)	25.82 (16.66, 44.68)	0.88 (0.64, 1.21) 0.4347	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.6275
>= 18 - < 65	102	49 (48.0)	N.A. (26.94, N.A.)	105	68 (64.8)	27.04 (17.12, 46.69)	0.68 (0.47, 0.98) 0.0369	
>= 65 - < 75	48	31 (64.6)	34.20 (17.08, 76.06)	64	44 (68.8)	25.23 (14.69, 54.24)	0.87 (0.55, 1.38) 0.5646	
>= 75	37	24 (64.9)	22.97 (16.95, N.A.)	32	23 (71.9)	21.45 (5.65, 61.77)	0.78 (0.44, 1.38) 0.3910	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.3479
< 65	102	49 (48.0)	N.A. (26.94, N.A.)	105	68 (64.8)	27.04 (17.12, 46.69)	0.68 (0.47, 0.98) 0.0369	
>= 65	85	55 (64.7)	30.82 (18.23, 55.82)	96	67 (69.8)	25.23 (14.46, 49.54)	0.85 (0.59, 1.21) 0.3675	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.3183
MALE	104	58 (55.8)	44.01 (21.09, N.A.)	116	73 (62.9)	33.18 (22.60, 59.07)	0.84 (0.59, 1.18) 0.3151	
FEMALE	83	46 (55.4)	36.96 (18.83, N.A.)	85	62 (72.9)	17.12 (12.32, 28.06)	0.64 (0.44, 0.94) 0.0217	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 6.1
Subgroup Analyses of Overall Survival
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.5342
USA/CANADA	17	7 (41.2)	N.A. (17.87, N.A.)	18	11 (61.1)	38.98 (9.72, N.A.)	0.56 (0.22, 1.46) 0.2320	
EUROPE	98	53 (54.1)	43.01 (20.93, N.A.)	105	73 (69.5)	25.23 (16.03, 42.41)	0.66 (0.46, 0.94) 0.0196	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	39 (68.4)	18.83 (9.13, 29.60)	62	45 (72.6)	19.55 (10.94, 35.45)	0.97 (0.63, 1.49) 0.8874	
AUSTRALIA/NZ	15	5 (33.3)	N.A. (53.26, N.A.)	16	6 (37.5)	N.A. (29.50, N.A.)	0.85 (0.26, 2.77) 0.7816	

NOV 2025 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified cox proportional hazards model. (3) Unstratified log rank-test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Anhang 4-G 7.2: EQ-5D-VAS − Zeit bis zur bestätigten Verschlechterung

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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
OVERALL	174	53 (30.5)	N.A. (67.25, N.A.)	183	45 (24.6)	N.A.	1.18 (0.79, 1.76) 0.4075	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.0080*
LAG-3 >= 1%	113	38 (33.6)	N.A. (41.76, N.A.)	112	22 (19.6)	N.A.	1.83 (1.08, 3.10) 0.0238	
LAG-3 < 1%	61	15 (24.6)	N.A. (67.22, N.A.)	71	23 (32.4)	N.A. (13.60, N.A.)	0.59 (0.31, 1.14) 0.1196	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.8332
LAG-3 >= 5%	33	9 (27.3)	N.A. (42.05, N.A.)	38	11 (28.9)	N.A. (33.51, N.A.)	1.05 (0.43, 2.57) 0.9150	
LAG-3 < 5%	141	44 (31.2)	N.A. (56.02, N.A.)	145	34 (23.4)	N.A.	1.20 (0.76, 1.87) 0.4322	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BRAF MUTATION STATUS								0.2819
BRAF MUTANT	73	21 (28.8)	N.A. (67.22, N.A.)	64	18 (28.1)	N.A. (29.96, N.A.)	0.92 (0.49, 1.73) 0.8011	
BRAF WILDTYPE	101	32 (31.7)	N.A. (41.46, N.A.)	119	27 (22.7)	N.A.	1.42 (0.85, 2.37) 0.1817	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AJCC STAGE								0.3289
M0/M1ANY[0]	117	39 (33.3)	N.A.	119	35 (29.4)	N.A. (65.84, N.A.)	1.05 (0.66, 1.66) 0.8376	
M1ANY[1]	57	14 (24.6)	67.25 (41.46, N.A.)	64	10 (15.6)	N.A.	1.55 (0.68, 3.53) 0.3015	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE METASTASIS STAGE								0.5752
M0	21	4 (19.0)	N.A. (42.05, N.A.)	10	2 (20.0)	N.A. (1.87, N.A.)	1.00 (0.18, 5.53) 0.9988	
M1A	40	13 (32.5)	N.A. (36.63, N.A.)	55	12 (21.8)	N.A.	1.49 (0.68, 3.27) 0.3225	
M1B	37	14 (37.8)	N.A. (10.78, N.A.)	43	8 (18.6)	N.A.	1.64 (0.68, 3.94) 0.2673	
M1C	72	21 (29.2)	N.A. (41.46, N.A.)	68	22 (32.4)	N.A. (17.64, N.A.)	0.88 (0.48, 1.61) 0.6873	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
DISEASE STAGE AT STUDY ENTRY								0.7838
STAGE III	21	4 (19.0)	N.A. (42.05, N.A.)	10	2 (20.0)	N.A. (1.87, N.A.)	1.00 (0.18, 5.53) 0.9988	
STAGE IV	153	49 (32.0)	N.A. (56.02, N.A.)	173	43 (24.9)	N.A.	1.23 (0.82, 1.85) 0.3251	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
HISTOLOGY (DISEASE SUBTYPE)								0.8854
CUTANEOUS ACRAL	19	7 (36.8)	10.78 (3.71, N.A.)	25	6 (24.0)	N.A. (17.08, N.A.)	1.88 (0.63, 5.64) 0.2578	
CUTANEOUS NON-ACRAL	115	38 (33.0)	N.A. (56.02, N.A.)	124	34 (27.4)	N.A.	1.19 (0.75, 1.89) 0.4699	
MUCOSAL	15	4 (26.7)	N.A. (3.71, N.A.)	20	4 (20.0)	N.A. (3.91, N.A.)	1.37 (0.34, 5.50) 0.6568	
OTHER	25	4 (16.0)	N.A.	14	1 (7.1)	N.A.	1.71 (0.19, 15.37) 0.6333	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE LDH I								0.3014
<= ULN	114	39 (34.2)	N.A. (42.05, N.A.)	115	35 (30.4)	N.A. (65.84, N.A.)	1.04 (0.66, 1.64) 0.8763	
> ULN	59	14 (23.7)	N.A. (41.46, N.A.)	68	10 (14.7)	N.A.	1.58 (0.69, 3.62) 0.2764	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE LDH II								0.9855
<= 2 X ULN	160	52 (32.5)	N.A. (67.22, N.A.)	169	45 (26.6)	N.A.	1.16 (0.78, 1.73) 0.4686	
> 2 X ULN	13	1 (7.7)	N.A. (2.76, N.A.)	14	0	N.E.	N.E.	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
TUMOR BURDEN AT BASELINE PER BICR								0.3795
< QUARTILE 1	34	9 (26.5)	N.A.	40	10 (25.0)	N.A. (65.84, N.A.)	0.98 (0.40, 2.44) 0.9731	
QUARTILE 1 TO < QUARTILE 3	78	29 (37.2)	67.22 (15.97, N.A.)	84	23 (27.4)	N.A.	1.30 (0.75, 2.25) 0.3488	
>= QUARTILE 3	42	13 (31.0)	67.25 (28.65, N.A.)	36	4 (11.1)	N.A.	2.69 (0.87, 8.37) 0.0869	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE ECOG PS								0.4790
0	115	42 (36.5)	N.A. (41.76, N.A.)	125	33 (26.4)	N.A.	1.29 (0.81, 2.03) 0.2793	
1	59	11 (18.6)	N.A. (67.25, N.A.)	58	12 (20.7)	N.A. (33.51, N.A.)	0.91 (0.40, 2.07) 0.8246	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
SMOKING STATUS								0.8405
CURRENT/FORMER	59	17 (28.8)	N.A. (28.65, N.A.)	70	16 (22.9)	N.A. (65.84, N.A.)	1.05 (0.53, 2.09) 0.8835	
NEVER SMOKED	108	31 (28.7)	N.A. (56.02, N.A.)	109	28 (25.7)	N.A.	1.19 (0.71, 1.98) 0.5073	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AGE CATEGORIZATION I								0.8959
>= 18 - < 65	95	26 (27.4)	N.A. (67.25, N.A.)	97	22 (22.7)	N.A.	1.15 (0.65, 2.03) 0.6364	
>= 65 - < 75	43	12 (27.9)	N.A. (42.05, N.A.)	59	14 (23.7)	N.A.	1.10 (0.51, 2.38) 0.8168	
>= 75	36	15 (41.7)	41.46 (8.77, N.A.)	27	9 (33.3)	65.84 (3.91, N.A.)	1.48 (0.63, 3.47) 0.3695	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AGE CATEGORIZATION II								0.9022
< 65	95	26 (27.4)	N.A. (67.25, N.A.)	97	22 (22.7)	N.A.	1.15 (0.65, 2.03) 0.6364	
>= 65	79	27 (34.2)	N.A. (22.70, N.A.)	86	23 (26.7)	N.A. (65.84, N.A.)	1.22 (0.70, 2.12) 0.4914	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
SEX								0.9237
MALE	98	31 (31.6)	N.A. (56.02, N.A.)	105	27 (25.7)	N.A.	1.17 (0.70, 1.96) 0.5500	
FEMALE	76	22 (28.9)	N.A. (42.05, N.A.)	78	18 (23.1)	N.A. (33.51, N.A.)	1.23 (0.65, 2.29) 0.5244	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.4
Subgroup Analyses of EQ-5D VAS Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

EQ-5D VAS (MID=15) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
REGION								0.2797
USA/CANADA	16	4 (25.0)	N.A. (5.55, N.A.)	16	3 (18.8)	N.A.	1.11 (0.25, 5.00) 0.8882	
EUROPE	93	28 (30.1)	N.A. (67.22, N.A.)	94	23 (24.5)	N.A. (65.84, N.A.)	1.22 (0.70, 2.11) 0.4893	
LATIN AMERICA (CENTRAL/ SOUTH AMERICA)	51	17 (33.3)	N.A. (10.58, N.A.)	58	13 (22.4)	N.A. (33.51, N.A.)	1.64 (0.80, 3.37) 0.1807	
AUSTRALIA/NZ	14	4 (28.6)	N.A. (41.46, N.A.)	15	6 (40.0)	N.A. (2.86, N.A.)	0.34 (0.09, 1.34) 0.1224	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Anhang 4-G 7.3: FACT-M − Zeit bis zur bestätigten Verschlechterung

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Table 7.2
Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
OVERALL	173	19 (11.0)	N.A.	182	22 (12.1)	N.A.	0.90 (0.48, 1.66) 0.7269	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.7009
LAG-3 >= 1%	110	12 (10.9)	N.A.	111	12 (10.8)	N.A.	1.00 (0.45, 2.22) 0.9929	
LAG-3 < 1%	63	7 (11.1)	N.A. (53.36, N.A.)	71	10 (14.1)	N.A. (46.03, N.A.)	0.75 (0.29, 1.99) 0.5687	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.2
Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.1773
LAG-3 >= 5%	32	1 (3.1)	N.A.	37	5 (13.5)	N.A. (29.83, N.A.)	0.23 (0.03, 1.97) 0.1791	
LAG-3 < 5%	141	18 (12.8)	N.A. (53.36, N.A.)	145	17 (11.7)	N.A.	1.07 (0.55, 2.07) 0.8459	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.2
Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BRAF MUTATION STATUS								0.5090
BRAF MUTANT	74	6 (8.1)	N.A. (43.43, N.A.)	67	8 (11.9)	N.A.	0.73 (0.25, 2.12) 0.5594	
BRAF WILDTYPE	99	13 (13.1)	N.A. (53.36, N.A.)	115	14 (12.2)	N.A.	1.08 (0.51, 2.32) 0.8382	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AJCC STAGE								0.8702
M0/M1ANY[0]	115	13 (11.3)	N.A.	117	15 (12.8)	N.A.	0.90 (0.43, 1.90) 0.7849	
M1ANY[1]	58	6 (10.3)	N.A. (28.09, N.A.)	65	7 (10.8)	N.A.	1.02 (0.34, 3.04) 0.9738	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE METASTASIS STAGE								0.1949
M0	20	1 (5.0)	N.A.	9	0	N.E.	N.E.	
M1A	39	3 (7.7)	N.A. (43.43, N.A.)	55	5 (9.1)	N.A.	0.79 (0.19, 3.31) 0.7449	
M1B	37	7 (18.9)	N.A. (18.66, N.A.)	44	2 (4.5)	N.A.	3.67 (0.76, 17.73) 0.1055	
M1C	73	7 (9.6)	N.A.	67	13 (19.4)	N.A. (29.83, N.A.)	0.52 (0.21, 1.30) 0.1595	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
DISEASE STAGE AT STUDY ENTRY								0.9899
STAGE III	20	1 (5.0)	N.A.	9	0	N.E.	N.E.	
STAGE IV	153	18 (11.8)	N.A. (53.36, N.A.)	173	22 (12.7)	N.A.	0.93 (0.50, 1.74) 0.8306	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
HISTOLOGY (DISEASE SUBTYPE)								0.8488
CUTANEOUS ACRAL	19	4 (21.1)	25.92 (6.51, N.A.)	26	4 (15.4)	N.A.	1.69 (0.40, 7.19) 0.4772	
CUTANEOUS NON-ACRAL	115	12 (10.4)	N.A.	124	14 (11.3)	N.A.	0.96 (0.44, 2.08) 0.9180	
MUCOSAL	14	3 (21.4)	53.36 (5.52, N.A.)	19	3 (15.8)	N.A. (14.03, N.A.)	1.87 (0.36, 9.79) 0.4569	
OTHER	25	0	N.E.	13	1 (7.7)	N.A. (3.02, N.A.)	N.E.	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE LDH I								0.8724
<= ULN	112	13 (11.6)	N.A. (53.36, N.A.)	113	15 (13.3)	N.A.	0.91 (0.43, 1.92) 0.8010	
> ULN	60	6 (10.0)	N.A.	69	7 (10.1)	N.A.	1.03 (0.35, 3.09) 0.9512	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE LDH II								0.9854
<= 2 X ULN	159	18 (11.3)	N.A.	168	22 (13.1)	N.A.	0.85 (0.46, 1.59) 0.6195	
> 2 X ULN	13	1 (7.7)	N.A. (5.52, N.A.)	14	0	N.E.	N.E.	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
TUMOR BURDEN AT BASELINE PER BICR								0.1283
< QUARTILE 1	34	7 (20.6)	N.A.	39	4 (10.3)	N.A.	1.84 (0.54, 6.30) 0.3305	
QUARTILE 1 TO < QUARTILE 3	79	6 (7.6)	N.A. (53.36, N.A.)	85	15 (17.6)	N.A.	0.43 (0.17, 1.11) 0.0826	
>= QUARTILE 3	42	4 (9.5)	N.A.	34	2 (5.9)	N.A. (46.03, N.A.)	1.52 (0.28, 8.36) 0.6306	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE ECOG PS								0.1767
0	114	15 (13.2)	N.A. (53.36, N.A.)	126	14 (11.1)	N.A.	1.15 (0.56, 2.39) 0.7034	
1	59	4 (6.8)	N.A.	56	8 (14.3)	N.A. (46.03, N.A.)	0.43 (0.13, 1.42) 0.1662	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
SMOKING STATUS								0.8833
CURRENT/FORMER	58	7 (12.1)	N.A. (53.36, N.A.)	70	9 (12.9)	N.A. (46.03, N.A.)	0.83 (0.31, 2.22) 0.7038	
NEVER SMOKED	108	11 (10.2)	N.A.	108	13 (12.0)	N.A.	0.92 (0.41, 2.06) 0.8441	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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FACT-M Total Score (MID=26) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AGE CATEGORIZATION I								0.9242
>= 18 - < 65	96	11 (11.5)	N.A.	98	12 (12.2)	N.A.	0.91 (0.40, 2.08) 0.8319	
>= 65 - < 75	43	4 (9.3)	N.A.	58	6 (10.3)	N.A. (46.03, N.A.)	0.89 (0.25, 3.25) 0.8651	
>= 75	34	4 (11.8)	N.A. (28.09, N.A.)	26	4 (15.4)	N.A. (33.61, N.A.)	0.59 (0.14, 2.50) 0.4716	

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	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AGE CATEGORIZATION II								0.9117
< 65	96	11 (11.5)	N.A.	98	12 (12.2)	N.A.	0.91 (0.40, 2.08) 0.8319	
>= 65	77	8 (10.4)	N.A. (53.36, N.A.)	84	10 (11.9)	N.A.	0.82 (0.32, 2.11) 0.6845	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
SEX								0.7921
MALE	94	12 (12.8)	N.A.	106	14 (13.2)	N.A.	0.97 (0.45, 2.10) 0.9412	
FEMALE	79	7 (8.9)	N.A. (53.36, N.A.)	76	8 (10.5)	N.A.	0.81 (0.29, 2.25) 0.6928	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
REGION								0.9908
USA/CANADA	15	0	N.E.	14	3 (21.4)	N.A. (4.93, N.A.)	N.E.	
EUROPE	93	9 (9.7)	N.A.	93	8 (8.6)	N.A.	1.05 (0.40, 2.73) 0.9170	
LATIN AMERICA (CENTRAL/ SOUTH AMERICA)	52	9 (17.3)	N.A. (43.43, N.A.)	59	9 (15.3)	N.A. (33.61, N.A.)	1.14 (0.45, 2.88) 0.7832	
AUSTRALIA/NZ	13	1 (7.7)	N.A.	16	2 (12.5)	N.A.	0.89 (0.08, 10.33) 0.9251	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.2
Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
FACT-G Total Score (MID=17) Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
OVERALL	173	29 (16.8)	N.A.	182	23 (12.6)	N.A.	1.30 (0.75, 2.26) 0.3424	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.8793
LAG-3 >= 1%	110	17 (15.5)	N.A.	111	13 (11.7)	N.A.	1.31 (0.64, 2.71) 0.4623	
LAG-3 < 1%	63	12 (19.0)	57.95 (30.39, N.A.)	71	10 (14.1)	N.A.	1.36 (0.58, 3.15) 0.4794	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
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Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.5527
LAG-3 >= 5%	32	4 (12.5)	N.A.	37	5 (13.5)	N.A.	0.95 (0.25, 3.58) 0.9410	
LAG-3 < 5%	141	25 (17.7)	N.A. (57.95, N.A.)	145	18 (12.4)	N.A. (56.18, N.A.)	1.39 (0.76, 2.56) 0.2847	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
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Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BRAF MUTATION STATUS								0.8832
BRAF MUTANT	74	9 (12.2)	N.A. (57.95, N.A.)	67	7 (10.4)	N.A. (56.18, N.A.)	1.28 (0.47, 3.48) 0.6257	
BRAF WILDTYPE	99	20 (20.2)	N.A. (30.39, N.A.)	115	16 (13.9)	N.A.	1.43 (0.73, 2.80) 0.2933	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AJCC STAGE								0.3607
M0/M1ANY[0]	115	25 (21.7)	N.A. (57.95, N.A.)	117	17 (14.5)	N.A.	1.53 (0.82, 2.84) 0.1821	
M1ANY[1]	58	4 (6.9)	N.A.	65	6 (9.2)	N.A.	0.84 (0.24, 2.99) 0.7878	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE METASTASIS STAGE								0.1241
M0	20	4 (20.0)	57.95 (11.83, N.A.)	9	0	N.E.	N.E.	
M1A	39	4 (10.3)	N.A.	55	8 (14.5)	N.A. (56.18, N.A.)	0.66 (0.20, 2.19) 0.4940	
M1B	37	11 (29.7)	21.22 (12.25, N.A.)	44	3 (6.8)	N.A.	4.26 (1.18, 15.41) 0.0271	
M1C	73	8 (11.0)	N.A.	67	11 (16.4)	N.A. (35.42, N.A.)	0.70 (0.28, 1.74) 0.4410	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
DISEASE STAGE AT STUDY ENTRY								0.9874
STAGE III	20	4 (20.0)	57.95 (11.83, N.A.)	9	0	N.E.	N.E.	
STAGE IV	153	25 (16.3)	N.A.	173	23 (13.3)	N.A.	1.23 (0.70, 2.17) 0.4799	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213 N	BMS-986213 Subjects with Event n (%)	BMS-986213 KME [95% CI](mon) (1)	Nivolumab N	Nivolumab Subjects with Event n (%)	Nivolumab KME [95% CI](mon) (1)	BMS-986213 vs. Nivolumab HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
HISTOLOGY (DISEASE SUBTYPE)								0.4911
CUTANEOUS ACRAL	19	5 (26.3)	11.86 (7.36, N.A.)	26	4 (15.4)	N.A.	2.51 (0.64, 9.91) 0.1881	
CUTANEOUS NON-ACRAL	115	16 (13.9)	N.A.	124	16 (12.9)	N.A.	1.07 (0.53, 2.14) 0.8500	
MUCOSAL	14	4 (28.6)	30.39 (4.63, N.A.)	19	2 (10.5)	N.A. (14.03, N.A.)	4.32 (0.73, 25.69) 0.1078	
OTHER	25	4 (16.0)	N.A. (12.09, N.A.)	13	1 (7.7)	N.A. (3.02, N.A.)	0.83 (0.07, 9.51) 0.8786	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE LDH I								0.5672
<= ULN	112	24 (21.4)	N.A. (57.95, N.A.)	113	17 (15.0)	N.A. (56.18, N.A.)	1.47 (0.78, 2.75) 0.2296	
> ULN	60	5 (8.3)	N.A.	69	6 (8.7)	N.A.	1.04 (0.31, 3.41) 0.9533	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE LDH II								0.9846
<= 2 X ULN	159	28 (17.6)	N.A.	168	23 (13.7)	N.A.	1.28 (0.73, 2.22) 0.3880	
> 2 X ULN	13	1 (7.7)	N.A. (4.63, N.A.)	14	0	N.E.	N.E.	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
TUMOR BURDEN AT BASELINE PER BICR								0.1881
< QUARTILE 1	34	11 (32.4)	N.A. (18.50, N.A.)	39	6 (15.4)	N.A. (56.18, N.A.)	1.92 (0.70, 5.24) 0.2047	
QUARTILE 1 TO < QUARTILE 3	79	10 (12.7)	N.A.	85	15 (17.6)	N.A.	0.72 (0.32, 1.62) 0.4304	
>= QUARTILE 3	42	5 (11.9)	N.A.	34	1 (2.9)	N.A. (36.86, N.A.)	3.04 (0.35, 26.35) 0.3136	

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FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
BASELINE ECOG PS								0.1511
0	114	22 (19.3)	N.A. (57.95, N.A.)	126	15 (11.9)	N.A.	1.65 (0.86, 3.19) 0.1347	
1	59	7 (11.9)	N.A.	56	8 (14.3)	N.A. (36.86, N.A.)	0.63 (0.23, 1.79) 0.3892	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
SMOKING STATUS								0.4469
CURRENT/FORMER	58	13 (22.4)	N.A. (30.39, N.A.)	70	9 (12.9)	N.A. (36.86, N.A.)	1.67 (0.71, 3.92) 0.2400	
NEVER SMOKED	108	14 (13.0)	N.A.	108	14 (13.0)	N.A.	1.06 (0.50, 2.22) 0.8810	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AGE CATEGORIZATION I								0.8803
>= 18 - < 65	96	15 (15.6)	N.A. (57.95, N.A.)	98	11 (11.2)	N.A.	1.38 (0.63, 3.01) 0.4157	
>= 65 - < 75	43	6 (14.0)	N.A.	58	8 (13.8)	N.A. (56.18, N.A.)	1.05 (0.36, 3.08) 0.9283	
>= 75	34	8 (23.5)	N.A. (11.83, N.A.)	26	4 (15.4)	N.A. (35.42, N.A.)	1.40 (0.41, 4.82) 0.5934	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
AGE CATEGORIZATION II								0.8470
< 65	96	15 (15.6)	N.A. (57.95, N.A.)	98	11 (11.2)	N.A.	1.38 (0.63, 3.01) 0.4157	
>= 65	77	14 (18.2)	N.A.	84	12 (14.3)	N.A. (56.18, N.A.)	1.29 (0.59, 2.82) 0.5319	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 7.2
Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
SEX								0.4082
MALE	94	13 (13.8)	N.A.	106	14 (13.2)	N.A.	1.05 (0.49, 2.25) 0.8957	
FEMALE	79	16 (20.3)	N.A. (30.39, N.A.)	76	9 (11.8)	N.A. (56.18, N.A.)	1.62 (0.71, 3.67) 0.2477	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Table 7.2
Subgroup Analyses of FACT-M Time to First Confirmed Deterioration
All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF)
Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing

FACT-G Total Score (MID=17) Subgroup	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)	Test for Interaction p-value (3)(4)
REGION								0.7687
USA/CANADA	15	1 (6.7)	N.A.	14	2 (14.3)	N.A.	0.40 (0.04, 4.52) 0.4613	
EUROPE	93	13 (14.0)	N.A.	93	9 (9.7)	N.A.	1.33 (0.57, 3.11) 0.5150	
LATIN AMERICA (CENTRAL/ SOUTH AMERICA)	52	14 (26.9)	57.95 (11.86, N.A.)	59	11 (18.6)	N.A. (36.86, N.A.)	1.46 (0.66, 3.23) 0.3454	
AUSTRALIA/NZ	13	1 (7.7)	N.A.	16	1 (6.3)	N.A.	2.03 (0.13, 32.79) 0.6191	

NOV 2025 DBL. HR = hazard ratio; KME=Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event.
(2) Unstratified Cox proportional hazards model with baseline PRO score as covariate.
(3) Unstratified Cox proportional hazards model with PRO baseline score, treatment, subgroup factor, and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
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Anhang 4-G 7.4: UE − Zeit bis zum ersten Ereignis

Anhang 4-G 7.4.1: UE-Hauptkategorien

Anhang 4-G 7.4.1.1: Schwere UE (CTCAE-Grad ≥ 3)

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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	95 (50.8)	15.90 (10.15, 23.46)	201	97 (48.3)	17.64 (10.12, 34.76)	1.10 (0.83, 1.46) 0.5203	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.4415
LAG-3 >= 1%	118	58 (49.2)	16.16 (11.33, 30.46)	120	60 (50.0)	17.64 (8.74, 34.76)	1.01 (0.70, 1.45) 0.9672	
LAG-3 < 1%	69	37 (53.6)	14.69 (4.80, 30.62)	81	37 (45.7)	19.25 (8.71, N.A.)	1.25 (0.79, 1.98) 0.3304	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.2286
LAG-3 >= 5%	35	16 (45.7)	24.97 (8.64, N.A.)	40	15 (37.5)	72.21 (10.38, N.A.)	1.52 (0.74, 3.13) 0.2463	
LAG-3 < 5%	152	79 (52.0)	15.84 (9.26, 23.46)	161	82 (50.9)	14.95 (8.71, 22.05)	0.98 (0.72, 1.34) 0.9223	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.1032
BRAF MUTANT	77	37 (48.1)	17.51 (11.53, 33.41)	75	42 (56.0)	10.38 (5.39, 35.91)	0.83 (0.53, 1.29) 0.3985	
BRAF WILDTYPE	110	58 (52.7)	14.69 (6.87, 25.46)	126	55 (43.7)	21.59 (11.43, 63.64)	1.32 (0.91, 1.91) 0.1387	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.7424
M0/M1ANY[0]	123	57 (46.3)	20.86 (14.69, 38.57)	125	52 (41.6)	34.73 (14.95, N.A.)	1.18 (0.81, 1.71) 0.3981	
M1ANY[1]	64	38 (59.4)	6.47 (4.30, 23.46)	76	45 (59.2)	6.41 (3.55, 20.50)	1.04 (0.67, 1.60) 0.8483	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.2312
M0	21	7 (33.3)	38.57 (9.89, N.A.)	10	6 (60.0)	15.84 (0.36, N.A.)	0.41 (0.14, 1.24) 0.1047	
M1A	42	21 (50.0)	18.07 (9.26, 45.21)	56	23 (41.1)	34.76 (10.38, N.A.)	1.35 (0.75, 2.44) 0.3208	
M1B	40	21 (52.5)	15.84 (8.21, 69.13)	46	17 (37.0)	72.21 (10.12, N.A.)	1.45 (0.76, 2.77) 0.2501	
M1C	80	45 (56.3)	8.64 (4.90, 22.57)	81	45 (55.6)	8.71 (4.04, 35.91)	1.04 (0.69, 1.58) 0.8449	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.0604
STAGE III	21	7 (33.3)	38.57 (9.89, N.A.)	10	6 (60.0)	15.84 (0.36, N.A.)	0.41 (0.14, 1.24) 0.1047	
STAGE IV	166	88 (53.0)	14.69 (8.64, 22.57)	190	90 (47.4)	20.50 (10.12, 35.91)	1.23 (0.91, 1.64) 0.1727	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.3928
CUTANEOUS ACRAL	23	12 (52.2)	5.32 (2.50, N.A.)	26	13 (50.0)	8.54 (5.39, N.A.)	1.33 (0.61, 2.93) 0.4705	
CUTANEOUS NON-ACRAL	122	63 (51.6)	16.16 (10.84, 23.46)	139	65 (46.8)	20.50 (11.43, 35.91)	1.12 (0.79, 1.59) 0.5151	
MUCOSAL	17	11 (64.7)	14.69 (3.19, N.A.)	20	10 (50.0)	10.58 (2.69, N.A.)	1.53 (0.63, 3.72) 0.3397	
OTHER	25	9 (36.0)	33.41 (5.32, N.A.)	16	9 (56.3)	12.81 (1.31, N.A.)	0.46 (0.17, 1.23) 0.1110	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.4514
<= ULN	120	57 (47.5)	18.07 (13.73, 33.41)	121	50 (41.3)	34.73 (14.95, N.A.)	1.24 (0.85, 1.81) 0.2718	
> ULN	66	38 (57.6)	6.87 (4.57, 25.46)	80	47 (58.8)	6.41 (3.55, 21.59)	0.97 (0.63, 1.49) 0.9105	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.5664
<= 2 X ULN	168	82 (48.8)	17.51 (11.53, 25.46)	181	83 (45.9)	21.19 (11.43, 57.36)	1.12 (0.82, 1.52) 0.4683	
> 2 X ULN	18	13 (72.2)	3.25 (1.05, N.A.)	20	14 (70.0)	1.84 (0.95, N.A.)	0.82 (0.38, 1.79) 0.6550	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.1140
< QUARTILE 1	35	17 (48.6)	30.46 (8.41, 69.13)	43	16 (37.2)	57.36 (10.58, N.A.)	1.28 (0.64, 2.56) 0.4864	
QUARTILE 1 TO < QUARTILE 3	84	42 (50.0)	14.69 (6.87, 24.97)	89	40 (44.9)	19.25 (10.12, N.A.)	1.27 (0.82, 1.96) 0.2780	
>= QUARTILE 3	46	21 (45.7)	23.46 (7.39, 67.45)	44	27 (61.4)	8.54 (2.40, 22.05)	0.65 (0.37, 1.16) 0.1447	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.9626
0	121	56 (46.3)	17.51 (11.53, 33.41)	136	60 (44.1)	21.19 (10.58, 57.36)	1.08 (0.75, 1.56) 0.6646	
1	66	39 (59.1)	9.89 (5.32, 25.46)	65	37 (56.9)	8.25 (4.17, 34.73)	1.07 (0.68, 1.68) 0.7566	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.5261
CURRENT/FORMER	63	33 (52.4)	15.84 (10.15, 22.64)	76	38 (50.0)	14.95 (8.71, 34.73)	1.00 (0.63, 1.60) 0.9897	
NEVER SMOKED	116	57 (49.1)	16.16 (6.87, 45.21)	121	55 (45.5)	21.59 (10.12, N.A.)	1.20 (0.83, 1.74) 0.3315	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.9910
>= 18 - < 65	102	45 (44.1)	24.97 (11.53, N.A.)	105	44 (41.9)	34.76 (11.43, N.A.)	1.10 (0.73, 1.68) 0.6372	
>= 65 - < 75	48	26 (54.2)	14.69 (5.32, 32.16)	64	34 (53.1)	17.64 (7.16, 57.36)	1.13 (0.67, 1.88) 0.6510	
>= 75	37	24 (64.9)	10.84 (5.91, 18.07)	32	19 (59.4)	8.54 (5.19, 20.50)	1.04 (0.57, 1.89) 0.9044	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.9267
< 65	102	45 (44.1)	24.97 (11.53, N.A.)	105	44 (41.9)	34.76 (11.43, N.A.)	1.10 (0.73, 1.68) 0.6372	
>= 65	85	50 (58.8)	11.33 (6.08, 18.07)	96	53 (55.2)	10.58 (8.25, 21.59)	1.15 (0.78, 1.69) 0.4822	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.4868
MALE	104	58 (55.8)	14.69 (7.39, 22.64)	116	59 (50.9)	14.95 (8.74, 34.73)	1.19 (0.83, 1.71) 0.3490	
FEMALE	83	37 (44.6)	18.07 (10.15, 38.57)	85	38 (44.7)	21.59 (8.34, N.A.)	0.98 (0.62, 1.55) 0.9435	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.1
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.2910
USA/CANADA	17	10 (58.8)	18.07 (1.31, N.A.)	18	11 (61.1)	7.16 (2.69, 15.84)	0.70 (0.28, 1.76) 0.4456	
EUROPE	98	38 (38.8)	22.57 (12.62, 33.41)	105	46 (43.8)	21.59 (10.38, N.A.)	0.91 (0.59, 1.40) 0.6789	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	37 (64.9)	8.64 (4.24, 22.64)	62	31 (50.0)	22.05 (8.54, 72.21)	1.48 (0.91, 2.40) 0.1059	
AUSTRALIA/NZ	15	10 (66.7)	5.91 (1.45, N.A.)	16	9 (56.3)	10.12 (3.55, N.A.)	1.45 (0.59, 3.60) 0.4160	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	78 (41.7)	24.97 (16.16, 55.95)	201	80 (39.8)	34.73 (17.74, 63.64)	1.08 (0.79, 1.47) 0.6326	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.3114
LAG-3 >= 1%	118	47 (39.8)	30.36 (18.07, N.A.)	120	50 (41.7)	27.43 (14.92, 63.64)	0.96 (0.64, 1.43) 0.8285	
LAG-3 < 1%	69	31 (44.9)	22.64 (8.41, N.A.)	81	30 (37.0)	34.73 (9.89, N.A.)	1.36 (0.82, 2.24) 0.2324	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.1090
LAG-3 >= 5%	35	17 (48.6)	24.97 (4.14, N.A.)	40	15 (37.5)	72.21 (20.50, N.A.)	1.74 (0.85, 3.53) 0.1232	
LAG-3 < 5%	152	61 (40.1)	26.45 (16.16, 55.95)	161	65 (40.4)	21.19 (13.14, 57.40)	0.94 (0.66, 1.33) 0.7085	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.4991
BRAF MUTANT	77	30 (39.0)	24.97 (12.62, N.A.)	75	31 (41.3)	57.40 (8.71, N.A.)	0.94 (0.57, 1.55) 0.8019	
BRAF WILDTYPE	110	48 (43.6)	23.46 (10.84, N.A.)	126	49 (38.9)	34.73 (17.74, N.A.)	1.17 (0.79, 1.74) 0.4378	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.7399
M0/M1ANY[0]	123	45 (36.6)	51.02 (20.86, N.A.)	125	46 (36.8)	46.75 (20.70, N.A.)	1.05 (0.70, 1.59) 0.8130	
M1ANY[1]	64	33 (51.6)	11.76 (4.90, 30.62)	76	34 (44.7)	11.73 (5.75, N.A.)	1.15 (0.71, 1.86) 0.5674	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.9947
M0	21	8 (38.1)	51.02 (9.33, N.A.)	10	3 (30.0)	N.A. (0.36, N.A.)	1.17 (0.31, 4.41) 0.8198	
M1A	42	19 (45.2)	23.46 (9.26, N.A.)	56	22 (39.3)	34.76 (13.14, N.A.)	1.20 (0.65, 2.22) 0.5587	
M1B	40	15 (37.5)	30.36 (8.41, N.A.)	46	15 (32.6)	46.75 (10.12, N.A.)	1.23 (0.60, 2.52) 0.5735	
M1C	80	36 (45.0)	16.16 (10.15, 55.95)	81	35 (43.2)	19.25 (7.46, N.A.)	1.08 (0.68, 1.72) 0.7554	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9806
STAGE III	21	8 (38.1)	51.02 (9.33, N.A.)	10	3 (30.0)	N.A. (0.36, N.A.)	1.17 (0.31, 4.41) 0.8198	
STAGE IV	166	70 (42.2)	23.46 (13.73, 70.77)	190	76 (40.0)	34.73 (17.74, 63.64)	1.11 (0.80, 1.54) 0.5240	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.8186
CUTANEOUS ACRAL	23	9 (39.1)	N.A. (2.50, N.A.)	26	10 (38.5)	8.61 (5.88, N.A.)	1.25 (0.51, 3.08) 0.6281	
CUTANEOUS NON-ACRAL	122	52 (42.6)	23.46 (12.62, 55.95)	139	54 (38.8)	34.73 (19.25, 63.64)	1.11 (0.76, 1.62) 0.5997	
MUCOSAL	17	8 (47.1)	30.62 (3.19, N.A.)	20	9 (45.0)	72.21 (3.22, N.A.)	1.13 (0.42, 3.02) 0.8054	
OTHER	25	9 (36.0)	N.A. (1.84, N.A.)	16	7 (43.8)	N.A. (2.10, N.A.)	0.82 (0.30, 2.19) 0.6869	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.8974
<= ULN	120	45 (37.5)	51.02 (20.86, N.A.)	121	45 (37.2)	34.76 (20.70, N.A.)	1.08 (0.71, 1.63) 0.7190	
> ULN	66	33 (50.0)	12.02 (5.91, 30.62)	80	35 (43.8)	13.14 (8.54, N.A.)	1.11 (0.69, 1.78) 0.6732	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.1720
<= 2 X ULN	168	69 (41.1)	24.97 (16.16, 70.77)	181	68 (37.6)	34.76 (19.25, 72.21)	1.15 (0.82, 1.61) 0.4189	
> 2 X ULN	18	9 (50.0)	30.62 (1.18, N.A.)	20	12 (60.0)	1.84 (0.95, N.A.)	0.58 (0.24, 1.44) 0.2318	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.6059
< QUARTILE 1	35	11 (31.4)	51.02 (26.45, N.A.)	43	11 (25.6)	57.40 (46.75, N.A.)	1.16 (0.50, 2.69) 0.7226	
QUARTILE 1 TO < QUARTILE 3	84	37 (44.0)	20.86 (10.15, N.A.)	89	36 (40.4)	27.43 (14.92, N.A.)	1.21 (0.76, 1.92) 0.4146	
>= QUARTILE 3	46	20 (43.5)	23.46 (5.91, N.A.)	44	21 (47.7)	20.50 (4.93, N.A.)	0.88 (0.47, 1.64) 0.6948	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.5436
0	121	46 (38.0)	51.02 (20.86, N.A.)	136	52 (38.2)	34.76 (19.25, 63.64)	0.99 (0.66, 1.47) 0.9402	
1	66	32 (48.5)	18.07 (5.98, 30.62)	65	28 (43.1)	17.74 (7.69, N.A.)	1.20 (0.72, 1.99) 0.4824	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.0476*
CURRENT/FORMER	63	24 (38.1)	22.64 (18.07, N.A.)	76	38 (50.0)	20.50 (8.71, 34.73)	0.67 (0.40, 1.13) 0.1302	
NEVER SMOKED	116	47 (40.5)	30.62 (12.02, N.A.)	121	41 (33.9)	N.A. (19.25, N.A.)	1.33 (0.88, 2.03) 0.1788	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.4996
>= 18 - < 65	102	38 (37.3)	55.95 (22.64, N.A.)	105	33 (31.4)	72.21 (17.74, N.A.)	1.24 (0.78, 1.98) 0.3659	
>= 65 - < 75	48	19 (39.6)	30.36 (9.33, N.A.)	64	26 (40.6)	46.75 (13.14, 63.64)	1.08 (0.60, 1.96) 0.7993	
>= 75	37	21 (56.8)	11.76 (5.91, 26.45)	32	21 (65.6)	8.34 (4.93, 15.84)	0.74 (0.41, 1.37) 0.3403	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.5234
< 65	102	38 (37.3)	55.95 (22.64, N.A.)	105	33 (31.4)	72.21 (17.74, N.A.)	1.24 (0.78, 1.98) 0.3659	
>= 65	85	40 (47.1)	18.07 (9.89, 30.62)	96	47 (49.0)	20.70 (8.54, 46.75)	1.01 (0.66, 1.53) 0.9806	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.5690
MALE	104	49 (47.1)	23.46 (11.76, 55.95)	116	48 (41.4)	27.43 (13.14, N.A.)	1.16 (0.78, 1.72) 0.4744	
FEMALE	83	29 (34.9)	30.62 (12.02, N.A.)	85	32 (37.6)	46.75 (9.89, N.A.)	0.96 (0.58, 1.59) 0.8862	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.2
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.5661
USA/CANADA	17	8 (47.1)	18.07 (1.31, N.A.)	18	8 (44.4)	11.73 (4.93, N.A.)	0.93 (0.34, 2.54) 0.8923	
EUROPE	98	34 (34.7)	51.02 (16.16, N.A.)	105	40 (38.1)	27.43 (14.92, N.A.)	0.88 (0.56, 1.40) 0.5975	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	27 (47.4)	24.97 (6.87, N.A.)	62	23 (37.1)	46.75 (20.70, N.A.)	1.46 (0.84, 2.55) 0.1802	
AUSTRALIA/NZ	15	9 (60.0)	13.73 (3.32, N.A.)	16	9 (56.3)	10.12 (3.55, N.A.)	1.19 (0.47, 3.01) 0.7107	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	45 (24.1)	N.A. (36.99, N.A.)	201	38 (18.9)	N.A. (42.78, N.A.)	1.28 (0.83, 1.98) 0.2550	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.1921
LAG-3 >= 1%	118	32 (27.1)	70.21 (25.17, N.A.)	120	20 (16.7)	N.A. (46.75, N.A.)	1.61 (0.92, 2.81) 0.0929	
LAG-3 < 1%	69	13 (18.8)	N.A.	81	18 (22.2)	41.43 (23.36, N.A.)	0.88 (0.43, 1.80) 0.7321	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.0957
LAG-3 >= 5%	35	11 (31.4)	70.21 (19.35, N.A.)	40	5 (12.5)	N.A. (46.75, N.A.)	2.79 (0.97, 8.04) 0.0478	
LAG-3 < 5%	152	34 (22.4)	N.A. (36.99, N.A.)	161	33 (20.5)	57.40 (37.03, N.A.)	1.05 (0.65, 1.70) 0.8307	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.7090
BRAF MUTANT	77	25 (32.5)	36.99 (21.42, N.A.)	75	18 (24.0)	42.78 (27.89, N.A.)	1.37 (0.75, 2.52) 0.3038	
BRAF WILDTYPE	110	20 (18.2)	N.A. (70.21, N.A.)	126	20 (15.9)	N.A.	1.15 (0.62, 2.13) 0.6648	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.8213
M0/M1ANY[0]	123	32 (26.0)	N.A. (25.17, N.A.)	125	27 (21.6)	57.40 (41.43, N.A.)	1.24 (0.75, 2.08) 0.4016	
M1ANY[1]	64	13 (20.3)	70.21 (33.71, N.A.)	76	11 (14.5)	N.A. (39.10, N.A.)	1.34 (0.60, 3.00) 0.4722	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.7547
M0	21	4 (19.0)	N.A. (12.88, N.A.)	10	1 (10.0)	N.A. (42.78, N.A.)	1.80 (0.20, 16.17) 0.5928	
M1A	42	10 (23.8)	N.A. (19.35, N.A.)	56	14 (25.0)	57.40 (37.03, N.A.)	0.92 (0.41, 2.08) 0.8462	
M1B	40	9 (22.5)	N.A. (23.82, N.A.)	46	8 (17.4)	N.A. (17.25, N.A.)	1.22 (0.47, 3.18) 0.6799	
M1C	80	20 (25.0)	70.21 (22.57, N.A.)	81	13 (16.0)	N.A. (39.10, N.A.)	1.66 (0.82, 3.35) 0.1510	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7943
STAGE III	21	4 (19.0)	N.A. (12.88, N.A.)	10	1 (10.0)	N.A. (42.78, N.A.)	1.80 (0.20, 16.17) 0.5928	
STAGE IV	166	41 (24.7)	N.A. (33.71, N.A.)	190	36 (18.9)	N.A. (41.43, N.A.)	1.35 (0.86, 2.11) 0.1885	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.5835
CUTANEOUS ACRAL	23	3 (13.0)	N.A. (12.88, N.A.)	26	6 (23.1)	N.A. (37.03, N.A.)	0.63 (0.16, 2.52) 0.5095	
CUTANEOUS NON-ACRAL	122	32 (26.2)	N.A. (25.17, N.A.)	139	26 (18.7)	N.A. (42.78, N.A.)	1.41 (0.84, 2.37) 0.1895	
MUCOSAL	17	3 (17.6)	N.A.	20	2 (10.0)	N.A. (14.78, N.A.)	1.92 (0.32, 11.47) 0.4690	
OTHER	25	7 (28.0)	70.21 (36.99, N.A.)	16	4 (25.0)	19.98 (19.98, N.A.)	0.77 (0.20, 2.90) 0.6991	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.6533
<= ULN	120	31 (25.8)	N.A. (25.17, N.A.)	121	27 (22.3)	57.40 (37.03, N.A.)	1.21 (0.72, 2.02) 0.4754	
> ULN	66	14 (21.2)	70.21 (33.71, N.A.)	80	11 (13.8)	N.A. (39.10, N.A.)	1.46 (0.66, 3.22) 0.3454	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.4349
<= 2 X ULN	168	42 (25.0)	N.A. (36.99, N.A.)	181	34 (18.8)	N.A. (42.78, N.A.)	1.35 (0.86, 2.12) 0.1916	
> 2 X ULN	18	3 (16.7)	N.A. (3.61, N.A.)	20	4 (20.0)	N.A. (4.01, N.A.)	0.83 (0.19, 3.74) 0.8104	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.1292
< QUARTILE 1	35	9 (25.7)	N.A. (21.42, N.A.)	43	14 (32.6)	42.78 (27.89, 57.40)	0.72 (0.31, 1.68) 0.4521	
QUARTILE 1 TO < QUARTILE 3	84	20 (23.8)	N.A. (25.17, N.A.)	89	11 (12.4)	N.A. (41.43, N.A.)	2.28 (1.09, 4.79) 0.0246	
>= QUARTILE 3	46	8 (17.4)	N.A. (70.21, N.A.)	44	7 (15.9)	N.A.	0.95 (0.34, 2.61) 0.9145	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.9152
0	121	29 (24.0)	N.A. (36.99, N.A.)	136	25 (18.4)	57.40 (41.43, N.A.)	1.30 (0.76, 2.22) 0.3378	
1	66	16 (24.2)	70.21 (15.34, N.A.)	65	13 (20.0)	N.A. (37.03, N.A.)	1.20 (0.58, 2.49) 0.6259	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.7029
CURRENT/FORMER	63	18 (28.6)	N.A. (21.42, N.A.)	76	14 (18.4)	N.A. (27.89, N.A.)	1.42 (0.70, 2.85) 0.3285	
NEVER SMOKED	116	24 (20.7)	N.A. (36.99, N.A.)	121	23 (19.0)	N.A. (41.43, N.A.)	1.18 (0.66, 2.09) 0.5765	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.5153
>= 18 - < 65	102	22 (21.6)	N.A. (36.99, N.A.)	105	20 (19.0)	N.A. (27.89, N.A.)	1.08 (0.59, 1.98) 0.8051	
>= 65 - < 75	48	7 (14.6)	N.A. (33.71, N.A.)	64	11 (17.2)	57.40 (37.03, N.A.)	1.03 (0.40, 2.68) 0.9465	
>= 75	37	16 (43.2)	19.35 (9.99, N.A.)	32	7 (21.9)	N.A. (8.54, N.A.)	1.65 (0.67, 4.07) 0.2678	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
CTC Version 5.0
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.4130
< 65	102	22 (21.6)	N.A. (36.99, N.A.)	105	20 (19.0)	N.A. (27.89, N.A.)	1.08 (0.59, 1.98) 0.8051	
>= 65	85	23 (27.1)	70.21 (19.35, N.A.)	96	18 (18.8)	57.40 (42.78, N.A.)	1.51 (0.81, 2.80) 0.1879	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.1673
MALE	104	25 (24.0)	N.A. (33.71, N.A.)	116	28 (24.1)	44.42 (33.38, N.A.)	1.03 (0.60, 1.77) 0.9079	
FEMALE	83	20 (24.1)	70.21 (23.82, N.A.)	85	10 (11.8)	N.A. (57.40, N.A.)	1.94 (0.91, 4.16) 0.0802	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 15.3
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.3625
USA/CANADA	17	3 (17.6)	N.A.	18	4 (22.2)	N.A. (6.44, N.A.)	0.68 (0.15, 3.07) 0.6119	
EUROPE	98	23 (23.5)	70.21 (36.99, N.A.)	105	15 (14.3)	N.A. (42.78, N.A.)	1.62 (0.84, 3.11) 0.1427	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	14 (24.6)	N.A. (19.35, N.A.)	62	16 (25.8)	57.40 (33.38, N.A.)	0.97 (0.48, 2.00) 0.9446	
AUSTRALIA/NZ	15	5 (33.3)	33.71 (9.99, N.A.)	16	3 (18.8)	N.A. (16.85, N.A.)	8.85 (0.97, 80.87) 0.0240	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazards model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Anhang 4-G 7.4.2: UE auf Ebene der SOC und PT (nur bei signifikantem Ergebnis auf Populationsebene)

Anhang 4-G 7.4.2.1: Jegliche UE auf Ebene der SOC und PT

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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	118 (63.1)	5.42 (3.68, 7.23)	201	105 (52.2)	11.17 (6.47, 15.90)	1.37 (1.05, 1.78) 0.0198	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.7792
LAG-3 >= 1%	118	75 (63.6)	6.41 (3.71, 8.51)	120	63 (52.5)	11.17 (5.13, 26.02)	1.32 (0.95, 1.85) 0.1013	
LAG-3 < 1%	69	43 (62.3)	3.78 (2.69, 10.12)	81	42 (51.9)	13.80 (3.71, 25.49)	1.41 (0.92, 2.16) 0.1121	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.1327
LAG-3 >= 5%	35	29 (82.9)	5.98 (1.94, 6.90)	40	21 (52.5)	13.96 (3.94, N.A.)	2.15 (1.20, 3.82) 0.0083	
LAG-3 < 5%	152	89 (58.6)	5.32 (3.25, 11.07)	161	84 (52.2)	10.35 (5.36, 18.46)	1.23 (0.91, 1.65) 0.1791	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.7289
BRAF MUTANT	77	52 (67.5)	4.34 (3.06, 6.47)	75	45 (60.0)	5.13 (2.23, 13.80)	1.25 (0.83, 1.86) 0.2858	
BRAF WILDTYPE	110	66 (60.0)	6.90 (3.65, 16.69)	126	60 (47.6)	13.96 (8.02, 41.17)	1.41 (0.99, 2.00) 0.0544	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.9768
M0/M1ANY[0]	123	79 (64.2)	5.98 (3.19, 10.12)	125	67 (53.6)	11.60 (6.05, 25.49)	1.37 (0.99, 1.90) 0.0556	
M1ANY[1]	64	39 (60.9)	5.16 (3.06, 8.51)	76	38 (50.0)	8.28 (2.46, 26.02)	1.36 (0.87, 2.13) 0.1753	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.3743
M0	21	11 (52.4)	9.33 (0.85, N.A.)	10	6 (60.0)	20.52 (0.10, N.A.)	0.82 (0.30, 2.26) 0.7025	
M1A	42	25 (59.5)	6.90 (2.79, 52.67)	56	25 (44.6)	14.23 (8.28, N.A.)	1.60 (0.92, 2.79) 0.0953	
M1B	40	27 (67.5)	5.32 (2.46, 10.12)	46	22 (47.8)	11.60 (7.66, 26.02)	1.87 (1.06, 3.31) 0.0278	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	53 (66.3)	4.63 (2.96, 7.39)	81	48 (59.3)	3.15 (1.87, 13.80)	1.15 (0.78, 1.71) 0.4824	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2678
STAGE III	21	11 (52.4)	9.33 (0.85, N.A.)	10	6 (60.0)	20.52 (0.10, N.A.)	0.82 (0.30, 2.26) 0.7025	
STAGE IV	166	107 (64.5)	5.32 (3.65, 7.10)	190	98 (51.6)	11.60 (6.47, 18.46)	1.45 (1.10, 1.92) 0.0073	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.0268*
CUTANEOUS ACRAL	23	11 (47.8)	6.41 (1.81, N.A.)	26	11 (42.3)	18.46 (1.74, N.A.)	1.33 (0.57, 3.11) 0.5046	
CUTANEOUS NON-ACRAL	122	85 (69.7)	4.80 (3.19, 6.70)	139	68 (48.9)	13.80 (8.21, 35.91)	1.68 (1.22, 2.32) 0.0013	
MUCOSAL	17	11 (64.7)	2.96 (0.99, N.A.)	20	14 (70.0)	3.83 (0.59, 10.35)	0.95 (0.42, 2.14) 0.9010	
OTHER	25	11 (44.0)	10.12 (2.79, N.A.)	16	12 (75.0)	3.14 (1.31, 7.03)	0.44 (0.19, 1.03) 0.0511	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.9139
<= ULN	120	77 (64.2)	5.98 (3.19, 9.33)	121	65 (53.7)	11.60 (6.47, 25.49)	1.40 (1.00, 1.94) 0.0471	
> ULN	66	41 (62.1)	5.16 (3.06, 12.85)	80	40 (50.0)	8.28 (2.46, 26.02)	1.35 (0.87, 2.09) 0.1775	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.7947
<= 2 X ULN	168	108 (64.3)	5.42 (3.68, 7.10)	181	97 (53.6)	11.17 (6.05, 18.46)	1.36 (1.03, 1.79) 0.0293	
> 2 X ULN	18	10 (55.6)	7.23 (0.36, N.A.)	20	8 (40.0)	13.96 (0.72, N.A.)	1.43 (0.56, 3.66) 0.4583	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.5202
< QUARTILE 1	35	22 (62.9)	6.18 (2.96, 29.47)	43	24 (55.8)	18.46 (3.71, 35.91)	1.30 (0.72, 2.32) 0.3847	
QUARTILE 1 TO < QUARTILE 3	84	55 (65.5)	4.60 (2.07, 7.10)	89	46 (51.7)	11.60 (5.59, 41.17)	1.53 (1.03, 2.27) 0.0340	
>= QUARTILE 3	46	27 (58.7)	6.51 (2.73, 12.85)	44	23 (52.3)	5.36 (0.89, N.A.)	1.01 (0.58, 1.77) 0.9633	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.2536
0	121	80 (66.1)	5.16 (3.19, 8.51)	136	69 (50.7)	13.80 (6.90, 25.49)	1.51 (1.09, 2.09) 0.0118	
1	66	38 (57.6)	6.51 (2.79, 16.69)	65	36 (55.4)	7.66 (1.31, 41.17)	1.09 (0.69, 1.71) 0.7243	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.9210
CURRENT/FORMER	63	40 (63.5)	5.32 (3.09, 8.51)	76	37 (48.7)	11.17 (2.89, N.A.)	1.38 (0.88, 2.16) 0.1523	
NEVER SMOKED	116	72 (62.1)	5.42 (3.25, 16.69)	121	65 (53.7)	11.83 (6.47, 18.46)	1.37 (0.98, 1.92) 0.0670	

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(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.8067
>= 18 - < 65	102	68 (66.7)	3.81 (2.79, 6.90)	105	57 (54.3)	8.28 (2.73, 15.90)	1.36 (0.95, 1.93) 0.0895	
>= 65 - < 75	48	26 (54.2)	6.47 (4.60, 20.27)	64	35 (54.7)	11.17 (5.59, 26.02)	1.34 (0.80, 2.26) 0.2683	
>= 75	37	24 (64.9)	6.51 (2.66, 26.15)	32	13 (40.6)	N.A. (1.68, N.A.)	1.68 (0.85, 3.31) 0.1310	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.9792
< 65	102	68 (66.7)	3.81 (2.79, 6.90)	105	57 (54.3)	8.28 (2.73, 15.90)	1.36 (0.95, 1.93) 0.0895	
>= 65	85	50 (58.8)	6.51 (4.60, 17.94)	96	48 (50.0)	13.96 (7.03, 35.91)	1.43 (0.96, 2.14) 0.0806	

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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.1229
MALE	104	60 (57.7)	7.10 (3.68, 16.69)	116	49 (42.2)	25.49 (11.60, N.A.)	1.64 (1.13, 2.40) 0.0095	
FEMALE	83	58 (69.9)	4.34 (2.07, 6.51)	85	56 (65.9)	3.71 (1.94, 7.03)	1.08 (0.75, 1.56) 0.6774	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.2748
USA/CANADA	17	14 (82.4)	4.60 (0.43, 7.23)	18	16 (88.9)	2.15 (0.72, 3.94)	0.64 (0.30, 1.35) 0.2378	
EUROPE	98	54 (55.1)	10.12 (3.94, 21.45)	105	49 (46.7)	18.46 (6.47, 42.48)	1.33 (0.90, 1.96) 0.1511	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	37 (64.9)	5.98 (2.96, 15.84)	62	28 (45.2)	11.83 (7.66, N.A.)	1.58 (0.97, 2.59) 0.0645	
AUSTRALIA/NZ	15	13 (86.7)	1.71 (0.20, 2.73)	16	12 (75.0)	4.25 (1.87, 15.90)	2.33 (1.01, 5.40) 0.0426	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	116 (62.0)	5.13 (3.68, 8.31)	201	103 (51.2)	8.21 (5.55, 22.44)	1.32 (1.02, 1.73) 0.0370	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.8797
LAG-3 >= 1%	118	72 (61.0)	5.59 (3.48, 9.20)	120	61 (50.8)	8.28 (5.19, N.A.)	1.33 (0.95, 1.87) 0.1000	
LAG-3 < 1%	69	44 (63.8)	4.96 (2.96, 11.27)	81	42 (51.9)	8.21 (4.01, 25.79)	1.27 (0.83, 1.95) 0.2592	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.6287
LAG-3 >= 5%	35	23 (65.7)	6.31 (2.33, 15.90)	40	19 (47.5)	8.44 (3.61, N.A.)	1.43 (0.78, 2.62) 0.2489	
LAG-3 < 5%	152	93 (61.2)	5.13 (3.06, 8.31)	161	84 (52.2)	7.69 (5.19, 14.92)	1.28 (0.95, 1.72) 0.1004	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.2102
BRAF MUTANT	77	47 (61.0)	5.13 (2.79, 7.10)	75	44 (58.7)	5.55 (2.63, 13.80)	1.07 (0.71, 1.61) 0.7523	
BRAF WILDTYPE	110	69 (62.7)	4.96 (2.96, 11.66)	126	59 (46.8)	10.58 (6.41, N.A.)	1.51 (1.07, 2.14) 0.0193	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.7655
M0/M1ANY[0]	123	79 (64.2)	4.63 (3.29, 7.10)	125	66 (52.8)	8.21 (5.55, 34.23)	1.36 (0.98, 1.89) 0.0651	
M1ANY[1]	64	37 (57.8)	6.08 (2.66, 11.27)	76	37 (48.7)	8.28 (3.55, 25.76)	1.28 (0.81, 2.02) 0.2885	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.2417
M0	21	12 (57.1)	6.67 (0.89, N.A.)	10	6 (60.0)	6.88 (0.49, N.A.)	1.01 (0.38, 2.71) 0.9876	
M1A	42	25 (59.5)	5.72 (3.06, 13.54)	56	32 (57.1)	8.44 (5.65, 25.76)	1.18 (0.69, 1.99) 0.5477	
M1B	40	27 (67.5)	4.96 (1.94, 11.66)	46	18 (39.1)	N.A. (7.66, N.A.)	2.17 (1.19, 3.95) 0.0090	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	50 (62.5)	4.63 (1.91, 10.28)	81	45 (55.6)	3.65 (1.87, 13.80)	1.13 (0.76, 1.70) 0.5436	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.4343
STAGE III	21	12 (57.1)	6.67 (0.89, N.A.)	10	6 (60.0)	6.88 (0.49, N.A.)	1.01 (0.38, 2.71) 0.9876	
STAGE IV	166	104 (62.7)	5.13 (3.29, 8.31)	190	97 (51.1)	8.28 (5.55, 25.76)	1.38 (1.04, 1.82) 0.0233	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.1353
CUTANEOUS ACRAL	23	11 (47.8)	5.26 (1.74, N.A.)	26	13 (50.0)	7.69 (3.15, N.A.)	1.27 (0.56, 2.86) 0.5682	
CUTANEOUS NON-ACRAL	122	80 (65.6)	4.34 (2.63, 6.31)	139	68 (48.9)	9.46 (6.08, 34.23)	1.54 (1.11, 2.13) 0.0086	
MUCOSAL	17	9 (52.9)	11.66 (3.68, N.A.)	20	13 (65.0)	2.04 (0.43, N.A.)	0.42 (0.17, 1.07) 0.0610	
OTHER	25	16 (64.0)	7.10 (1.12, 12.91)	16	9 (56.3)	4.27 (0.99, N.A.)	1.20 (0.53, 2.74) 0.6618	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.8874
<= ULN	120	77 (64.2)	4.63 (3.02, 7.10)	121	65 (53.7)	7.69 (5.19, 34.23)	1.34 (0.96, 1.87) 0.0805	
> ULN	66	39 (59.1)	6.08 (2.66, 11.27)	80	38 (47.5)	8.44 (3.61, 25.76)	1.31 (0.84, 2.05) 0.2347	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.5527
<= 2 X ULN	168	105 (62.5)	5.26 (3.68, 8.31)	181	91 (50.3)	8.34 (6.08, 25.79)	1.37 (1.03, 1.81) 0.0285	
> 2 X ULN	18	11 (61.1)	3.71 (0.66, N.A.)	20	12 (60.0)	3.61 (0.89, 8.44)	1.08 (0.47, 2.46) 0.8540	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.6745
< QUARTILE 1	35	24 (68.6)	6.54 (1.81, 15.90)	43	23 (53.5)	10.58 (4.01, N.A.)	1.36 (0.77, 2.42) 0.2909	
QUARTILE 1 TO < QUARTILE 3	84	54 (64.3)	4.34 (2.56, 8.77)	89	44 (49.4)	13.80 (4.83, N.A.)	1.53 (1.02, 2.28) 0.0365	
>= QUARTILE 3	46	24 (52.2)	6.08 (2.79, 27.33)	44	20 (45.5)	8.21 (3.38, N.A.)	1.07 (0.59, 1.94) 0.8202	

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Significant SOC/PT
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SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.9622
0	121	78 (64.5)	5.13 (3.29, 10.28)	136	73 (53.7)	7.66 (4.27, 25.79)	1.33 (0.96, 1.83) 0.0817	
1	66	38 (57.6)	5.52 (2.63, 9.20)	65	30 (46.2)	8.28 (4.83, N.A.)	1.33 (0.82, 2.15) 0.2421	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.9860
CURRENT/FORMER	63	42 (66.7)	5.13 (2.79, 10.28)	76	40 (52.6)	7.66 (2.60, N.A.)	1.31 (0.85, 2.02) 0.2206	
NEVER SMOKED	116	67 (57.8)	5.59 (2.96, 13.54)	121	60 (49.6)	9.46 (6.08, 25.79)	1.34 (0.94, 1.89) 0.1022	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.7358
>= 18 - < 65	102	64 (62.7)	3.75 (2.63, 6.31)	105	53 (50.5)	8.34 (4.01, N.A.)	1.38 (0.96, 1.98) 0.0839	
>= 65 - < 75	48	30 (62.5)	5.52 (2.96, 10.28)	64	32 (50.0)	7.69 (4.27, N.A.)	1.44 (0.87, 2.38) 0.1496	
>= 75	37	22 (59.5)	9.20 (2.96, 27.33)	32	18 (56.3)	7.66 (2.50, 25.79)	1.08 (0.58, 2.02) 0.8067	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.7415
< 65	102	64 (62.7)	3.75 (2.63, 6.31)	105	53 (50.5)	8.34 (4.01, N.A.)	1.38 (0.96, 1.98) 0.0839	
>= 65	85	52 (61.2)	6.54 (4.14, 11.27)	96	50 (52.1)	7.69 (5.19, 25.79)	1.29 (0.87, 1.90) 0.1999	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.6522
MALE	104	62 (59.6)	5.26 (3.48, 8.77)	116	61 (52.6)	8.28 (4.60, 34.23)	1.25 (0.88, 1.78) 0.2119	
FEMALE	83	54 (65.1)	4.63 (1.94, 10.28)	85	42 (49.4)	7.66 (4.63, N.A.)	1.42 (0.95, 2.12) 0.0890	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.7077
USA/CANADA	17	14 (82.4)	2.17 (0.49, 5.52)	18	13 (72.2)	1.30 (0.30, 6.41)	0.97 (0.45, 2.10) 0.9430	
EUROPE	98	59 (60.2)	5.59 (3.71, 12.09)	105	56 (53.3)	8.34 (4.63, 22.44)	1.28 (0.89, 1.85) 0.1892	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	30 (52.6)	6.31 (3.02, 45.01)	62	22 (35.5)	N.A. (7.66, N.A.)	1.65 (0.95, 2.86) 0.0714	
AUSTRALIA/NZ	15	13 (86.7)	1.81 (0.56, 6.67)	16	12 (75.0)	1.63 (0.46, 34.23)	1.09 (0.49, 2.44) 0.8575	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	60 (32.1)	45.01 (22.51, N.A.)	201	40 (19.9)	N.A.	1.72 (1.16, 2.57) 0.0069	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.0568
LAG-3 >= 1%	118	44 (37.3)	N.A. (14.78, N.A.)	120	22 (18.3)	N.A.	2.28 (1.36, 3.80) 0.0012	
LAG-3 < 1%	69	16 (23.2)	45.01 (28.45, N.A.)	81	18 (22.2)	N.A.	1.01 (0.51, 1.98) 0.9774	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.7198
LAG-3 >= 5%	35	12 (34.3)	N.A. (18.04, N.A.)	40	9 (22.5)	N.A.	1.47 (0.62, 3.49) 0.3781	
LAG-3 < 5%	152	48 (31.6)	45.01 (28.45, N.A.)	161	31 (19.3)	N.A.	1.79 (1.14, 2.81) 0.0106	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.1097
BRAF MUTANT	77	27 (35.1)	22.51 (14.78, N.A.)	75	22 (29.3)	N.A. (20.50, N.A.)	1.21 (0.69, 2.13) 0.4984	
BRAF WILDTYPE	110	33 (30.0)	45.01 (28.45, N.A.)	126	18 (14.3)	N.A.	2.34 (1.32, 4.16) 0.0028	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.5995
M0/M1ANY[0]	123	42 (34.1)	45.01 (22.51, N.A.)	125	25 (20.0)	N.A.	1.87 (1.14, 3.06) 0.0121	
M1ANY[1]	64	18 (28.1)	28.45 (10.28, N.A.)	76	15 (19.7)	N.A.	1.47 (0.74, 2.92) 0.2651	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.4291
M0	21	10 (47.6)	29.63 (0.92, N.A.)	10	1 (10.0)	N.A. (0.95, N.A.)	6.07 (0.78, 47.50) 0.0500	
M1A	42	14 (33.3)	41.40 (12.91, N.A.)	56	14 (25.0)	N.A.	1.41 (0.67, 2.95) 0.3661	
M1B	40	12 (30.0)	N.A. (8.31, N.A.)	46	7 (15.2)	N.A.	2.23 (0.88, 5.67) 0.0834	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	22 (27.5)	28.45 (19.58, N.A.)	81	18 (22.2)	N.A.	1.22 (0.65, 2.28) 0.5289	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2047
STAGE III	21	10 (47.6)	29.63 (0.92, N.A.)	10	1 (10.0)	N.A. (0.95, N.A.)	6.07 (0.78, 47.50) 0.0500	
STAGE IV	166	50 (30.1)	45.01 (22.51, N.A.)	190	39 (20.5)	N.A.	1.55 (1.02, 2.36) 0.0377	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.4135
CUTANEOUS ACRAL	23	2 (8.7)	N.A.	26	5 (19.2)	N.A.	0.51 (0.10, 2.66) 0.4185	
CUTANEOUS NON-ACRAL	122	44 (36.1)	29.63 (18.04, N.A.)	139	28 (20.1)	N.A.	1.92 (1.19, 3.08) 0.0061	
MUCOSAL	17	4 (23.5)	45.01 (8.77, N.A.)	20	4 (20.0)	N.A.	1.09 (0.27, 4.36) 0.9047	
OTHER	25	10 (40.0)	N.A. (1.81, N.A.)	16	3 (18.8)	N.A.	2.24 (0.61, 8.15) 0.2097	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.7560
<= ULN	120	41 (34.2)	N.A. (22.51, N.A.)	121	25 (20.7)	N.A.	1.81 (1.10, 2.97) 0.0181	
> ULN	66	19 (28.8)	28.45 (12.91, N.A.)	80	15 (18.8)	N.A.	1.57 (0.80, 3.09) 0.1876	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.7198
<= 2 X ULN	168	56 (33.3)	45.01 (22.51, N.A.)	181	38 (21.0)	N.A.	1.69 (1.12, 2.56) 0.0113	
> 2 X ULN	18	4 (22.2)	28.45 (3.71, N.A.)	20	2 (10.0)	N.A.	2.09 (0.38, 11.61) 0.3880	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
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SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.6846
< QUARTILE 1	35	12 (34.3)	N.A. (16.79, N.A.)	43	7 (16.3)	N.A.	2.34 (0.92, 5.93) 0.0667	
QUARTILE 1 TO < QUARTILE 3	84	26 (31.0)	41.40 (19.58, N.A.)	89	21 (23.6)	N.A.	1.43 (0.80, 2.55) 0.2189	
>= QUARTILE 3	46	11 (23.9)	N.A. (14.78, N.A.)	44	6 (13.6)	N.A.	1.69 (0.63, 4.59) 0.2929	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.5612
0	121	45 (37.2)	41.40 (16.79, N.A.)	136	29 (21.3)	N.A.	1.86 (1.17, 2.97) 0.0079	
1	66	15 (22.7)	N.A. (18.04, N.A.)	65	11 (16.9)	N.A.	1.42 (0.65, 3.08) 0.3796	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
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SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.7166
CURRENT/FORMER	63	23 (36.5)	28.45 (14.78, N.A.)	76	18 (23.7)	N.A.	1.55 (0.83, 2.87) 0.1634	
NEVER SMOKED	116	33 (28.4)	N.A. (29.63, N.A.)	121	21 (17.4)	N.A.	1.81 (1.05, 3.13) 0.0312	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.6459
>= 18 - < 65	102	32 (31.4)	41.40 (18.04, N.A.)	105	23 (21.9)	N.A.	1.49 (0.87, 2.55) 0.1425	
>= 65 - < 75	48	17 (35.4)	28.45 (10.28, N.A.)	64	11 (17.2)	N.A.	2.35 (1.10, 5.04) 0.0231	
>= 75	37	11 (29.7)	N.A. (45.01, N.A.)	32	6 (18.8)	N.A.	1.68 (0.62, 4.54) 0.3036	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.4395
< 65	102	32 (31.4)	41.40 (18.04, N.A.)	105	23 (21.9)	N.A.	1.49 (0.87, 2.55) 0.1425	
>= 65	85	28 (32.9)	45.01 (19.58, N.A.)	96	17 (17.7)	N.A.	2.02 (1.10, 3.69) 0.0198	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.4962
MALE	104	34 (32.7)	N.A. (18.04, N.A.)	116	26 (22.4)	N.A.	1.54 (0.92, 2.57) 0.0936	
FEMALE	83	26 (31.3)	41.40 (16.79, N.A.)	85	14 (16.5)	N.A.	2.09 (1.09, 4.00) 0.0232	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.6068
USA/CANADA	17	9 (52.9)	18.04 (0.66, N.A.)	18	8 (44.4)	20.50 (0.95, N.A.)	1.14 (0.44, 2.98) 0.7863	
EUROPE	98	31 (31.6)	41.40 (22.51, N.A.)	105	17 (16.2)	N.A.	2.15 (1.19, 3.88) 0.0097	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	8 (14.0)	N.A. (45.01, N.A.)	62	7 (11.3)	N.A.	1.33 (0.48, 3.66) 0.5856	
AUSTRALIA/NZ	15	12 (80.0)	2.73 (0.56, 8.77)	16	8 (50.0)	4.60 (0.95, N.A.)	1.69 (0.69, 4.16) 0.2563	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	99 (52.9)	8.21 (5.75, 17.38)	201	83 (41.3)	18.30 (13.34, 29.14)	1.38 (1.03, 1.84) 0.0315	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.5713
LAG-3 >= 1%	118	59 (50.0)	8.28 (7.36, 28.29)	120	43 (35.8)	29.14 (15.84, N.A.)	1.51 (1.02, 2.23) 0.0398	
LAG-3 < 1%	69	40 (58.0)	5.72 (2.73, 17.38)	81	40 (49.4)	12.02 (7.39, 19.65)	1.24 (0.79, 1.92) 0.3460	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.7977
LAG-3 >= 5%	35	17 (48.6)	8.21 (5.32, N.A.)	40	17 (42.5)	29.14 (7.66, N.A.)	1.24 (0.63, 2.43) 0.5346	
LAG-3 < 5%	152	82 (53.9)	8.02 (4.34, 18.89)	161	66 (41.0)	15.84 (12.02, 21.39)	1.38 (1.00, 1.91) 0.0513	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.2875
BRAF MUTANT	77	39 (50.6)	9.33 (3.71, 25.82)	75	33 (44.0)	18.30 (3.98, N.A.)	1.14 (0.72, 1.81) 0.5803	
BRAF WILDTYPE	110	60 (54.5)	7.62 (5.32, 28.29)	126	50 (39.7)	19.65 (13.63, 29.14)	1.55 (1.06, 2.26) 0.0214	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.6461
M0/M1ANY[0]	123	71 (57.7)	8.21 (3.71, 25.82)	125	56 (44.8)	18.30 (13.63, 26.09)	1.43 (1.01, 2.04) 0.0436	
M1ANY[1]	64	28 (43.8)	8.02 (5.72, N.A.)	76	27 (35.5)	42.78 (10.97, N.A.)	1.24 (0.73, 2.10) 0.4305	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.1870
M0	21	9 (42.9)	27.24 (3.71, N.A.)	10	5 (50.0)	29.14 (0.13, N.A.)	0.94 (0.31, 2.80) 0.9059	
M1A	42	28 (66.7)	5.32 (1.71, 9.33)	56	26 (46.4)	14.65 (6.47, N.A.)	1.77 (1.04, 3.04) 0.0343	
M1B	40	23 (57.5)	4.70 (3.06, 15.70)	46	14 (30.4)	38.64 (13.34, N.A.)	2.33 (1.19, 4.56) 0.0112	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	37 (46.3)	18.89 (7.62, 32.82)	81	35 (43.2)	18.30 (9.23, 42.78)	1.02 (0.64, 1.62) 0.9355	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.3787
STAGE III	21	9 (42.9)	27.24 (3.71, N.A.)	10	5 (50.0)	29.14 (0.13, N.A.)	0.94 (0.31, 2.80) 0.9059	
STAGE IV	166	90 (54.2)	8.02 (5.32, 15.70)	190	77 (40.5)	19.65 (13.34, 38.64)	1.48 (1.09, 2.01) 0.0114	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.1098
CUTANEOUS ACRAL	23	12 (52.2)	3.06 (1.08, N.A.)	26	8 (30.8)	14.65 (13.63, N.A.)	2.37 (0.96, 5.83) 0.0552	
CUTANEOUS NON-ACRAL	122	69 (56.6)	8.21 (4.34, 18.89)	139	64 (46.0)	18.30 (10.97, 29.14)	1.28 (0.91, 1.80) 0.1521	
MUCOSAL	17	5 (29.4)	49.74 (10.71, N.A.)	20	8 (40.0)	8.57 (5.52, N.A.)	0.49 (0.15, 1.63) 0.2344	
OTHER	25	13 (52.0)	7.36 (1.12, N.A.)	16	3 (18.8)	N.A.	3.07 (0.87, 10.80) 0.0650	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.5037
<= ULN	120	70 (58.3)	7.39 (3.71, 17.38)	121	54 (44.6)	18.30 (13.34, 26.09)	1.48 (1.03, 2.11) 0.0316	
> ULN	66	29 (43.9)	8.28 (7.36, 32.46)	80	29 (36.3)	29.14 (10.97, 45.73)	1.18 (0.71, 1.98) 0.5212	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.6699
<= 2 X ULN	168	92 (54.8)	8.21 (5.75, 17.38)	181	78 (43.1)	18.30 (13.34, 29.14)	1.36 (1.00, 1.84) 0.0462	
> 2 X ULN	18	7 (38.9)	N.A. (1.02, N.A.)	20	5 (25.0)	N.A. (0.95, N.A.)	1.55 (0.49, 4.90) 0.4562	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.3684
< QUARTILE 1	35	20 (57.1)	5.32 (2.69, N.A.)	43	21 (48.8)	21.39 (5.52, 45.73)	1.30 (0.70, 2.41) 0.3989	
QUARTILE 1 TO < QUARTILE 3	84	48 (57.1)	8.02 (2.73, 15.70)	89	36 (40.4)	19.65 (12.02, 42.78)	1.70 (1.10, 2.62) 0.0152	
>= QUARTILE 3	46	18 (39.1)	18.89 (7.62, 49.74)	44	15 (34.1)	29.14 (5.85, N.A.)	0.92 (0.46, 1.83) 0.8099	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.5321
0	121	64 (52.9)	9.33 (6.47, 25.82)	136	58 (42.6)	20.24 (12.02, 42.78)	1.29 (0.90, 1.84) 0.1650	
1	66	35 (53.0)	7.36 (2.30, 27.24)	65	25 (38.5)	15.84 (11.73, 29.14)	1.56 (0.93, 2.62) 0.0886	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.0362*
CURRENT/FORMER	63	39 (61.9)	6.47 (1.71, 10.71)	76	27 (35.5)	19.65 (8.57, N.A.)	2.05 (1.26, 3.36) 0.0034	
NEVER SMOKED	116	52 (44.8)	25.82 (8.21, 37.19)	121	53 (43.8)	16.85 (12.02, 38.64)	1.04 (0.71, 1.53) 0.8301	

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Significant SOC/PT
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SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.9153
>= 18 - < 65	102	54 (52.9)	9.33 (5.32, 27.24)	105	39 (37.1)	19.65 (13.63, N.A.)	1.50 (0.99, 2.27) 0.0557	
>= 65 - < 75	48	27 (56.3)	5.32 (2.69, 8.28)	64	33 (51.6)	13.34 (5.06, 26.09)	1.33 (0.80, 2.23) 0.2711	
>= 75	37	18 (48.6)	10.71 (3.71, N.A.)	32	11 (34.4)	20.24 (11.73, N.A.)	1.43 (0.68, 3.04) 0.3431	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
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SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.5173
< 65	102	54 (52.9)	9.33 (5.32, 27.24)	105	39 (37.1)	19.65 (13.63, N.A.)	1.50 (0.99, 2.27) 0.0557	
>= 65	85	45 (52.9)	7.39 (3.71, 28.29)	96	44 (45.8)	15.84 (7.39, 29.14)	1.26 (0.83, 1.90) 0.2843	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.8094
MALE	104	57 (54.8)	7.56 (2.99, 28.29)	116	51 (44.0)	14.65 (10.97, 26.09)	1.36 (0.93, 1.99) 0.1095	
FEMALE	83	42 (50.6)	8.28 (7.10, 18.89)	85	32 (37.6)	20.24 (13.34, 42.78)	1.53 (0.96, 2.45) 0.0704	

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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.1031
USA/CANADA	17	14 (82.4)	2.17 (0.59, 6.47)	18	10 (55.6)	10.18 (0.95, N.A.)	2.03 (0.89, 4.62) 0.0820	
EUROPE	98	51 (52.0)	8.28 (5.72, 28.29)	105	37 (35.2)	25.76 (16.85, N.A.)	1.63 (1.07, 2.50) 0.0229	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	26 (45.6)	18.89 (5.32, N.A.)	62	24 (38.7)	18.30 (8.57, N.A.)	1.26 (0.72, 2.20) 0.4123	
AUSTRALIA/NZ	15	8 (53.3)	8.02 (1.64, N.A.)	16	12 (75.0)	3.98 (1.71, 7.39)	0.52 (0.21, 1.28) 0.1465	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	49 (26.2)	49.74 (28.65, N.A.)	201	34 (16.9)	N.A. (34.73, N.A.)	1.65 (1.06, 2.55) 0.0244	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.6984
LAG-3 >= 1%	118	30 (25.4)	N.A. (28.65, N.A.)	120	17 (14.2)	N.A. (38.64, N.A.)	1.82 (1.00, 3.30) 0.0458	
LAG-3 < 1%	69	19 (27.5)	34.23 (24.77, N.A.)	81	17 (21.0)	34.73 (17.51, N.A.)	1.48 (0.77, 2.84) 0.2418	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.3175
LAG-3 >= 5%	35	8 (22.9)	N.A. (15.28, N.A.)	40	9 (22.5)	N.A. (26.09, N.A.)	1.06 (0.41, 2.76) 0.8982	
LAG-3 < 5%	152	41 (27.0)	37.19 (27.24, N.A.)	161	25 (15.5)	N.A. (34.73, N.A.)	1.83 (1.11, 3.00) 0.0163	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.4551
BRAF MUTANT	77	16 (20.8)	N.A. (25.82, N.A.)	75	12 (16.0)	N.A. (34.04, N.A.)	1.33 (0.63, 2.80) 0.4617	
BRAF WILDTYPE	110	33 (30.0)	34.23 (27.24, N.A.)	126	22 (17.5)	N.A. (31.57, N.A.)	1.89 (1.10, 3.24) 0.0188	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.3304
M0/M1ANY[0]	123	35 (28.5)	37.19 (27.24, N.A.)	125	27 (21.6)	N.A. (34.04, N.A.)	1.45 (0.87, 2.39) 0.1489	
M1ANY[1]	64	14 (21.9)	N.A. (33.81, N.A.)	76	7 (9.2)	N.A. (45.73, N.A.)	2.37 (0.96, 5.89) 0.0547	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.3358
M0	21	3 (14.3)	N.A. (27.24, N.A.)	10	2 (20.0)	N.A. (5.45, N.A.)	0.80 (0.13, 4.87) 0.8109	
M1A	42	16 (38.1)	37.19 (7.39, N.A.)	56	9 (16.1)	N.A.	2.92 (1.29, 6.62) 0.0072	
M1B	40	8 (20.0)	N.A. (24.77, N.A.)	46	8 (17.4)	45.73 (38.64, N.A.)	1.15 (0.43, 3.08) 0.7821	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	22 (27.5)	32.82 (25.82, N.A.)	81	13 (16.0)	N.A. (18.30, N.A.)	1.73 (0.87, 3.45) 0.1123	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.3296
STAGE III	21	3 (14.3)	N.A. (27.24, N.A.)	10	2 (20.0)	N.A. (5.45, N.A.)	0.80 (0.13, 4.87) 0.8109	
STAGE IV	166	46 (27.7)	49.74 (28.65, N.A.)	190	32 (16.8)	N.A. (34.73, N.A.)	1.79 (1.14, 2.81) 0.0104	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.0387*
CUTANEOUS ACRAL	23	7 (30.4)	24.77 (3.25, N.A.)	26	2 (7.7)	N.A. (13.63, N.A.)	4.32 (0.89, 21.01) 0.0492	
CUTANEOUS NON-ACRAL	122	35 (28.7)	N.A. (28.65, N.A.)	139	25 (18.0)	N.A. (34.73, N.A.)	1.73 (1.04, 2.90) 0.0339	
MUCOSAL	17	1 (5.9)	N.A. (49.74, N.A.)	20	6 (30.0)	N.A. (5.52, N.A.)	<0.01 (<0.01, N.A.) 0.0111	
OTHER	25	6 (24.0)	25.82 (7.56, N.A.)	16	1 (6.3)	N.A.	2.86 (0.33, 24.71) 0.3192	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.4029
<= ULN	120	34 (28.3)	49.74 (27.24, N.A.)	121	26 (21.5)	N.A. (34.04, N.A.)	1.46 (0.88, 2.44) 0.1444	
> ULN	66	15 (22.7)	N.A. (33.81, N.A.)	80	8 (10.0)	N.A. (31.57, N.A.)	2.18 (0.92, 5.15) 0.0685	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9836
<= 2 X ULN	168	45 (26.8)	49.74 (28.65, N.A.)	181	34 (18.8)	N.A. (34.73, N.A.)	1.51 (0.97, 2.35) 0.0692	
> 2 X ULN	18	4 (22.2)	N.A. (4.96, N.A.)	20	0	N.E.	N.E. 0.0365	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.6577
< QUARTILE 1	35	8 (22.9)	N.A. (24.77, N.A.)	43	9 (20.9)	45.73 (34.04, N.A.)	1.05 (0.40, 2.74) 0.9185	
QUARTILE 1 TO < QUARTILE 3	84	23 (27.4)	N.A. (25.82, N.A.)	89	16 (18.0)	N.A. (25.76, N.A.)	1.75 (0.92, 3.32) 0.0827	
>= QUARTILE 3	46	11 (23.9)	33.81 (27.24, N.A.)	44	5 (11.4)	34.73 (31.57, N.A.)	1.64 (0.57, 4.74) 0.3589	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.4621
0	121	30 (24.8)	N.A. (28.65, N.A.)	136	24 (17.6)	N.A. (38.64, N.A.)	1.44 (0.84, 2.47) 0.1788	
1	66	19 (28.8)	33.81 (15.28, N.A.)	65	10 (15.4)	N.A. (26.09, N.A.)	2.07 (0.96, 4.46) 0.0577	

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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.5463
CURRENT/FORMER	63	17 (27.0)	N.A. (21.42, N.A.)	76	15 (19.7)	N.A. (18.30, N.A.)	1.31 (0.65, 2.64) 0.4429	
NEVER SMOKED	116	26 (22.4)	37.19 (32.82, N.A.)	121	18 (14.9)	N.A. (38.64, N.A.)	1.70 (0.93, 3.10) 0.0805	

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Significant SOC/PT
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.6470
>= 18 - < 65	102	28 (27.5)	37.19 (25.82, N.A.)	105	16 (15.2)	N.A.	1.83 (0.99, 3.39) 0.0502	
>= 65 - < 75	48	12 (25.0)	N.A. (24.77, N.A.)	64	15 (23.4)	38.64 (26.09, N.A.)	1.32 (0.61, 2.83) 0.4790	
>= 75	37	9 (24.3)	N.A. (28.65, N.A.)	32	3 (9.4)	N.A. (31.57, N.A.)	2.51 (0.68, 9.31) 0.1533	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.6336
< 65	102	28 (27.5)	37.19 (25.82, N.A.)	105	16 (15.2)	N.A.	1.83 (0.99, 3.39) 0.0502	
>= 65	85	21 (24.7)	N.A. (28.65, N.A.)	96	18 (18.8)	45.73 (31.57, N.A.)	1.49 (0.79, 2.80) 0.2136	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.3484
MALE	104	34 (32.7)	49.74 (24.77, N.A.)	116	22 (19.0)	45.73 (34.04, N.A.)	1.92 (1.12, 3.29) 0.0152	
FEMALE	83	15 (18.1)	37.19 (33.81, N.A.)	85	12 (14.1)	N.A. (38.64, N.A.)	1.28 (0.60, 2.75) 0.5189	

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Significant SOC/PT
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SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.0951
USA/CANADA	17	9 (52.9)	13.67 (2.14, N.A.)	18	4 (22.2)	N.A. (8.57, N.A.)	2.25 (0.69, 7.37) 0.1685	
EUROPE	98	25 (25.5)	37.19 (28.65, N.A.)	105	13 (12.4)	N.A. (31.57, N.A.)	2.33 (1.19, 4.55) 0.0111	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	13 (22.8)	N.A. (27.24, N.A.)	62	9 (14.5)	N.A. (34.73, N.A.)	1.65 (0.71, 3.87) 0.2415	
AUSTRALIA/NZ	15	2 (13.3)	N.A. (21.42, N.A.)	16	8 (50.0)	16.85 (5.52, N.A.)	0.25 (0.05, 1.18) 0.0593	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	53 (28.3)	N.A. (20.21, N.A.)	201	33 (16.4)	N.A.	1.93 (1.25, 2.98) 0.0026	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.0896
LAG-3 >= 1%	118	28 (23.7)	N.A. (22.51, N.A.)	120	21 (17.5)	N.A.	1.44 (0.82, 2.54) 0.2035	
LAG-3 < 1%	69	25 (36.2)	20.14 (13.67, N.A.)	81	12 (14.8)	N.A.	2.91 (1.46, 5.81) 0.0015	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.1523
LAG-3 >= 5%	35	11 (31.4)	N.A. (8.25, N.A.)	40	12 (30.0)	N.A. (16.03, N.A.)	1.19 (0.52, 2.70) 0.6782	
LAG-3 < 5%	152	42 (27.6)	N.A. (20.14, N.A.)	161	21 (13.0)	N.A.	2.36 (1.39, 3.98) 0.0010	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.0234*
BRAF MUTANT	77	17 (22.1)	N.A. (22.24, N.A.)	75	16 (21.3)	N.A. (26.25, N.A.)	1.04 (0.52, 2.05) 0.9190	
BRAF WILDTYPE	110	36 (32.7)	22.51 (14.78, N.A.)	126	17 (13.5)	N.A.	2.92 (1.64, 5.21) 0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.5905
M0/M1ANY[0]	123	40 (32.5)	28.58 (20.14, N.A.)	125	26 (20.8)	N.A.	1.80 (1.10, 2.95) 0.0186	
M1ANY[1]	64	13 (20.3)	N.A. (8.25, N.A.)	76	7 (9.2)	N.A.	2.43 (0.97, 6.09) 0.0511	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.2283
M0	21	7 (33.3)	22.51 (13.67, N.A.)	10	4 (40.0)	16.76 (0.95, N.A.)	0.92 (0.27, 3.19) 0.9033	
M1A	42	9 (21.4)	N.A. (28.58, N.A.)	56	11 (19.6)	N.A.	1.14 (0.47, 2.75) 0.7700	
M1B	40	15 (37.5)	20.21 (12.02, N.A.)	46	11 (23.9)	N.A. (26.25, N.A.)	1.66 (0.76, 3.63) 0.1960	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	21 (26.3)	N.A. (17.54, N.A.)	81	7 (8.6)	N.A.	3.48 (1.48, 8.20) 0.0024	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2284
STAGE III	21	7 (33.3)	22.51 (13.67, N.A.)	10	4 (40.0)	16.76 (0.95, N.A.)	0.92 (0.27, 3.19) 0.9033	
STAGE IV	166	46 (27.7)	N.A. (20.21, N.A.)	190	29 (15.3)	N.A.	2.03 (1.28, 3.24) 0.0023	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.1350
CUTANEOUS ACRAL	23	7 (30.4)	20.21 (4.50, N.A.)	26	2 (7.7)	N.A. (16.03, N.A.)	6.47 (1.28, 32.77) 0.0113	
CUTANEOUS NON-ACRAL	122	38 (31.1)	N.A. (17.54, N.A.)	139	23 (16.5)	N.A.	2.13 (1.27, 3.57) 0.0035	
MUCOSAL	17	2 (11.8)	N.A. (20.14, N.A.)	20	5 (25.0)	N.A. (4.37, N.A.)	0.43 (0.08, 2.24) 0.3048	
OTHER	25	6 (24.0)	28.58 (8.25, N.A.)	16	3 (18.8)	N.A. (3.78, N.A.)	0.94 (0.23, 3.88) 0.9365	

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SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.9174
<= ULN	120	39 (32.5)	28.58 (20.14, N.A.)	121	24 (19.8)	N.A.	1.90 (1.14, 3.17) 0.0120	
> ULN	66	14 (21.2)	N.A. (8.25, N.A.)	80	9 (11.3)	N.A.	2.00 (0.87, 4.62) 0.0980	

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All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.8617
<= 2 X ULN	168	51 (30.4)	N.A. (20.21, N.A.)	181	32 (17.7)	N.A.	1.92 (1.23, 2.98) 0.0034	
> 2 X ULN	18	2 (11.1)	N.A.	20	1 (5.0)	N.A. (16.03, N.A.)	2.76 (0.25, 31.07) 0.3922	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.5434
< QUARTILE 1	35	14 (40.0)	22.51 (8.71, N.A.)	43	7 (16.3)	N.A.	2.98 (1.20, 7.39) 0.0139	
QUARTILE 1 TO < QUARTILE 3	84	28 (33.3)	28.58 (14.78, N.A.)	89	16 (18.0)	N.A.	2.27 (1.22, 4.21) 0.0077	
>= QUARTILE 3	46	8 (17.4)	N.A. (13.67, N.A.)	44	5 (11.4)	N.A. (16.03, N.A.)	1.29 (0.42, 3.97) 0.6536	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.8251
0	121	37 (30.6)	28.58 (20.14, N.A.)	136	25 (18.4)	N.A.	1.89 (1.14, 3.14) 0.0126	
1	66	16 (24.2)	N.A. (8.71, N.A.)	65	8 (12.3)	N.A.	2.07 (0.89, 4.84) 0.0858	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.8681
CURRENT/FORMER	63	19 (30.2)	N.A. (20.14, N.A.)	76	13 (17.1)	N.A. (24.64, N.A.)	1.75 (0.86, 3.54) 0.1172	
NEVER SMOKED	116	30 (25.9)	N.A. (20.21, N.A.)	121	20 (16.5)	N.A.	1.87 (1.06, 3.31) 0.0282	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.7571
>= 18 - < 65	102	28 (27.5)	N.A. (22.51, N.A.)	105	14 (13.3)	N.A.	2.25 (1.18, 4.28) 0.0108	
>= 65 - < 75	48	15 (31.3)	20.21 (12.02, N.A.)	64	15 (23.4)	N.A.	1.58 (0.77, 3.26) 0.2071	
>= 75	37	10 (27.0)	N.A. (17.54, N.A.)	32	4 (12.5)	N.A. (16.03, N.A.)	2.41 (0.75, 7.73) 0.1279	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.4943
< 65	102	28 (27.5)	N.A. (22.51, N.A.)	105	14 (13.3)	N.A.	2.25 (1.18, 4.28) 0.0108	
>= 65	85	25 (29.4)	22.24 (15.41, N.A.)	96	19 (19.8)	N.A.	1.72 (0.94, 3.13) 0.0741	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.7593
MALE	104	29 (27.9)	N.A. (20.21, N.A.)	116	20 (17.2)	N.A.	1.81 (1.02, 3.20) 0.0385	
FEMALE	83	24 (28.9)	28.58 (14.78, N.A.)	85	13 (15.3)	N.A.	2.12 (1.08, 4.17) 0.0264	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.4342
USA/CANADA	17	7 (41.2)	22.24 (1.84, N.A.)	18	4 (22.2)	N.A. (3.61, N.A.)	1.69 (0.49, 5.86) 0.4020	
EUROPE	98	23 (23.5)	N.A. (17.54, N.A.)	105	17 (16.2)	N.A.	1.62 (0.86, 3.04) 0.1293	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	14 (24.6)	N.A. (20.14, N.A.)	62	9 (14.5)	N.A.	1.93 (0.83, 4.46) 0.1196	
AUSTRALIA/NZ	15	9 (60.0)	1.91 (0.89, N.A.)	16	3 (18.8)	N.A. (10.58, N.A.)	5.23 (1.40, 19.52) 0.0064	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	97 (51.9)	9.30 (7.39, 12.85)	201	83 (41.3)	16.39 (13.70, 27.43)	1.44 (1.07, 1.94) 0.0144	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.0965
LAG-3 >= 1%	118	59 (50.0)	10.32 (8.11, 18.14)	120	51 (42.5)	16.39 (9.23, 35.58)	1.19 (0.82, 1.73) 0.3634	
LAG-3 < 1%	69	38 (55.1)	7.00 (5.72, 10.97)	81	32 (39.5)	19.25 (12.98, 41.43)	2.13 (1.30, 3.50) 0.0021	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.0583
LAG-3 >= 5%	35	17 (48.6)	16.62 (7.00, N.A.)	40	21 (52.5)	13.27 (6.60, 35.58)	0.82 (0.43, 1.56) 0.5415	
LAG-3 < 5%	152	80 (52.6)	8.31 (7.00, 10.97)	161	62 (38.5)	20.04 (15.21, 41.43)	1.69 (1.21, 2.36) 0.0021	

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Significant SOC/PT
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SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.0468*
BRAF MUTANT	77	34 (44.2)	9.30 (7.39, 24.84)	75	35 (46.7)	15.21 (9.23, 20.99)	0.98 (0.61, 1.57) 0.9319	
BRAF WILDTYPE	110	63 (57.3)	10.25 (7.00, 13.63)	126	48 (38.1)	20.50 (13.27, 42.84)	1.89 (1.29, 2.78) 0.0009	

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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.6820
M0/M1ANY[0]	123	70 (56.9)	9.30 (7.52, 12.85)	125	61 (48.8)	15.84 (12.88, 27.43)	1.40 (0.99, 1.98) 0.0586	
M1ANY[1]	64	27 (42.2)	10.32 (6.87, 30.62)	76	22 (28.9)	20.50 (10.38, 56.97)	1.54 (0.88, 2.71) 0.1314	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.4098
M0	21	16 (76.2)	7.00 (2.50, 12.85)	10	4 (40.0)	35.58 (0.36, N.A.)	4.12 (1.18, 14.43) 0.0170	
M1A	42	21 (50.0)	10.25 (7.00, 18.43)	56	25 (44.6)	15.21 (9.23, 42.84)	1.17 (0.65, 2.10) 0.5950	
M1B	40	20 (50.0)	9.17 (6.47, 16.62)	46	16 (34.8)	27.33 (20.04, N.A.)	1.55 (0.80, 3.00) 0.1897	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	39 (48.8)	9.30 (6.90, 20.96)	81	35 (43.2)	13.70 (8.05, 27.43)	1.25 (0.79, 1.99) 0.3348	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.1265
STAGE III	21	16 (76.2)	7.00 (2.50, 12.85)	10	4 (40.0)	35.58 (0.36, N.A.)	4.12 (1.18, 14.43) 0.0170	
STAGE IV	166	81 (48.8)	10.25 (7.52, 13.73)	190	79 (41.6)	16.39 (12.98, 27.33)	1.31 (0.96, 1.79) 0.0898	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.0011*
CUTANEOUS ACRAL	23	14 (60.9)	5.72 (2.50, N.A.)	26	8 (30.8)	45.44 (45.44, N.A.)	2.85 (1.14, 7.10) 0.0187	
CUTANEOUS NON-ACRAL	122	65 (53.3)	9.30 (7.39, 13.73)	139	56 (40.3)	20.04 (15.21, 35.58)	1.65 (1.15, 2.36) 0.0062	
MUCOSAL	17	10 (58.8)	10.97 (3.19, N.A.)	20	11 (55.0)	6.41 (1.84, N.A.)	0.42 (0.15, 1.19) 0.0953	
OTHER	25	8 (32.0)	18.14 (6.90, N.A.)	16	8 (50.0)	4.86 (0.85, N.A.)	0.34 (0.12, 0.96) 0.0324	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.8588
<= ULN	120	68 (56.7)	9.30 (7.39, 12.32)	121	58 (47.9)	15.84 (12.88, 27.43)	1.42 (1.00, 2.03) 0.0501	
> ULN	66	29 (43.9)	10.32 (6.87, 25.07)	80	25 (31.3)	20.50 (10.38, 56.97)	1.49 (0.87, 2.55) 0.1421	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.1347
<= 2 X ULN	168	89 (53.0)	9.72 (7.52, 12.85)	181	74 (40.9)	19.25 (13.70, 35.58)	1.54 (1.13, 2.10) 0.0062	
> 2 X ULN	18	8 (44.4)	7.00 (2.10, N.A.)	20	9 (45.0)	20.50 (1.18, N.A.)	0.69 (0.25, 1.90) 0.4720	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.1469
< QUARTILE 1	35	22 (62.9)	8.11 (6.47, 13.63)	43	17 (39.5)	27.33 (12.88, N.A.)	1.98 (1.04, 3.78) 0.0347	
QUARTILE 1 TO < QUARTILE 3	84	41 (48.8)	9.17 (6.60, 10.97)	89	39 (43.8)	16.39 (13.27, 27.43)	1.43 (0.92, 2.23) 0.1130	
>= QUARTILE 3	46	20 (43.5)	15.28 (6.93, 30.62)	44	18 (40.9)	10.38 (6.60, 41.43)	0.91 (0.48, 1.72) 0.7620	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.1380
0	121	62 (51.2)	9.72 (7.52, 12.32)	136	53 (39.0)	20.04 (14.88, 41.86)	1.74 (1.19, 2.54) 0.0037	
1	66	35 (53.0)	9.30 (6.47, 18.14)	65	30 (46.2)	13.27 (6.60, 35.58)	1.09 (0.67, 1.77) 0.7365	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.5698
CURRENT/FORMER	63	32 (50.8)	8.11 (7.00, 10.97)	76	32 (42.1)	13.70 (7.16, 42.84)	1.24 (0.76, 2.02) 0.4010	
NEVER SMOKED	116	59 (50.9)	10.25 (6.87, 18.14)	121	50 (41.3)	19.25 (14.88, 35.58)	1.52 (1.04, 2.23) 0.0290	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.9325
>= 18 - < 65	102	52 (51.0)	8.31 (6.90, 14.92)	105	43 (41.0)	14.88 (11.53, 20.99)	1.31 (0.87, 1.96) 0.1916	
>= 65 - < 75	48	21 (43.8)	12.32 (7.52, 24.84)	64	24 (37.5)	41.86 (12.98, 46.46)	1.49 (0.82, 2.72) 0.1853	
>= 75	37	24 (64.9)	9.30 (5.16, 10.97)	32	16 (50.0)	15.74 (5.09, 20.50)	1.42 (0.74, 2.73) 0.2821	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.6176
< 65	102	52 (51.0)	8.31 (6.90, 14.92)	105	43 (41.0)	14.88 (11.53, 20.99)	1.31 (0.87, 1.96) 0.1916	
>= 65	85	45 (52.9)	10.15 (7.39, 13.63)	96	40 (41.7)	20.50 (12.98, 41.86)	1.59 (1.03, 2.45) 0.0354	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.8136
MALE	104	53 (51.0)	10.15 (7.00, 14.92)	116	51 (44.0)	19.25 (12.98, 27.43)	1.41 (0.96, 2.07) 0.0816	
FEMALE	83	44 (53.0)	8.31 (6.60, 18.14)	85	32 (37.6)	15.84 (9.23, N.A.)	1.46 (0.92, 2.32) 0.1072	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.1098
USA/CANADA	17	9 (52.9)	7.39 (1.74, N.A.)	18	11 (61.1)	9.31 (0.99, N.A.)	0.58 (0.23, 1.45) 0.2375	
EUROPE	98	42 (42.9)	13.63 (9.17, 18.14)	105	37 (35.2)	15.74 (12.98, 35.58)	1.34 (0.86, 2.09) 0.1963	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	36 (63.2)	7.00 (4.11, 10.15)	62	24 (38.7)	41.43 (12.88, 56.97)	2.02 (1.20, 3.39) 0.0069	
AUSTRALIA/NZ	15	10 (66.7)	5.54 (0.66, 8.11)	16	11 (68.8)	15.80 (3.29, 41.86)	1.72 (0.68, 4.33) 0.2439	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	11 (5.9)	N.A.	201	4 (2.0)	N.A.	3.03 (0.96, 9.53) 0.0458	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								N.M.E.
LAG-3 >= 1%	118	6 (5.1)	N.M.E.	120	3 (2.5)	N.M.E.	N.M.E.	
LAG-3 < 1%	69	5 (7.2)	N.M.E.	81	1 (1.2)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.5192
LAG-3 >= 5%	35	1 (2.9)	N.A.	40	1 (2.5)	N.A. (51.61, N.A.)	1.32 (0.08, 21.35) 0.8454	
LAG-3 < 5%	152	10 (6.6)	N.A.	161	3 (1.9)	N.A.	3.50 (0.96, 12.71) 0.0427	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.7532
BRAF MUTANT	77	4 (5.2)	N.A.	75	1 (1.3)	N.A.	3.88 (0.43, 34.76) 0.1907	
BRAF WILDTYPE	110	7 (6.4)	N.A.	126	3 (2.4)	N.A.	2.72 (0.70, 10.54) 0.1307	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.8646
M0/M1ANY[0]	123	8 (6.5)	N.A.	125	3 (2.4)	N.A.	2.85 (0.75, 10.75) 0.1063	
M1ANY[1]	64	3 (4.7)	N.A.	76	1 (1.3)	N.A. (51.61, N.A.)	3.73 (0.39, 35.94) 0.2220	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: Infections and Infestations. PT: Influenza

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								N.M.E.
M0	21	1 (4.8)	N.M.E.	10	0	N.M.E.	N.M.E.	
M1A	42	1 (2.4)	N.M.E.	56	2 (3.6)	N.M.E.	N.M.E.	
M1B	40	3 (7.5)	N.M.E.	46	1 (2.2)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	5 (6.3)	N.M.E.	81	1 (1.2)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9941
STAGE III	21	1 (4.8)	N.A. (12.85, N.A.)	10	0	N.E.	N.E. 0.5271	
STAGE IV	166	10 (6.0)	N.A.	190	4 (2.1)	N.A.	3.02 (0.94, 9.63) 0.0502	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								N.M.E.
CUTANEOUS ACRAL	23	2 (8.7)	N.M.E.	26	1 (3.8)	N.M.E.	N.M.E.	
CUTANEOUS NON-ACRAL	122	7 (5.7)	N.M.E.	139	2 (1.4)	N.M.E.	N.M.E.	
MUCOSAL	17	2 (11.8)	N.M.E.	20	1 (5.0)	N.M.E.	N.M.E.	
OTHER	25	0	N.M.E.	16	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.8693
<= ULN	120	8 (6.7)	N.A.	121	3 (2.5)	N.A.	2.85 (0.75, 10.77) 0.1060	
> ULN	66	3 (4.5)	N.A.	80	1 (1.3)	N.A. (51.61, N.A.)	3.64 (0.38, 35.08) 0.2312	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations. PT: Influenza

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9937
<= 2 X ULN	168	10 (6.0)	N.A.	181	4 (2.2)	N.A.	2.77 (0.87, 8.84) 0.0725	
> 2 X ULN	18	1 (5.6)	N.A.	20	0	N.E.	N.E. 0.2918	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								N.M.E.
< QUARTILE 1	35	0	N.M.E.	43	0	N.M.E.	N.M.E.	
QUARTILE 1 TO < QUARTILE 3	84	5 (6.0)	N.M.E.	89	2 (2.2)	N.M.E.	N.M.E.	
>= QUARTILE 3	46	4 (8.7)	N.M.E.	44	1 (2.3)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								N.M.E.
0	121	6 (5.0)	N.M.E.	136	1 (0.7)	N.M.E.	N.M.E.	
1	66	5 (7.6)	N.M.E.	65	3 (4.6)	N.M.E.	N.M.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.3724
CURRENT/FORMER	63	3 (4.8)	N.A.	76	2 (2.6)	N.A.	1.48 (0.25, 8.88) 0.6685	
NEVER SMOKED	116	8 (6.9)	N.A.	121	2 (1.7)	N.A.	4.67 (0.99, 22.06) 0.0320	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								>0.9999
>= 18 - < 65	102	8 (7.8)	N.A.	105	4 (3.8)	N.A. (51.61, N.A.)	2.07 (0.62, 6.89) 0.2240	
>= 65 - < 75	48	1 (2.1)	N.A.	64	0	N.E.	N.E. 0.2557	
>= 75	37	2 (5.4)	N.A.	32	0	N.E.	N.E. 0.1993	

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AGE CATEGORIZATION II								0.9931
< 65	102	8 (7.8)	N.A.	105	4 (3.8)	N.A. (51.61, N.A.)	2.07 (0.62, 6.89) 0.2240	
>= 65	85	3 (3.5)	N.A.	96	0	N.E.	N.E. 0.0589	

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SEX								N.M.E.
MALE	104	7 (6.7)	N.M.E.	116	2 (1.7)	N.M.E.	N.M.E.	
FEMALE	83	4 (4.8)	N.M.E.	85	2 (2.4)	N.M.E.	N.M.E.	

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REGION								>0.9999
USA/CANADA	17	0	N.E.	18	0	N.E.	N.E. N.E.	
EUROPE	98	0	N.E.	105	2 (1.9)	N.A.	N.E. 0.1646	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	9 (15.8)	N.A. (41.40, N.A.)	62	2 (3.2)	N.A. (51.61, N.A.)	5.52 (1.19, 25.63) 0.0141	
AUSTRALIA/NZ	15	2 (13.3)	N.A. (9.43, N.A.)	16	0	N.E.	N.E. 0.1164	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	30 (16.0)	N.A.	201	17 (8.5)	N.A.	1.95 (1.07, 3.53) 0.0253	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.9198
LAG-3 >= 1%	118	22 (18.6)	N.A.	120	12 (10.0)	N.A.	1.88 (0.93, 3.81) 0.0733	
LAG-3 < 1%	69	8 (11.6)	N.A.	81	5 (6.2)	N.A.	2.01 (0.66, 6.15) 0.2123	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.9072
LAG-3 >= 5%	35	8 (22.9)	N.A. (22.51, N.A.)	40	5 (12.5)	N.A. (46.19, N.A.)	2.35 (0.76, 7.28) 0.1284	
LAG-3 < 5%	152	22 (14.5)	N.A.	161	12 (7.5)	N.A.	1.93 (0.96, 3.91) 0.0616	

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BRAF MUTATION STATUS								0.8109
BRAF MUTANT	77	13 (16.9)	N.A. (27.63, N.A.)	75	6 (8.0)	N.A.	2.21 (0.84, 5.82) 0.0996	
BRAF WILDTYPE	110	17 (15.5)	N.A.	126	11 (8.7)	N.A.	1.82 (0.85, 3.88) 0.1182	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.8405
M0/M1ANY[0]	123	24 (19.5)	N.A.	125	13 (10.4)	N.A.	2.01 (1.02, 3.95) 0.0382	
M1ANY[1]	64	6 (9.4)	N.A.	76	4 (5.3)	N.A.	1.73 (0.49, 6.13) 0.3913	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.9180
M0	21	3 (14.3)	N.A.	10	0	N.E.	N.E. 0.2058	
M1A	42	6 (14.3)	N.A.	56	4 (7.1)	N.A.	2.18 (0.61, 7.74) 0.2156	
M1B	40	8 (20.0)	N.A. (15.90, N.A.)	46	4 (8.7)	N.A. (46.19, N.A.)	2.41 (0.72, 8.02) 0.1393	

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All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	13 (16.3)	N.A. (23.29, N.A.)	81	9 (11.1)	N.A.	1.47 (0.63, 3.45) 0.3708	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9886
STAGE III	21	3 (14.3)	N.A.	10	0	N.E.	N.E. 0.2058	
STAGE IV	166	27 (16.3)	N.A.	190	17 (8.9)	N.A.	1.88 (1.03, 3.45) 0.0381	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.2140
CUTANEOUS ACRAL	23	5 (21.7)	N.A. (11.14, N.A.)	26	1 (3.8)	N.A. (13.86, N.A.)	5.98 (0.70, 51.33) 0.0646	
CUTANEOUS NON-ACRAL	122	19 (15.6)	N.A.	139	10 (7.2)	N.A.	2.23 (1.04, 4.79) 0.0354	
MUCOSAL	17	2 (11.8)	N.A.	20	5 (25.0)	N.A. (5.98, N.A.)	0.46 (0.09, 2.40) 0.3480	
OTHER	25	4 (16.0)	N.A. (23.29, N.A.)	16	1 (6.3)	N.A.	2.19 (0.24, 19.68) 0.4728	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.6868
<= ULN	120	22 (18.3)	N.A.	121	13 (10.7)	N.A.	1.81 (0.91, 3.60) 0.0849	
> ULN	66	8 (12.1)	N.A.	80	4 (5.0)	N.A.	2.37 (0.71, 7.87) 0.1470	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9750
<= 2 X ULN	168	28 (16.7)	N.A.	181	16 (8.8)	N.A.	1.95 (1.05, 3.60) 0.0301	
> 2 X ULN	18	2 (11.1)	N.A.	20	1 (5.0)	N.A.	2.15 (0.20, 23.77) 0.5206	

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TUMOR BURDEN AT BASELINE PER BICR								0.3373
< QUARTILE 1	35	4 (11.4)	N.A.	43	5 (11.6)	N.A. (46.19, N.A.)	0.93 (0.25, 3.48) 0.9117	
QUARTILE 1 TO < QUARTILE 3	84	15 (17.9)	N.A. (23.29, N.A.)	89	9 (10.1)	N.A.	1.88 (0.82, 4.30) 0.1294	
>= QUARTILE 3	46	7 (15.2)	N.A. (27.63, N.A.)	44	1 (2.3)	N.A.	6.49 (0.80, 52.75) 0.0439	

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BASELINE ECOG PS								0.4892
0	121	20 (16.5)	N.A.	136	10 (7.4)	N.A.	2.29 (1.07, 4.89) 0.0281	
1	66	10 (15.2)	N.A.	65	7 (10.8)	N.A.	1.45 (0.55, 3.82) 0.4459	

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SMOKING STATUS								0.0964
CURRENT/FORMER	63	7 (11.1)	N.A.	76	8 (10.5)	N.A.	0.98 (0.36, 2.71) 0.9761	
NEVER SMOKED	116	22 (19.0)	N.A. (27.63, N.A.)	121	9 (7.4)	N.A.	2.91 (1.34, 6.32) 0.0048	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.3804
>= 18 - < 65	102	16 (15.7)	N.A.	105	10 (9.5)	N.A.	1.64 (0.74, 3.61) 0.2168	
>= 65 - < 75	48	6 (12.5)	N.A.	64	6 (9.4)	N.A.	1.47 (0.47, 4.59) 0.5008	
>= 75	37	8 (21.6)	N.A. (15.90, N.A.)	32	1 (3.1)	N.A.	7.40 (0.92, 59.29) 0.0268	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.5214
< 65	102	16 (15.7)	N.A.	105	10 (9.5)	N.A.	1.64 (0.74, 3.61) 0.2168	
>= 65	85	14 (16.5)	N.A.	96	7 (7.3)	N.A.	2.38 (0.96, 5.91) 0.0537	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.3031
MALE	104	18 (17.3)	N.A.	116	13 (11.2)	N.A.	1.59 (0.78, 3.25) 0.1994	
FEMALE	83	12 (14.5)	N.A.	85	4 (4.7)	N.A.	3.21 (1.04, 9.97) 0.0327	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
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SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.1523
USA/CANADA	17	4 (23.5)	N.A. (11.14, N.A.)	18	5 (27.8)	N.A. (5.98, N.A.)	0.72 (0.19, 2.73) 0.6326	
EUROPE	98	13 (13.3)	N.A. (27.63, N.A.)	105	6 (5.7)	N.A.	2.40 (0.91, 6.33) 0.0668	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	12 (21.1)	N.A.	62	4 (6.5)	N.A.	3.70 (1.19, 11.49) 0.0153	
AUSTRALIA/NZ	15	1 (6.7)	N.A. (8.21, N.A.)	16	2 (12.5)	N.A.	0.51 (0.05, 5.63) 0.5763	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	10 (5.3)	N.A.	201	22 (10.9)	N.A.	0.47 (0.22, 1.00) 0.0456	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.7174
LAG-3 >= 1%	118	7 (5.9)	N.A.	120	13 (10.8)	N.A.	0.53 (0.21, 1.34) 0.1743	
LAG-3 < 1%	69	3 (4.3)	N.A.	81	9 (11.1)	N.A.	0.39 (0.11, 1.44) 0.1427	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.7534
LAG-3 >= 5%	35	2 (5.7)	N.A.	40	4 (10.0)	N.A.	0.60 (0.11, 3.28) 0.5499	
LAG-3 < 5%	152	8 (5.3)	N.A.	161	18 (11.2)	N.A.	0.45 (0.19, 1.03) 0.0512	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.9777
BRAF MUTANT	77	5 (6.5)	N.A.	75	10 (13.3)	N.A.	0.44 (0.15, 1.30) 0.1277	
BRAF WILDTYPE	110	5 (4.5)	N.A.	126	12 (9.5)	N.A.	0.47 (0.16, 1.33) 0.1426	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.1743
M0/M1ANY[0]	123	9 (7.3)	N.A.	125	14 (11.2)	N.A.	0.66 (0.28, 1.52) 0.3212	
M1ANY[1]	64	1 (1.6)	N.A.	76	8 (10.5)	N.A. (36.67, N.A.)	0.14 (0.02, 1.15) 0.0331	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.5679
M0	21	0	N.E.	10	0	N.E.	N.E. N.E.	
M1A	42	3 (7.1)	N.A.	56	9 (16.1)	N.A. (38.60, N.A.)	0.41 (0.11, 1.53) 0.1719	
M1B	40	3 (7.5)	N.A.	46	2 (4.3)	N.A.	1.74 (0.29, 10.40) 0.5398	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
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SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	4 (5.0)	N.A.	81	10 (12.3)	N.A. (36.67, N.A.)	0.40 (0.12, 1.26) 0.1044	

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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9998
STAGE III	21	0	N.E.	10	0	N.E.	N.E. N.E.	
STAGE IV	166	10 (6.0)	N.A.	190	22 (11.6)	N.A.	0.51 (0.24, 1.08) 0.0750	

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HISTOLOGY (DISEASE SUBTYPE)								>0.9999
CUTANEOUS ACRAL	23	0	N.E.	26	4 (15.4)	32.39 (32.39, N.A.)	N.E. 0.0612	
CUTANEOUS NON-ACRAL	122	8 (6.6)	N.A.	139	15 (10.8)	N.A.	0.59 (0.25, 1.39) 0.2243	
MUCOSAL	17	0	N.E.	20	3 (15.0)	36.67 (36.67, N.A.)	N.E. 0.0985	
OTHER	25	2 (8.0)	N.A. (15.41, N.A.)	16	0	N.E.	N.E. 0.3393	

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Significant SOC/PT
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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.1766
<= ULN	120	9 (7.5)	N.A.	121	14 (11.6)	N.A.	0.65 (0.28, 1.51) 0.3182	
> ULN	66	1 (1.5)	N.A.	80	8 (10.0)	N.A. (36.67, N.A.)	0.14 (0.02, 1.15) 0.0332	

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SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9900
<= 2 X ULN	168	10 (6.0)	N.A.	181	20 (11.0)	N.A.	0.53 (0.25, 1.13) 0.0937	
> 2 X ULN	18	0	N.E.	20	2 (10.0)	N.A.	N.E. 0.1881	

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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.6058
< QUARTILE 1	35	4 (11.4)	N.A.	43	7 (16.3)	N.A. (32.39, N.A.)	0.67 (0.20, 2.30) 0.5228	
QUARTILE 1 TO < QUARTILE 3	84	1 (1.2)	N.A.	89	5 (5.6)	N.A.	0.21 (0.02, 1.80) 0.1165	
>= QUARTILE 3	46	2 (4.3)	N.A.	44	6 (13.6)	N.A. (22.05, N.A.)	0.32 (0.06, 1.57) 0.1380	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.8008
0	121	7 (5.8)	N.A.	136	15 (11.0)	N.A.	0.51 (0.21, 1.24) 0.1285	
1	66	3 (4.5)	N.A.	65	7 (10.8)	N.A. (36.67, N.A.)	0.42 (0.11, 1.61) 0.1892	

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SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.6899
CURRENT/FORMER	63	4 (6.3)	N.A.	76	10 (13.2)	N.A.	0.43 (0.14, 1.38) 0.1462	
NEVER SMOKED	116	6 (5.2)	N.A.	121	12 (9.9)	N.A.	0.57 (0.21, 1.53) 0.2598	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.2385
>= 18 - < 65	102	3 (2.9)	N.A.	105	12 (11.4)	N.A.	0.24 (0.07, 0.85) 0.0165	
>= 65 - < 75	48	5 (10.4)	N.A.	64	7 (10.9)	N.A. (38.60, N.A.)	1.05 (0.33, 3.32) 0.9323	
>= 75	37	2 (5.4)	N.A. (17.51, N.A.)	32	3 (9.4)	N.A.	0.54 (0.09, 3.27) 0.4962	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.1333
< 65	102	3 (2.9)	N.A.	105	12 (11.4)	N.A.	0.24 (0.07, 0.85) 0.0165	
>= 65	85	7 (8.2)	N.A.	96	10 (10.4)	N.A.	0.83 (0.31, 2.18) 0.7011	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.2350
MALE	104	6 (5.8)	N.A.	116	18 (15.5)	N.A.	0.36 (0.14, 0.91) 0.0238	
FEMALE	83	4 (4.8)	N.A.	85	4 (4.7)	N.A.	0.98 (0.24, 3.91) 0.9733	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.2173
USA/CANADA	17	1 (5.9)	N.A.	18	3 (16.7)	N.A.	0.33 (0.03, 3.19) 0.3158	
EUROPE	98	5 (5.1)	N.A.	105	4 (3.8)	N.A.	1.28 (0.34, 4.78) 0.7091	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	3 (5.3)	N.A.	62	14 (22.6)	N.A. (32.39, N.A.)	0.23 (0.07, 0.81) 0.0120	
AUSTRALIA/NZ	15	1 (6.7)	N.A.	16	1 (6.3)	N.A. (38.60, N.A.)	>99.99 (<0.01, N.A.) 0.3173	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	54 (28.9)	N.A. (43.86, N.A.)	201	38 (18.9)	N.A.	1.54 (1.01, 2.33) 0.0408	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.4487
LAG-3 >= 1%	118	33 (28.0)	N.A. (49.87, N.A.)	120	24 (20.0)	N.A.	1.36 (0.80, 2.30) 0.2482	
LAG-3 < 1%	69	21 (30.4)	43.86 (9.20, N.A.)	81	14 (17.3)	N.A.	1.95 (0.99, 3.84) 0.0493	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.9407
LAG-3 >= 5%	35	11 (31.4)	N.A. (8.31, N.A.)	40	8 (20.0)	N.A.	1.58 (0.63, 3.93) 0.3230	
LAG-3 < 5%	152	43 (28.3)	N.A. (43.86, N.A.)	161	30 (18.6)	N.A.	1.52 (0.95, 2.42) 0.0777	

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Significant SOC/PT
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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.8046
BRAF MUTANT	77	17 (22.1)	N.A.	75	10 (13.3)	N.A.	1.65 (0.76, 3.61) 0.2030	
BRAF WILDTYPE	110	37 (33.6)	49.87 (12.91, N.A.)	126	28 (22.2)	N.A.	1.50 (0.92, 2.45) 0.1021	

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SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.6727
M0/M1ANY[0]	123	39 (31.7)	N.A. (43.86, N.A.)	125	28 (22.4)	N.A.	1.45 (0.89, 2.35) 0.1332	
M1ANY[1]	64	15 (23.4)	N.A. (12.91, N.A.)	76	10 (13.2)	N.A.	1.76 (0.79, 3.91) 0.1618	

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SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.5636
M0	21	7 (33.3)	49.87 (5.59, N.A.)	10	0	N.E.	N.E. 0.0511	
M1A	42	13 (31.0)	43.86 (11.53, N.A.)	56	8 (14.3)	N.A.	2.29 (0.95, 5.53) 0.0577	
M1B	40	12 (30.0)	N.A. (9.20, N.A.)	46	13 (28.3)	N.A.	1.03 (0.47, 2.26) 0.9346	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	21 (26.3)	N.A.	81	17 (21.0)	N.A.	1.18 (0.62, 2.23) 0.6182	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
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SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9827
STAGE III	21	7 (33.3)	49.87 (5.59, N.A.)	10	0	N.E.	N.E. 0.0511	
STAGE IV	166	47 (28.3)	N.A. (43.86, N.A.)	190	38 (20.0)	N.A.	1.41 (0.92, 2.17) 0.1102	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.3131
CUTANEOUS ACRAL	23	8 (34.8)	18.33 (3.22, N.A.)	26	11 (42.3)	N.A. (4.11, N.A.)	0.97 (0.39, 2.43) 0.9546	
CUTANEOUS NON-ACRAL	122	37 (30.3)	N.A. (43.86, N.A.)	139	20 (14.4)	N.A.	2.12 (1.23, 3.65) 0.0056	
MUCOSAL	17	5 (29.4)	N.A. (5.75, N.A.)	20	6 (30.0)	N.A. (4.60, N.A.)	0.76 (0.23, 2.51) 0.6480	
OTHER	25	4 (16.0)	N.A. (10.12, N.A.)	16	1 (6.3)	N.A.	2.17 (0.24, 19.59) 0.4787	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
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SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.6523
<= ULN	120	39 (32.5)	N.A. (43.86, N.A.)	121	28 (23.1)	N.A.	1.44 (0.89, 2.34) 0.1383	
> ULN	66	15 (22.7)	N.A. (12.91, N.A.)	80	10 (12.5)	N.A.	1.78 (0.80, 3.95) 0.1536	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9640
<= 2 X ULN	168	50 (29.8)	N.A. (43.86, N.A.)	181	35 (19.3)	N.A.	1.54 (1.00, 2.38) 0.0471	
> 2 X ULN	18	4 (22.2)	N.A. (5.75, N.A.)	20	3 (15.0)	N.A. (3.75, N.A.)	1.33 (0.30, 5.99) 0.7046	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.4463
< QUARTILE 1	35	12 (34.3)	49.87 (11.43, N.A.)	43	9 (20.9)	N.A.	1.65 (0.69, 3.93) 0.2518	
QUARTILE 1 TO < QUARTILE 3	84	31 (36.9)	43.86 (9.26, N.A.)	89	15 (16.9)	N.A.	2.46 (1.33, 4.56) 0.0031	
>= QUARTILE 3	46	9 (19.6)	N.A. (12.91, N.A.)	44	6 (13.6)	N.A.	1.19 (0.42, 3.35) 0.7366	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.5736
0	121	39 (32.2)	N.A. (43.86, N.A.)	136	27 (19.9)	N.A.	1.66 (1.02, 2.72) 0.0401	
1	66	15 (22.7)	N.A. (12.91, N.A.)	65	11 (16.9)	N.A.	1.29 (0.59, 2.80) 0.5248	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.6942
CURRENT/FORMER	63	20 (31.7)	N.A. (12.91, N.A.)	76	14 (18.4)	N.A.	1.66 (0.84, 3.30) 0.1398	
NEVER SMOKED	116	32 (27.6)	N.A. (43.86, N.A.)	121	24 (19.8)	N.A.	1.43 (0.84, 2.42) 0.1864	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.0586
>= 18 - < 65	102	29 (28.4)	N.A. (43.86, N.A.)	105	28 (26.7)	N.A.	1.01 (0.60, 1.70) 0.9622	
>= 65 - < 75	48	13 (27.1)	N.A. (11.43, N.A.)	64	8 (12.5)	N.A.	2.43 (1.01, 5.89) 0.0415	
>= 75	37	12 (32.4)	N.A. (6.47, N.A.)	32	2 (6.3)	N.A.	4.86 (1.09, 21.71) 0.0220	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.0197*
< 65	102	29 (28.4)	N.A. (43.86, N.A.)	105	28 (26.7)	N.A.	1.01 (0.60, 1.70) 0.9622	
>= 65	85	25 (29.4)	N.A. (18.33, N.A.)	96	10 (10.4)	N.A.	2.97 (1.42, 6.18) 0.0023	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.2818
MALE	104	27 (26.0)	N.A. (18.33, N.A.)	116	16 (13.8)	N.A.	1.95 (1.05, 3.62) 0.0312	
FEMALE	83	27 (32.5)	N.A. (43.86, N.A.)	85	22 (25.9)	N.A.	1.24 (0.70, 2.17) 0.4562	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
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SOC: Endocrine Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.2562
USA/CANADA	17	4 (23.5)	N.A. (5.55, N.A.)	18	2 (11.1)	N.A.	2.02 (0.37, 11.19) 0.4103	
EUROPE	98	29 (29.6)	49.87 (12.91, N.A.)	105	15 (14.3)	N.A.	2.14 (1.15, 4.00) 0.0137	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	18 (31.6)	N.A. (7.66, N.A.)	62	15 (24.2)	N.A.	1.38 (0.70, 2.75) 0.3513	
AUSTRALIA/NZ	15	3 (20.0)	N.A. (3.22, N.A.)	16	6 (37.5)	N.A. (4.11, N.A.)	0.48 (0.12, 1.91) 0.2788	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	13 (7.0)	N.A.	201	5 (2.5)	N.A.	2.81 (1.00, 7.89) 0.0401	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.9917
LAG-3 >= 1%	118	6 (5.1)	N.A.	120	0	N.E.	N.E. 0.0149	
LAG-3 < 1%	69	7 (10.1)	N.A.	81	5 (6.2)	N.A.	1.69 (0.53, 5.32) 0.3661	

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Significant SOC/PT
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SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.9998
LAG-3 >= 5%	35	0	N.E.	40	0	N.E.	N.E. N.E.	
LAG-3 < 5%	152	13 (8.6)	N.A.	161	5 (3.1)	N.A.	2.75 (0.98, 7.71) 0.0454	

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SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.9040
BRAF MUTANT	77	8 (10.4)	N.A. (51.09, N.A.)	75	3 (4.0)	N.A.	2.53 (0.67, 9.55) 0.1575	
BRAF WILDTYPE	110	5 (4.5)	N.A.	126	2 (1.6)	N.A.	2.92 (0.57, 15.07) 0.1792	

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All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.7992
M0/M1ANY[0]	123	10 (8.1)	N.A.	125	4 (3.2)	N.A.	2.57 (0.81, 8.20) 0.0977	
M1ANY[1]	64	3 (4.7)	N.A.	76	1 (1.3)	N.A.	3.57 (0.37, 34.30) 0.2399	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								N.M.E.
M0	21	0	N.M.E.	10	0	N.M.E.	N.M.E.	
M1A	42	5 (11.9)	N.M.E.	56	1 (1.8)	N.M.E.	N.M.E.	
M1B	40	4 (10.0)	N.M.E.	46	2 (4.3)	N.M.E.	N.M.E.	

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SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	4 (5.0)	N.M.E.	81	2 (2.5)	N.M.E.	N.M.E.	

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Significant SOC/PT
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SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9997
STAGE III	21	0	N.E.	10	0	N.E.	N.E. N.E.	
STAGE IV	166	13 (7.8)	N.A.	190	5 (2.6)	N.A.	3.03 (1.08, 8.50) 0.0267	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								>0.9999
CUTANEOUS ACRAL	23	0	N.E.	26	1 (3.8)	N.A.	N.E. 0.3469	
CUTANEOUS NON-ACRAL	122	10 (8.2)	N.A.	139	4 (2.9)	N.A.	2.82 (0.88, 8.99) 0.0675	
MUCOSAL	17	2 (11.8)	N.A.	20	0	N.E.	N.E. 0.1134	
OTHER	25	1 (4.0)	N.A.	16	0	N.E.	N.E. 0.4237	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.7880
<= ULN	120	10 (8.3)	N.A.	121	4 (3.3)	N.A.	2.56 (0.80, 8.16) 0.0998	
> ULN	66	3 (4.5)	N.A.	80	1 (1.3)	N.A.	3.64 (0.38, 35.03) 0.2311	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9918
<= 2 X ULN	168	11 (6.5)	N.A.	181	5 (2.8)	N.A.	2.36 (0.82, 6.79) 0.1012	
> 2 X ULN	18	2 (11.1)	N.A.	20	0	N.E.	N.E. 0.1274	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								N.M.E.
< QUARTILE 1	35	4 (11.4)	N.M.E.	43	1 (2.3)	N.M.E.	N.M.E.	
QUARTILE 1 TO < QUARTILE 3	84	7 (8.3)	N.M.E.	89	2 (2.2)	N.M.E.	N.M.E.	
>= QUARTILE 3	46	1 (2.2)	N.M.E.	44	2 (4.5)	N.M.E.	N.M.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.9895
0	121	7 (5.8)	N.A.	136	5 (3.7)	N.A.	1.55 (0.49, 4.87) 0.4530	
1	66	6 (9.1)	N.A.	65	0	N.E.	N.E. 0.0139	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	63	5 (7.9)	N.M.E.	76	3 (3.9)	N.M.E.	N.M.E.	
NEVER SMOKED	116	6 (5.2)	N.M.E.	121	2 (1.7)	N.M.E.	N.M.E.	

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AGE CATEGORIZATION I								0.7805
>= 18 - < 65	102	8 (7.8)	N.A.	105	2 (1.9)	N.A.	4.02 (0.85, 18.98) 0.0563	
>= 65 - < 75	48	3 (6.3)	N.A.	64	2 (3.1)	N.A.	1.94 (0.32, 11.58) 0.4615	
>= 75	37	2 (5.4)	N.A.	32	1 (3.1)	N.A.	1.68 (0.15, 18.51) 0.6698	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.4811
< 65	102	8 (7.8)	N.A.	105	2 (1.9)	N.A.	4.02 (0.85, 18.98) 0.0563	
>= 65	85	5 (5.9)	N.A.	96	3 (3.1)	N.A.	1.85 (0.44, 7.75) 0.3920	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.2380
MALE	104	6 (5.8)	N.A.	116	4 (3.4)	N.A.	1.64 (0.46, 5.80) 0.4401	
FEMALE	83	7 (8.4)	N.A.	85	1 (1.2)	N.A.	7.28 (0.90, 59.20) 0.0295	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								N.M.E.
USA/CANADA	17	3 (17.6)	N.M.E.	18	0	N.M.E.	N.M.E.	
EUROPE	98	4 (4.1)	N.M.E.	105	2 (1.9)	N.M.E.	N.M.E.	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	5 (8.8)	N.M.E.	62	3 (4.8)	N.M.E.	N.M.E.	
AUSTRALIA/NZ	15	1 (6.7)	N.M.E.	16	0	N.M.E.	N.M.E.	

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(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	33 (17.6)	N.A.	201	19 (9.5)	N.A.	1.97 (1.12, 3.47) 0.0161	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.1599
LAG-3 >= 1%	118	21 (17.8)	N.A.	120	15 (12.5)	N.A. (60.19, N.A.)	1.48 (0.76, 2.87) 0.2470	
LAG-3 < 1%	69	12 (17.4)	N.A. (41.40, N.A.)	81	4 (4.9)	N.A.	3.90 (1.26, 12.12) 0.0110	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.0215*
LAG-3 >= 5%	35	5 (14.3)	N.A. (33.51, N.A.)	40	9 (22.5)	N.A. (39.59, N.A.)	0.70 (0.23, 2.09) 0.5165	
LAG-3 < 5%	152	28 (18.4)	N.A.	161	10 (6.2)	N.A.	3.12 (1.51, 6.42) 0.0011	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.8402
BRAF MUTANT	77	19 (24.7)	N.A. (16.79, N.A.)	75	10 (13.3)	N.A. (60.19, N.A.)	1.99 (0.92, 4.28) 0.0733	
BRAF WILDTYPE	110	14 (12.7)	N.A.	126	9 (7.1)	N.A.	1.82 (0.79, 4.21) 0.1548	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.0367*
M0/M1ANY[0]	123	28 (22.8)	N.A.	125	11 (8.8)	N.A.	2.89 (1.44, 5.80) 0.0018	
M1ANY[1]	64	5 (7.8)	N.A. (33.51, N.A.)	76	8 (10.5)	N.A. (39.59, N.A.)	0.74 (0.24, 2.27) 0.5977	

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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.7757
M0	21	3 (14.3)	N.A.	10	0	N.E.	N.E. 0.2160	
M1A	42	12 (28.6)	N.A. (14.03, N.A.)	56	6 (10.7)	N.A. (60.19, N.A.)	2.98 (1.12, 7.97) 0.0219	
M1B	40	7 (17.5)	N.A.	46	5 (10.9)	N.A. (37.59, N.A.)	1.72 (0.54, 5.42) 0.3541	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	11 (13.8)	N.A. (33.51, N.A.)	81	8 (9.9)	N.A.	1.42 (0.57, 3.55) 0.4494	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9881
STAGE III	21	3 (14.3)	N.A.	10	0	N.E.	N.E. 0.2160	
STAGE IV	166	30 (18.1)	N.A.	190	19 (10.0)	N.A.	1.93 (1.09, 3.43) 0.0225	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.8651
CUTANEOUS ACRAL	23	3 (13.0)	N.A.	26	3 (11.5)	N.A.	1.25 (0.25, 6.18) 0.7878	
CUTANEOUS NON-ACRAL	122	24 (19.7)	N.A.	139	13 (9.4)	N.A. (60.19, N.A.)	2.24 (1.14, 4.40) 0.0164	
MUCOSAL	17	2 (11.8)	N.A. (8.80, N.A.)	20	2 (10.0)	39.59 (39.59, N.A.)	1.24 (0.17, 8.88) 0.8317	
OTHER	25	4 (16.0)	N.A. (33.51, N.A.)	16	1 (6.3)	N.A.	1.66 (0.17, 16.17) 0.6574	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.0733
<= ULN	120	27 (22.5)	N.A.	121	11 (9.1)	N.A. (60.19, N.A.)	2.78 (1.38, 5.60) 0.0029	
> ULN	66	6 (9.1)	N.A. (33.51, N.A.)	80	8 (10.0)	N.A. (39.59, N.A.)	0.90 (0.31, 2.59) 0.8408	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.6270
<= 2 X ULN	168	32 (19.0)	N.A.	181	18 (9.9)	N.A.	2.04 (1.14, 3.63) 0.0136	
> 2 X ULN	18	1 (5.6)	N.A. (8.80, N.A.)	20	1 (5.0)	N.A.	0.86 (0.05, 14.07) 0.9161	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.9686
< QUARTILE 1	35	7 (20.0)	N.A.	43	4 (9.3)	N.A. (37.59, N.A.)	2.38 (0.70, 8.16) 0.1531	
QUARTILE 1 TO < QUARTILE 3	84	16 (19.0)	N.A. (41.40, N.A.)	89	9 (10.1)	N.A. (60.19, N.A.)	2.22 (0.97, 5.10) 0.0533	
>= QUARTILE 3	46	4 (8.7)	N.A. (33.51, N.A.)	44	2 (4.5)	N.A. (39.59, N.A.)	1.89 (0.34, 10.45) 0.4571	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.6441
0	121	20 (16.5)	N.A.	136	13 (9.6)	N.A. (60.19, N.A.)	1.79 (0.89, 3.60) 0.0972	
1	66	13 (19.7)	N.A. (33.51, N.A.)	65	6 (9.2)	N.A.	2.25 (0.85, 5.92) 0.0921	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.8561
CURRENT/FORMER	63	14 (22.2)	N.A.	76	8 (10.5)	N.A. (60.19, N.A.)	2.05 (0.86, 4.89) 0.0977	
NEVER SMOKED	116	16 (13.8)	N.A. (41.40, N.A.)	121	10 (8.3)	N.A.	1.89 (0.86, 4.17) 0.1092	

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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.3280
>= 18 - < 65	102	14 (13.7)	N.A.	105	11 (10.5)	N.A. (60.19, N.A.)	1.31 (0.59, 2.88) 0.5065	
>= 65 - < 75	48	10 (20.8)	N.A. (14.69, N.A.)	64	6 (9.4)	N.A.	2.69 (0.97, 7.45) 0.0482	
>= 75	37	9 (24.3)	N.A. (14.03, N.A.)	32	2 (6.3)	N.A.	3.82 (0.82, 17.69) 0.0656	

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(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.1428
< 65	102	14 (13.7)	N.A.	105	11 (10.5)	N.A. (60.19, N.A.)	1.31 (0.59, 2.88) 0.5065	
>= 65	85	19 (22.4)	N.A. (33.51, N.A.)	96	8 (8.3)	N.A.	3.07 (1.34, 7.04) 0.0054	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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SOC: Eye Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.2696
MALE	104	18 (17.3)	N.A.	116	8 (6.9)	N.A.	2.68 (1.17, 6.17) 0.0156	
FEMALE	83	15 (18.1)	N.A. (33.51, N.A.)	85	11 (12.9)	N.A. (39.59, N.A.)	1.49 (0.68, 3.25) 0.3154	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.7537
USA/CANADA	17	6 (35.3)	N.A. (3.81, N.A.)	18	3 (16.7)	N.A.	1.96 (0.49, 7.83) 0.3267	
EUROPE	98	13 (13.3)	N.A. (41.40, N.A.)	105	7 (6.7)	N.A.	2.04 (0.81, 5.11) 0.1213	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	13 (22.8)	N.A. (14.03, N.A.)	62	7 (11.3)	N.A. (39.59, N.A.)	2.42 (0.96, 6.10) 0.0525	
AUSTRALIA/NZ	15	1 (6.7)	N.A.	16	2 (12.5)	N.A.	0.50 (0.05, 5.51) 0.5627	

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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	10 (5.3)	N.A.	201	3 (1.5)	N.A.	3.61 (0.99, 13.12) 0.0370	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.7234
LAG-3 >= 1%	118	8 (6.8)	N.A.	120	2 (1.7)	N.A.	4.04 (0.86, 19.04) 0.0558	
LAG-3 < 1%	69	2 (2.9)	N.A.	81	1 (1.2)	N.A.	2.68 (0.24, 29.71) 0.4025	

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Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.7431
LAG-3 >= 5%	35	2 (5.7)	N.A. (33.77, N.A.)	40	1 (2.5)	N.A.	2.68 (0.24, 29.69) 0.4038	
LAG-3 < 5%	152	8 (5.3)	N.A.	161	2 (1.2)	N.A.	4.14 (0.88, 19.49) 0.0511	

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Significant SOC/PT
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SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								N.M.E.
BRAF MUTANT	77	7 (9.1)	N.M.E.	75	1 (1.3)	N.M.E.	N.M.E.	
BRAF WILDTYPE	110	3 (2.7)	N.M.E.	126	2 (1.6)	N.M.E.	N.M.E.	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								N.M.E.
M0/M1ANY[0]	123	7 (5.7)	N.M.E.	125	0	N.M.E.	N.M.E.	
M1ANY[1]	64	3 (4.7)	N.M.E.	76	3 (3.9)	N.M.E.	N.M.E.	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								N.M.E.
M0	21	1 (4.8)	N.M.E.	10	0	N.M.E.	N.M.E.	
M1A	42	3 (7.1)	N.M.E.	56	2 (3.6)	N.M.E.	N.M.E.	
M1B	40	1 (2.5)	N.M.E.	46	1 (2.2)	N.M.E.	N.M.E.	

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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	5 (6.3)	N.M.E.	81	0	N.M.E.	N.M.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9947
STAGE III	21	1 (4.8)	N.A.	10	0	N.E.	N.E. 0.4902	
STAGE IV	166	9 (5.4)	N.A.	190	3 (1.6)	N.A.	3.54 (0.96, 13.09) 0.0429	

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HISTOLOGY (DISEASE SUBTYPE)								0.8690
CUTANEOUS ACRAL	23	1 (4.3)	N.A.	26	1 (3.8)	N.A.	1.16 (0.07, 18.55) 0.9163	
CUTANEOUS NON-ACRAL	122	8 (6.6)	N.A.	139	2 (1.4)	N.A.	4.65 (0.99, 21.93) 0.0322	
MUCOSAL	17	0	N.E.	20	0	N.E.	N.E. N.E.	
OTHER	25	1 (4.0)	N.A. (33.77, N.A.)	16	0	N.E.	N.E. N.A.	

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BASELINE LDH I								N.M.E.
<= ULN	120	6 (5.0)	N.M.E.	121	0	N.M.E.	N.M.E.	
> ULN	66	4 (6.1)	N.M.E.	80	3 (3.8)	N.M.E.	N.M.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9996
<= 2 X ULN	168	10 (6.0)	N.A.	181	3 (1.7)	N.A.	3.65 (1.01, 13.28) 0.0350	
> 2 X ULN	18	0	N.E.	20	0	N.E.	N.E. N.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								N.M.E.
< QUARTILE 1	35	2 (5.7)	N.M.E.	43	1 (2.3)	N.M.E.	N.M.E.	
QUARTILE 1 TO < QUARTILE 3	84	4 (4.8)	N.M.E.	89	0	N.M.E.	N.M.E.	
>= QUARTILE 3	46	2 (4.3)	N.M.E.	44	0	N.M.E.	N.M.E.	

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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								N.M.E.
0	121	5 (4.1)	N.M.E.	136	2 (1.5)	N.M.E.	N.M.E.	
1	66	5 (7.6)	N.M.E.	65	1 (1.5)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	63	7 (11.1)	N.M.E.	76	1 (1.3)	N.M.E.	N.M.E.	
NEVER SMOKED	116	3 (2.6)	N.M.E.	121	2 (1.7)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								N.M.E.
>= 18 - < 65	102	3 (2.9)	N.M.E.	105	2 (1.9)	N.M.E.	N.M.E.	
>= 65 - < 75	48	3 (6.3)	N.M.E.	64	1 (1.6)	N.M.E.	N.M.E.	
>= 75	37	4 (10.8)	N.M.E.	32	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								N.M.E.
< 65	102	3 (2.9)	N.M.E.	105	2 (1.9)	N.M.E.	N.M.E.	
>= 65	85	7 (8.2)	N.M.E.	96	1 (1.0)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								N.M.E.
MALE	104	5 (4.8)	N.M.E.	116	1 (0.9)	N.M.E.	N.M.E.	
FEMALE	83	5 (6.0)	N.M.E.	85	2 (2.4)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.1
Adverse Events: Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders. PT: Vision Blurred

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								N.M.E.
USA/CANADA	17	3 (17.6)	N.M.E.	18	0	N.M.E.	N.M.E.	
EUROPE	98	2 (2.0)	N.M.E.	105	2 (1.9)	N.M.E.	N.M.E.	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	5 (8.8)	N.M.E.	62	1 (1.6)	N.M.E.	N.M.E.	
AUSTRALIA/NZ	15	0	N.M.E.	16	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Anhang 4-G 7.4.2.2: Schwere UE (CTCAE-Grad ≥ 3) auf Ebene der SOC und PT

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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	26 (13.9)	N.A. (70.77, N.A.)	201	48 (23.9)	N.A. (47.90, N.A.)	0.57 (0.35, 0.92) 0.0197	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.0897
LAG-3 >= 1%	118	11 (9.3)	N.A. (70.77, N.A.)	120	28 (23.3)	N.A. (41.13, N.A.)	0.39 (0.19, 0.78) 0.0059	
LAG-3 < 1%	69	15 (21.7)	N.A.	81	20 (24.7)	N.A. (32.69, N.A.)	0.89 (0.46, 1.74) 0.7379	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.3160
LAG-3 >= 5%	35	2 (5.7)	N.A.	40	9 (22.5)	N.A. (41.13, N.A.)	0.28 (0.06, 1.30) 0.0827	
LAG-3 < 5%	152	24 (15.8)	N.A. (70.77, N.A.)	161	39 (24.2)	N.A. (36.24, N.A.)	0.63 (0.38, 1.04) 0.0676	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.6112
BRAF MUTANT	77	6 (7.8)	N.A.	75	12 (16.0)	N.A.	0.48 (0.18, 1.29) 0.1381	
BRAF WILDTYPE	110	20 (18.2)	70.77 (70.77, N.A.)	126	36 (28.6)	N.A. (36.24, N.A.)	0.63 (0.37, 1.09) 0.0962	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.0067*
M0/M1ANY[0]	123	5 (4.1)	N.A. (70.77, N.A.)	125	24 (19.2)	N.A. (47.90, N.A.)	0.21 (0.08, 0.56) 0.0006	
M1ANY[1]	64	21 (32.8)	N.A.	76	24 (31.6)	N.A. (13.24, N.A.)	0.99 (0.55, 1.79) 0.9834	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								0.7892
M0	21	0	N.E.	10	2 (20.0)	N.A. (4.21, N.A.)	N.E. 0.0400	
M1A	42	3 (7.1)	N.A.	56	11 (19.6)	N.A. (32.69, N.A.)	0.36 (0.10, 1.30) 0.1055	
M1B	40	4 (10.0)	N.A.	46	9 (19.6)	47.90 (22.77, N.A.)	0.51 (0.16, 1.66) 0.2527	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	18 (22.5)	70.77 (70.77, N.A.)	81	24 (29.6)	N.A. (36.24, N.A.)	0.72 (0.39, 1.32) 0.2849	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9796
STAGE III	21	0	N.E.	10	2 (20.0)	N.A. (4.21, N.A.)	N.E. 0.0400	
STAGE IV	166	26 (15.7)	N.A. (70.77, N.A.)	190	45 (23.7)	N.A. (41.13, N.A.)	0.66 (0.41, 1.07) 0.0871	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								0.1096
CUTANEOUS ACRAL	23	7 (30.4)	N.A. (4.30, N.A.)	26	6 (23.1)	N.A. (8.61, N.A.)	1.51 (0.51, 4.50) 0.4559	
CUTANEOUS NON-ACRAL	122	12 (9.8)	N.A.	139	30 (21.6)	N.A. (47.90, N.A.)	0.44 (0.22, 0.86) 0.0130	
MUCOSAL	17	4 (23.5)	70.77 (N.A., N.A.)	20	5 (25.0)	N.A. (22.77, N.A.)	0.96 (0.26, 3.59) 0.9523	
OTHER	25	3 (12.0)	N.A.	16	7 (43.8)	N.A. (2.86, N.A.)	0.24 (0.06, 0.95) 0.0268	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.0201*
<= ULN	120	5 (4.2)	N.A. (70.77, N.A.)	121	22 (18.2)	N.A. (47.90, N.A.)	0.23 (0.09, 0.62) 0.0014	
> ULN	66	20 (30.3)	N.A.	80	26 (32.5)	N.A. (12.25, N.A.)	0.88 (0.49, 1.58) 0.6674	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.0039*
<= 2 X ULN	168	14 (8.3)	N.A. (70.77, N.A.)	181	42 (23.2)	N.A. (47.90, N.A.)	0.35 (0.19, 0.65) 0.0004	
> 2 X ULN	18	11 (61.1)	3.61 (2.20, N.A.)	20	6 (30.0)	N.A. (2.56, N.A.)	2.11 (0.78, 5.72) 0.1326	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								0.6839
< QUARTILE 1	35	0	N.E.	43	6 (14.0)	N.A. (47.90, N.A.)	N.E. 0.0182	
QUARTILE 1 TO < QUARTILE 3	84	9 (10.7)	N.A.	89	22 (24.7)	N.A. (36.24, N.A.)	0.48 (0.22, 1.04) 0.0556	
>= QUARTILE 3	46	14 (30.4)	70.77 (70.77, N.A.)	44	15 (34.1)	N.A. (4.57, N.A.)	0.75 (0.36, 1.55) 0.4341	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.4819
0	121	11 (9.1)	N.A. (70.77, N.A.)	136	26 (19.1)	N.A. (47.90, N.A.)	0.47 (0.23, 0.95) 0.0309	
1	66	15 (22.7)	N.A.	65	22 (33.8)	N.A. (15.80, N.A.)	0.66 (0.34, 1.26) 0.2038	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								0.3459
CURRENT/FORMER	63	8 (12.7)	N.A.	76	20 (26.3)	N.A. (36.24, N.A.)	0.44 (0.19, 0.99) 0.0418	
NEVER SMOKED	116	18 (15.5)	N.A. (70.77, N.A.)	121	27 (22.3)	N.A. (41.13, N.A.)	0.72 (0.40, 1.31) 0.2803	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								0.0707
>= 18 - < 65	102	18 (17.6)	N.A. (70.77, N.A.)	105	21 (20.0)	N.A. (41.13, N.A.)	0.88 (0.47, 1.66) 0.6941	
>= 65 - < 75	48	7 (14.6)	N.A.	64	17 (26.6)	N.A. (32.69, N.A.)	0.57 (0.24, 1.39) 0.2103	
>= 75	37	1 (2.7)	N.A.	32	10 (31.3)	N.A. (7.95, N.A.)	0.08 (<0.01, 0.59) 0.0013	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.0546
< 65	102	18 (17.6)	N.A. (70.77, N.A.)	105	21 (20.0)	N.A. (41.13, N.A.)	0.88 (0.47, 1.66) 0.6941	
>= 65	85	8 (9.4)	N.A.	96	27 (28.1)	N.A. (36.24, N.A.)	0.33 (0.15, 0.72) 0.0034	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.1538
MALE	104	17 (16.3)	N.A. (70.77, N.A.)	116	25 (21.6)	N.A.	0.78 (0.42, 1.44) 0.4195	
FEMALE	83	9 (10.8)	N.A.	85	23 (27.1)	N.A. (36.86, N.A.)	0.38 (0.17, 0.82) 0.0102	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								0.1741
USA/CANADA	17	1 (5.9)	N.A.	18	3 (16.7)	N.A.	0.34 (0.04, 3.30) 0.3317	
EUROPE	98	8 (8.2)	N.A. (70.77, N.A.)	105	24 (22.9)	N.A. (41.13, N.A.)	0.34 (0.15, 0.75) 0.0054	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	15 (26.3)	N.A.	62	16 (25.8)	N.A. (36.24, N.A.)	1.03 (0.51, 2.09) 0.9269	
AUSTRALIA/NZ	15	2 (13.3)	N.A.	16	5 (31.3)	N.A. (6.87, N.A.)	0.43 (0.08, 2.24) 0.3047	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	10 (5.3)	N.A.	201	2 (1.0)	N.A.	5.33 (1.17, 24.32) 0.0155	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								N.M.E.
LAG-3 >= 1%	118	6 (5.1)	N.M.E.	120	1 (0.8)	N.M.E.	N.M.E.	
LAG-3 < 1%	69	4 (5.8)	N.M.E.	81	1 (1.2)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.9930
LAG-3 >= 5%	35	2 (5.7)	N.A.	40	0	N.E.	N.E. 0.1165	
LAG-3 < 5%	152	8 (5.3)	N.A.	161	2 (1.2)	N.A.	4.02 (0.85, 18.95) 0.0567	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								N.M.E.
BRAF MUTANT	77	4 (5.2)	N.M.E.	75	0	N.M.E.	N.M.E.	
BRAF WILDTYPE	110	6 (5.5)	N.M.E.	126	2 (1.6)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								N.M.E.
M0/M1ANY[0]	123	6 (4.9)	N.M.E.	125	1 (0.8)	N.M.E.	N.M.E.	
M1ANY[1]	64	4 (6.3)	N.M.E.	76	1 (1.3)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								N.M.E.
M0	21	0	N.M.E.	10	0	N.M.E.	N.M.E.	
M1A	42	3 (7.1)	N.M.E.	56	2 (3.6)	N.M.E.	N.M.E.	
M1B	40	3 (7.5)	N.M.E.	46	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	4 (5.0)	N.M.E.	81	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9997
STAGE III	21	0	N.E.	10	0	N.E.	N.E. N.E.	
STAGE IV	166	10 (6.0)	N.A.	190	2 (1.1)	N.A.	5.77 (1.26, 26.34) 0.0104	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								N.M.E.
CUTANEOUS ACRAL	23	2 (8.7)	N.M.E.	26	0	N.M.E.	N.M.E.	
CUTANEOUS NON-ACRAL	122	7 (5.7)	N.M.E.	139	2 (1.4)	N.M.E.	N.M.E.	
MUCOSAL	17	1 (5.9)	N.M.E.	20	0	N.M.E.	N.M.E.	
OTHER	25	0	N.M.E.	16	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								N.M.E.
<= ULN	120	6 (5.0)	N.M.E.	121	1 (0.8)	N.M.E.	N.M.E.	
> ULN	66	4 (6.1)	N.M.E.	80	1 (1.3)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								N.M.E.
<= 2 X ULN	168	8 (4.8)	N.M.E.	181	1 (0.6)	N.M.E.	N.M.E.	
> 2 X ULN	18	2 (11.1)	N.M.E.	20	1 (5.0)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								N.M.E.
< QUARTILE 1	35	1 (2.9)	N.M.E.	43	0	N.M.E.	N.M.E.	
QUARTILE 1 TO < QUARTILE 3	84	5 (6.0)	N.M.E.	89	1 (1.1)	N.M.E.	N.M.E.	
>= QUARTILE 3	46	2 (4.3)	N.M.E.	44	1 (2.3)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								N.M.E.
0	121	6 (5.0)	N.M.E.	136	1 (0.7)	N.M.E.	N.M.E.	
1	66	4 (6.1)	N.M.E.	65	1 (1.5)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	63	4 (6.3)	N.M.E.	76	2 (2.6)	N.M.E.	N.M.E.	
NEVER SMOKED	116	5 (4.3)	N.M.E.	121	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION I								N.M.E.
>= 18 - < 65	102	5 (4.9)	N.M.E.	105	2 (1.9)	N.M.E.	N.M.E.	
>= 65 - < 75	48	3 (6.3)	N.M.E.	64	0	N.M.E.	N.M.E.	
>= 75	37	2 (5.4)	N.M.E.	32	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								N.M.E.
< 65	102	5 (4.9)	N.M.E.	105	2 (1.9)	N.M.E.	N.M.E.	
>= 65	85	5 (5.9)	N.M.E.	96	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								N.M.E.
MALE	104	6 (5.8)	N.M.E.	116	2 (1.7)	N.M.E.	N.M.E.	
FEMALE	83	4 (4.8)	N.M.E.	85	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Hepatobiliary Disorders

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								N.M.E.
USA/CANADA	17	0	N.M.E.	18	0	N.M.E.	N.M.E.	
EUROPE	98	2 (2.0)	N.M.E.	105	1 (1.0)	N.M.E.	N.M.E.	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	5 (8.8)	N.M.E.	62	1 (1.6)	N.M.E.	N.M.E.	
AUSTRALIA/NZ	15	3 (20.0)	N.M.E.	16	0	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
OVERALL	187	4 (2.1)	N.A.	201	14 (7.0)	N.A.	0.30 (0.10, 0.91) 0.0244	
LAG-3 STATUS AT BASELINE USING 1% CUT-OFF								0.6636
LAG-3 >= 1%	118	2 (1.7)	N.A.	120	8 (6.7)	N.A.	0.24 (0.05, 1.15) 0.0537	
LAG-3 < 1%	69	2 (2.9)	N.A.	81	6 (7.4)	N.A.	0.39 (0.08, 1.96) 0.2388	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
LAG-3 STATUS AT BASELINE USING 5% CUT-OFF								0.5423
LAG-3 >= 5%	35	1 (2.9)	N.A.	40	2 (5.0)	N.A.	0.59 (0.05, 6.54) 0.6658	
LAG-3 < 5%	152	3 (2.0)	N.A.	161	12 (7.5)	N.A.	0.25 (0.07, 0.90) 0.0216	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BRAF MUTATION STATUS								0.6786
BRAF MUTANT	77	2 (2.6)	N.A.	75	8 (10.7)	N.A.	0.24 (0.05, 1.13) 0.0497	
BRAF WILDTYPE	110	2 (1.8)	N.A.	126	6 (4.8)	N.A.	0.39 (0.08, 1.91) 0.2256	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AJCC STAGE								0.5890
M0/M1ANY[0]	123	3 (2.4)	N.A.	125	8 (6.4)	N.A.	0.38 (0.10, 1.44) 0.1384	
M1ANY[1]	64	1 (1.6)	N.A.	76	6 (7.9)	N.A. (35.91, N.A.)	0.19 (0.02, 1.61) 0.0896	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE METASTASIS STAGE								>0.9999
M0	21	0	N.E.	10	2 (20.0)	N.A. (0.85, N.A.)	N.E. 0.0377	
M1A	42	0	N.E.	56	1 (1.8)	N.A.	N.E. 0.3954	
M1B	40	1 (2.5)	N.A.	46	3 (6.5)	N.A.	0.37 (0.04, 3.57) 0.3711	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
M1C	80	3 (3.8)	N.A.	81	8 (9.9)	N.A.	0.38 (0.10, 1.44) 0.1394	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9915
STAGE III	21	0	N.E.	10	2 (20.0)	N.A. (0.85, N.A.)	N.E. 0.0377	
STAGE IV	166	4 (2.4)	N.A.	190	12 (6.3)	N.A.	0.38 (0.12, 1.18) 0.0814	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
HISTOLOGY (DISEASE SUBTYPE)								>0.9999
CUTANEOUS ACRAL	23	0	N.E.	26	2 (7.7)	N.A.	N.E. 0.2653	
CUTANEOUS NON-ACRAL	122	4 (3.3)	N.A.	139	10 (7.2)	N.A.	0.44 (0.14, 1.41) 0.1551	
MUCOSAL	17	0	N.E.	20	0	N.E.	N.E. N.E.	
OTHER	25	0	N.E.	16	2 (12.5)	N.A.	N.E. 0.0704	

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All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

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	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH I								0.4443
<= ULN	120	3 (2.5)	N.A.	121	7 (5.8)	N.A.	0.44 (0.11, 1.68) 0.2152	
> ULN	66	1 (1.5)	N.A.	80	7 (8.8)	N.A. (35.91, N.A.)	0.17 (0.02, 1.36) 0.0569	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
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CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
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All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE LDH II								0.9706
<= 2 X ULN	168	3 (1.8)	N.A.	181	11 (6.1)	N.A.	0.29 (0.08, 1.04) 0.0426	
> 2 X ULN	18	1 (5.6)	N.A.	20	3 (15.0)	N.A.	0.35 (0.04, 3.38) 0.3439	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
TUMOR BURDEN AT BASELINE PER BICR								N.M.E.
< QUARTILE 1	35	1 (2.9)	N.M.E.	43	1 (2.3)	N.M.E.	N.M.E.	
QUARTILE 1 TO < QUARTILE 3	84	1 (1.2)	N.M.E.	89	7 (7.9)	N.M.E.	N.M.E.	
>= QUARTILE 3	46	1 (2.2)	N.M.E.	44	4 (9.1)	N.M.E.	N.M.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
BASELINE ECOG PS								0.0449*
0	121	1 (0.8)	N.A.	136	12 (8.8)	N.A.	0.09 (0.01, 0.69) 0.0036	
1	66	3 (4.5)	N.A.	65	2 (3.1)	N.A.	1.42 (0.24, 8.51) 0.6988	

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SMOKING STATUS								N.M.E.
CURRENT/FORMER	63	2 (3.2)	N.M.E.	76	6 (7.9)	N.M.E.	N.M.E.	
NEVER SMOKED	116	2 (1.7)	N.M.E.	121	7 (5.8)	N.M.E.	N.M.E.	

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AGE CATEGORIZATION I								N.M.E.
>= 18 - < 65	102	3 (2.9)	N.M.E.	105	5 (4.8)	N.M.E.	N.M.E.	
>= 65 - < 75	48	1 (2.1)	N.M.E.	64	5 (7.8)	N.M.E.	N.M.E.	
>= 75	37	0	N.M.E.	32	4 (12.5)	N.M.E.	N.M.E.	

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Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
AGE CATEGORIZATION II								0.2124
< 65	102	3 (2.9)	N.A.	105	5 (4.8)	N.A.	0.59 (0.14, 2.49) 0.4699	
>= 65	85	1 (1.2)	N.A.	96	9 (9.4)	N.A.	0.12 (0.02, 0.96) 0.0168	

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(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-tsubsoc-ebr2586_b5.sas 12FEB2026:12:01:40

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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
SEX								0.5117
MALE	104	2 (1.9)	N.A.	116	10 (8.6)	N.A.	0.23 (0.05, 1.03) 0.0356	
FEMALE	83	2 (2.4)	N.A.	85	4 (4.7)	N.A.	0.49 (0.09, 2.68) 0.4016	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-tsubsoc-ebr2586_b5.sas 12FEB2026:12:01:40

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Table 17.2
CTCAE Grade 3-4-5 Adverse Events : Subgroup Time-Adjusted Analyses
Significant SOC/PT
All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

	BMS-986213			Nivolumab			BMS-986213 vs. Nivolumab	
Subgroup	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	N	Subjects with Event n (%)	KME [95% CI](mon) (1)	HR [95% CI] p-value (2)(3)	Test for Interaction p-value (4)(5)
REGION								N.M.E.
USA/CANADA	17	0	N.M.E.	18	2 (11.1)	N.M.E.	N.M.E.	
EUROPE	98	1 (1.0)	N.M.E.	105	8 (7.6)	N.M.E.	N.M.E.	
LATIN AMERICA (CENTRAL/SOUTH AMERICA)	57	3 (5.3)	N.M.E.	62	3 (4.8)	N.M.E.	N.M.E.	
AUSTRALIA/NZ	15	0	N.M.E.	16	1 (6.3)	N.M.E.	N.M.E.	

NOV 2025 DBL. Based on events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. Two-sided 95% CI computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup factor and treatment*subgroup factor interaction to assess the significance of the interaction between treatment and the subgroup factor.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 28.0; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/tables
Program Name: rt-ae-tsubsoc-ebr2586_b5.sas 12FEB2026:12:01:40

Anhang 4-G 8: Kaplan-Meier-Kurven

Anhang 4-G 8.1: Kaplan-Meier-Kurven zu EQ-5D-VAS, FACT-M und UE

Anhang 4-G 8.1.1: EQ-5D-VAS − Zeit bis zur bestätigten Verschlechterung

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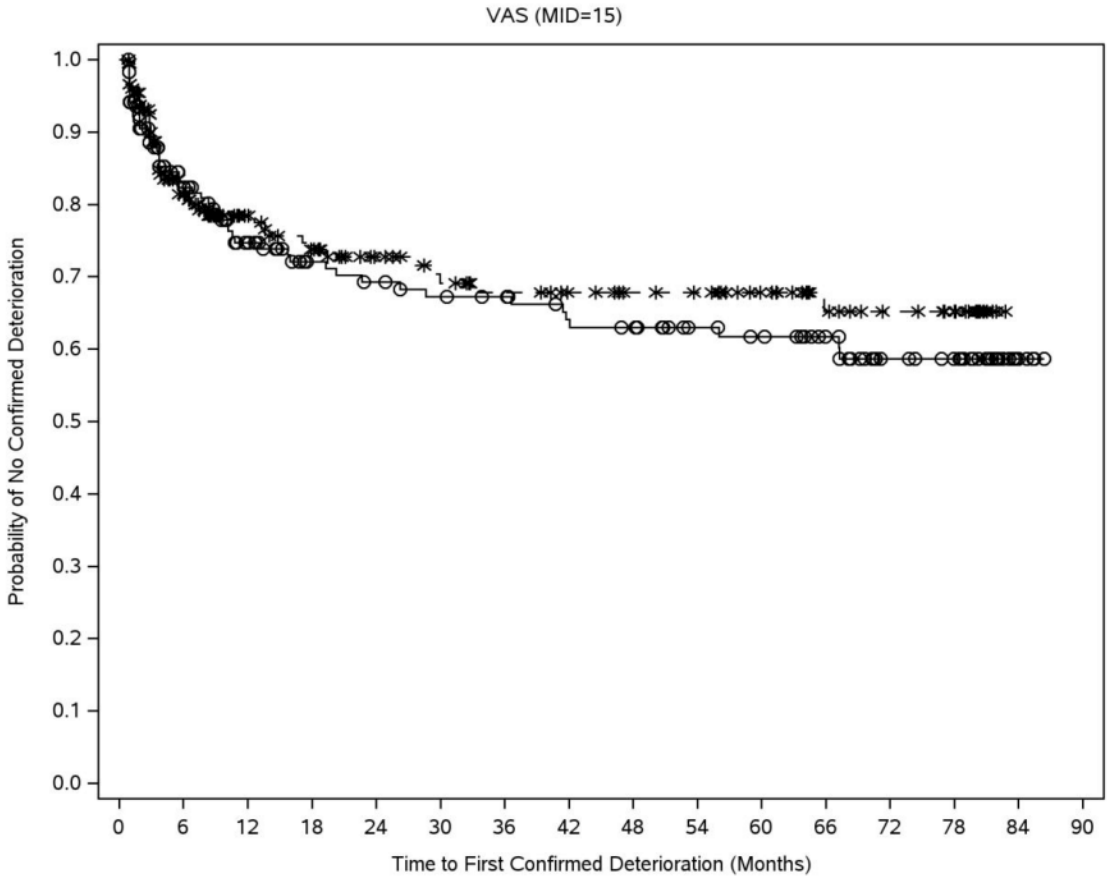
Figure 5.4
Plot of EQ-5D VAS Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	174	115	92	76	72	68	66	60	58	51	48	41	29	25	4	0
	(0)	(31)	(44)	(57)	(58)	(60)	(62)	(65)	(66)	(73)	(75)	(82)	(92)	(96)	(117)	(121)
Nivolumab	183	116	87	76	65	57	52	48	44	42	35	25	20	16	0	0
	(0)	(37)	(62)	(68)	(78)	(83)	(87)	(91)	(95)	(97)	(104)	(113)	(118)	(122)	(138)	(138)

—o— BMS-986213 (events: 53/174), median and 95% CI: N.A. (67.25, N.A.)
— * - Nivolumab (events: 45/183), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.18 (0.79, 1.76)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:02

Anhang 4-G 8.1.2: FACT-M − Zeit bis zur bestätigten Verschlechterung

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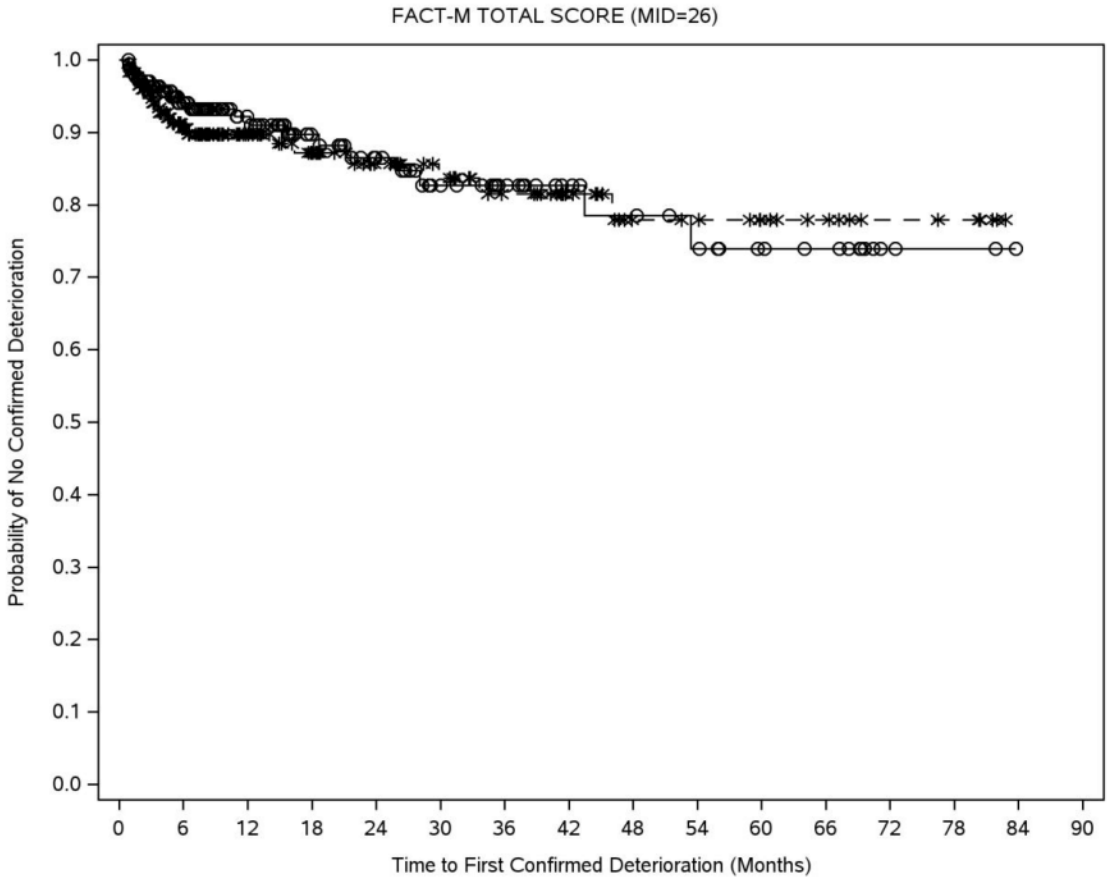
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	173	114	82	59	48	36	30	22	19	16	12	10	3	2	0	0
	(0)	(50)	(80)	(101)	(110)	(120)	(126)	(134)	(136)	(138)	(142)	(144)	(151)	(152)	(154)	(154)
Nivolumab	182	119	78	65	51	43	35	27	18	17	13	10	6	5	0	0
	(0)	(48)	(88)	(99)	(112)	(119)	(126)	(134)	(142)	(143)	(147)	(150)	(154)	(155)	(160)	(160)

—o— BMS-986213 (events: 19/173), median and 95% CI: N.A.
— * - Nivolumab (events: 22/182), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.90 (0.48, 1.66)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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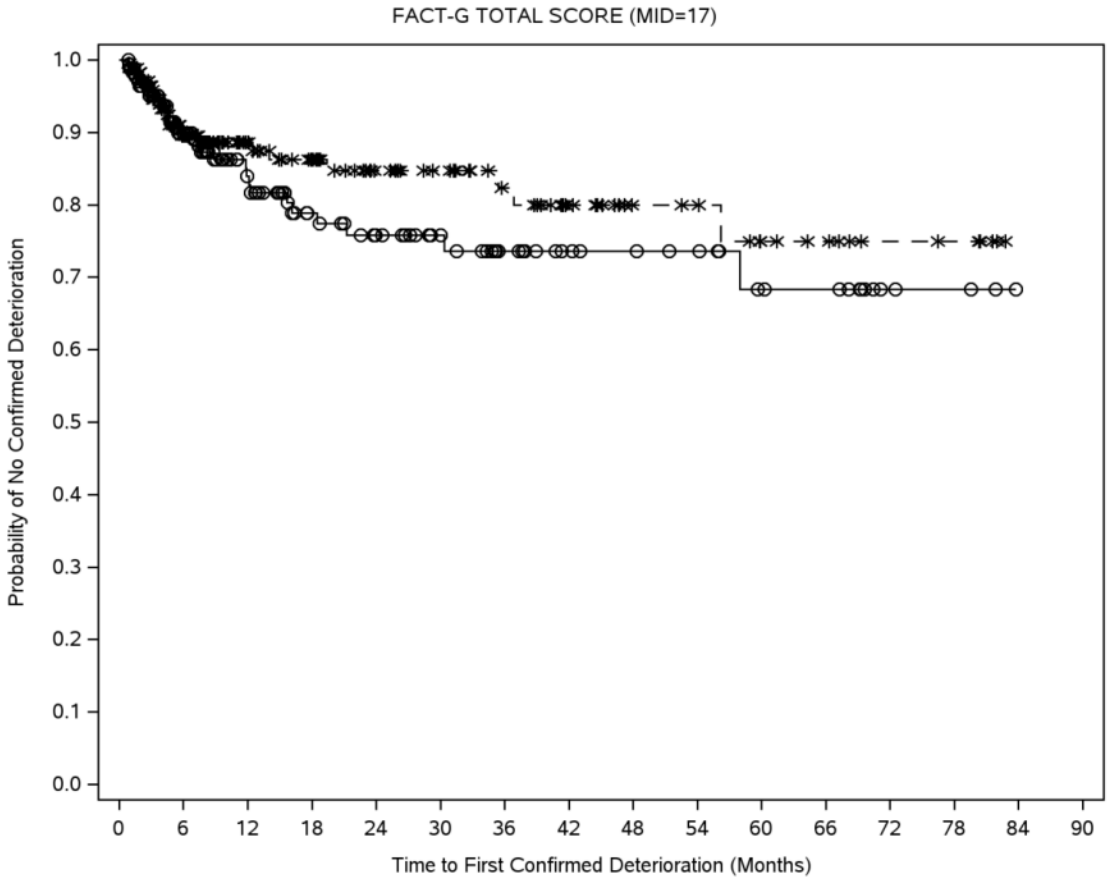
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	173	109	73	52	44	35	27	21	19	17	12	11	4	3	0	0
	(0)	(49)	(79)	(96)	(102)	(111)	(118)	(124)	(126)	(128)	(132)	(133)	(140)	(141)	(144)	(144)
Nivolumab	182	117	76	64	49	42	34	26	18	17	12	10	6	5	0	0
	(0)	(49)	(89)	(99)	(113)	(120)	(127)	(134)	(142)	(143)	(147)	(149)	(153)	(154)	(159)	(159)

—o— BMS-986213 (events: 29/173), median and 95% CI: N.A.
— * - Nivolumab (events: 23/182), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.30 (0.75, 2.26)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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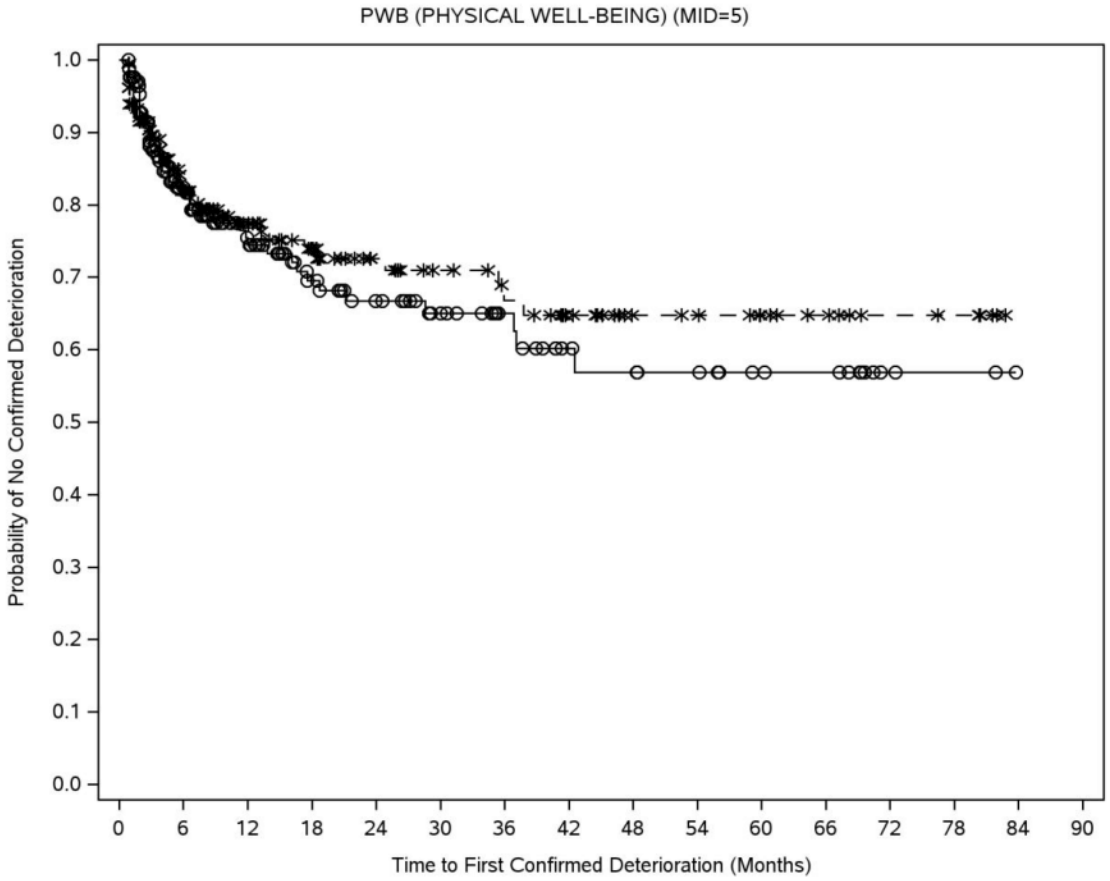
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	173	105	72	53	44	34	27	19	17	15	11	10	3	2	0	0
	(0)	(41)	(65)	(80)	(87)	(96)	(103)	(109)	(110)	(112)	(116)	(117)	(124)	(125)	(127)	(127)
Nivolumab	184	108	72	58	44	37	32	26	18	17	13	10	6	5	0	0
	(0)	(47)	(78)	(89)	(102)	(108)	(111)	(116)	(124)	(125)	(129)	(132)	(136)	(137)	(142)	(142)

—o— BMS-986213 (events: 46/173), median and 95% CI: N.A. (37.09, N.A.)
— * - Nivolumab (events: 42/184), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.18 (0.78, 1.80)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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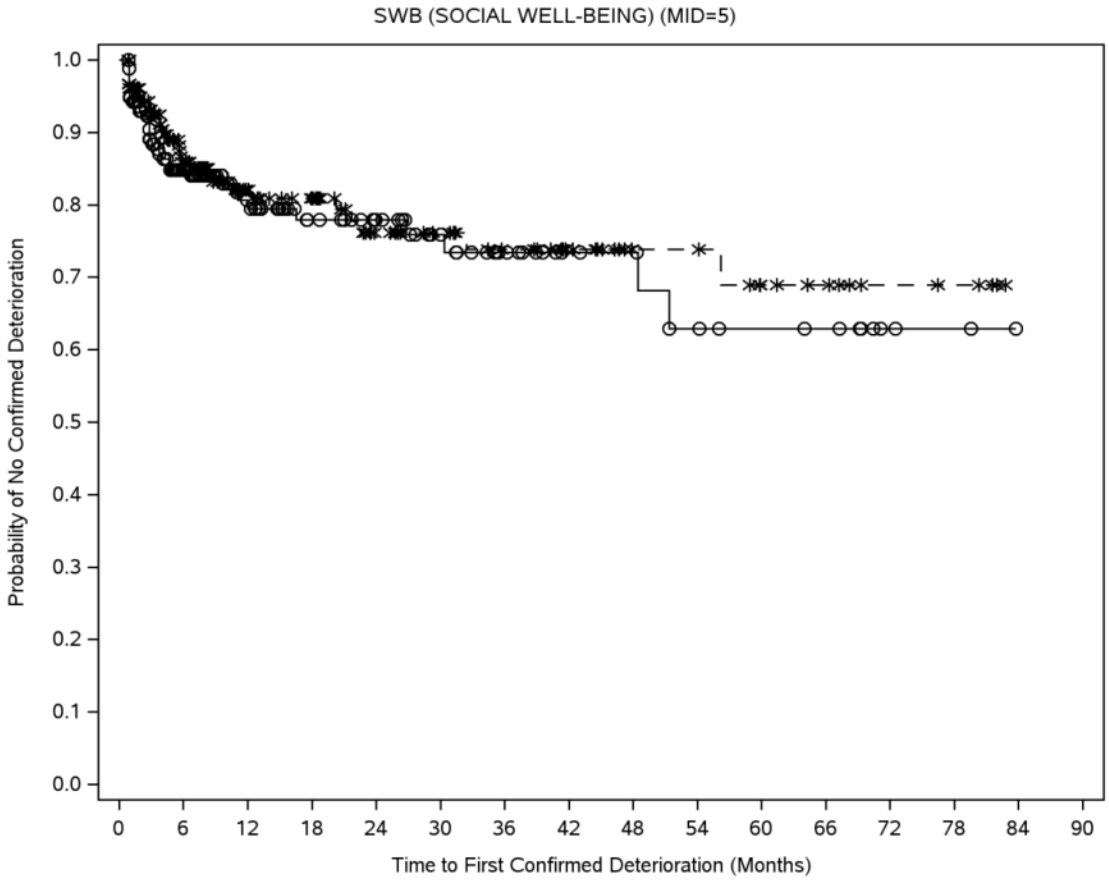
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	175	104	67	50	42	31	23	16	15	11	9	8	3	2	0	0
	(0)	(47)	(79)	(95)	(103)	(113)	(120)	(127)	(128)	(130)	(132)	(133)	(138)	(139)	(141)	(141)
Nivolumab	183	110	69	60	43	36	30	24	16	16	11	9	5	4	0	0
	(0)	(51)	(88)	(96)	(110)	(117)	(122)	(128)	(136)	(136)	(140)	(142)	(146)	(147)	(151)	(151)

—o— BMS-986213 (events: 34/175), median and 95% CI: N.A. (51.35, N.A.)
— * - Nivolumab (events: 32/183), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.12 (0.69, 1.81)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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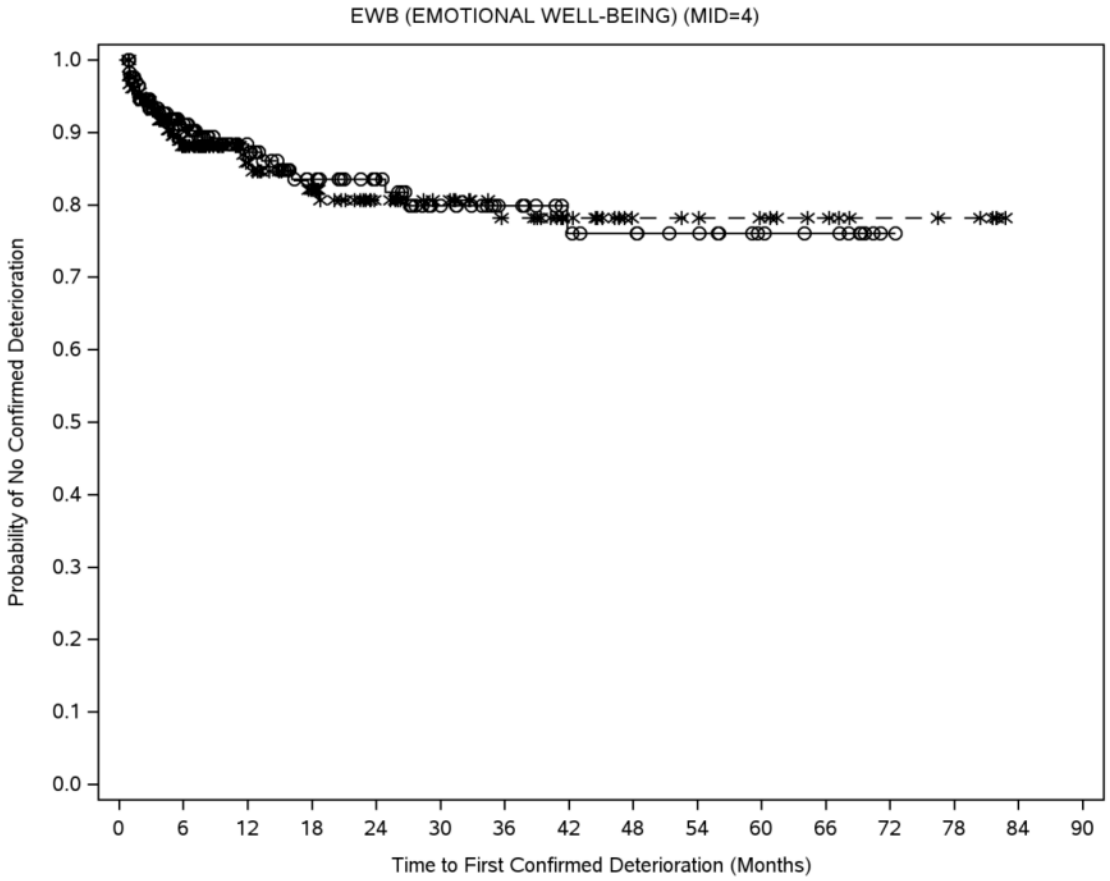
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	174	113	80	58	49	35	27	20	18	15	10	8	1	0	0	0
	(0)	(47)	(77)	(95)	(104)	(116)	(124)	(130)	(132)	(135)	(140)	(142)	(149)	(150)	(150)	(150)
Nivolumab	183	114	75	62	45	38	30	23	15	14	12	9	6	5	0	0
	(0)	(50)	(87)	(97)	(113)	(120)	(127)	(134)	(142)	(143)	(145)	(148)	(151)	(152)	(157)	(157)

—o— BMS-986213 (events: 24/174), median and 95% CI: N.A.
— * - Nivolumab (events: 26/183), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.92 (0.53, 1.61)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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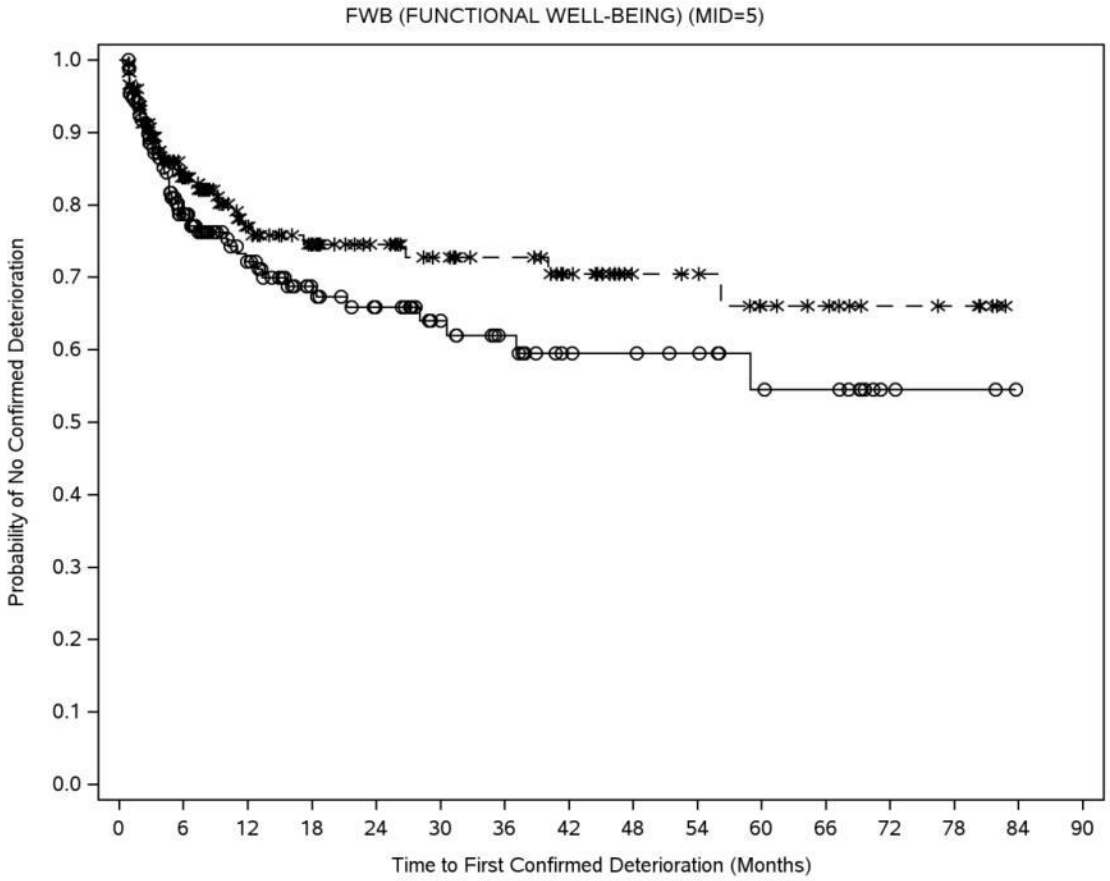
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	175	101	69	49	41	31	25	18	17	15	11	10	3	2	0	0
	(0)	(41)	(66)	(83)	(89)	(98)	(103)	(109)	(110)	(112)	(115)	(116)	(123)	(124)	(126)	(126)
Nivolumab	182	109	69	57	46	38	34	27	18	17	12	10	6	5	0	0
	(0)	(47)	(80)	(90)	(101)	(108)	(112)	(118)	(127)	(128)	(132)	(134)	(138)	(139)	(144)	(144)

—o— BMS-986213 (events: 49/175), median and 95% CI: N.A. (37.09, N.A.)
— * - Nivolumab (events: 38/182), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.28 (0.83, 1.95)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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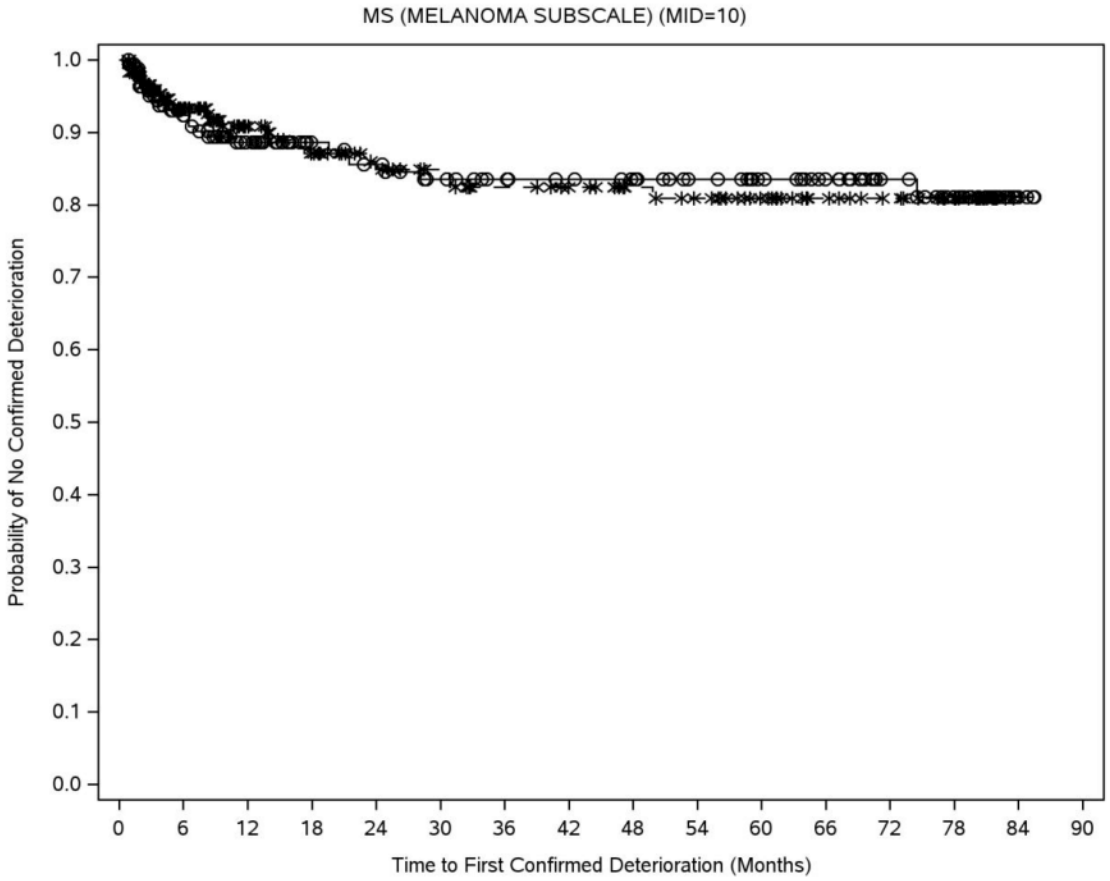
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	175	128	107	89	84	77	72	69	66	59	53	46	35	26	3	0
	(0)	(35)	(51)	(69)	(71)	(76)	(81)	(84)	(87)	(94)	(100)	(107)	(118)	(126)	(149)	(152)
Nivolumab	187	132	101	89	77	70	64	60	53	49	41	32	27	20	0	0
	(0)	(44)	(72)	(80)	(90)	(97)	(101)	(105)	(112)	(115)	(123)	(132)	(137)	(144)	(164)	(164)

—o— BMS-986213 (events: 23/175), median and 95% CI: N.A.
— * - Nivolumab (events: 23/187), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.02 (0.57, 1.82)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

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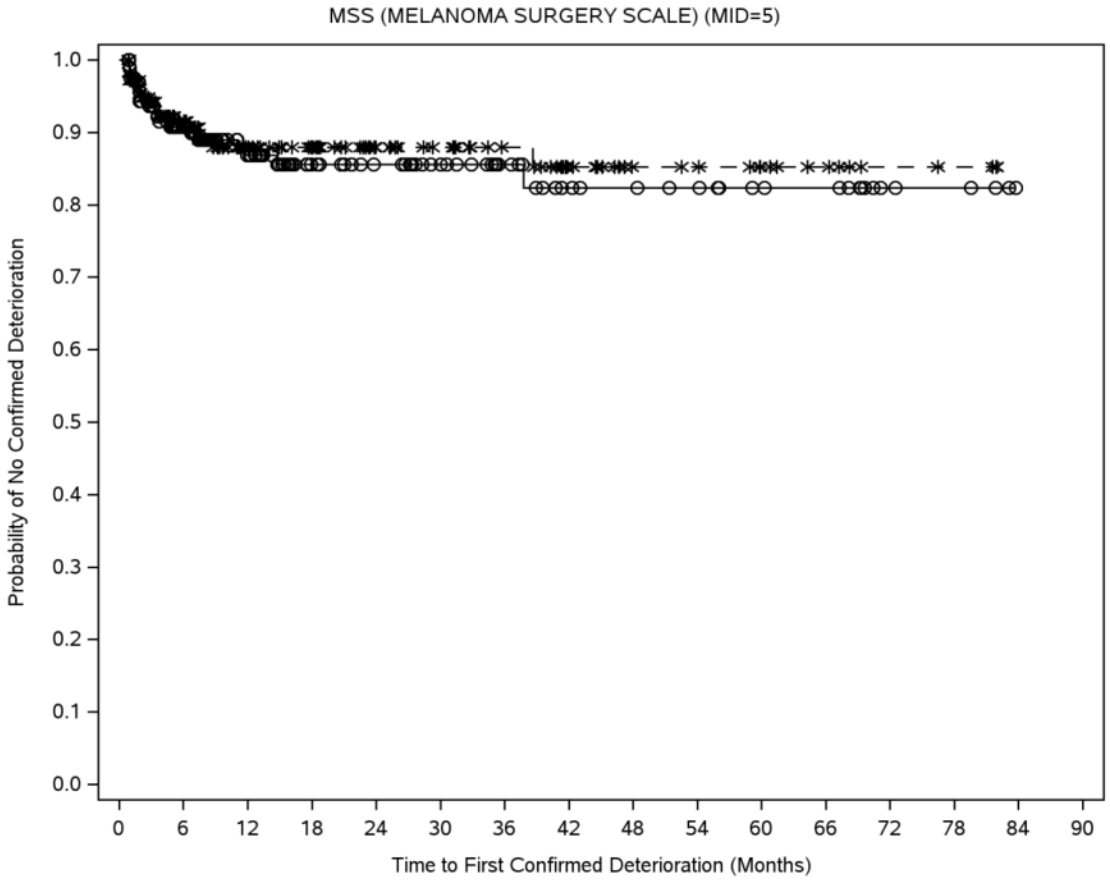
Figure 5.2
Plot of FACT-M Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	167	112	78	54	46	38	30	21	19	17	13	12	5	4	0	0
	(0)	(41)	(71)	(94)	(102)	(110)	(118)	(126)	(128)	(130)	(134)	(135)	(142)	(143)	(147)	(147)
Nivolumab	183	118	73	63	47	40	33	24	16	15	11	8	4	3	0	0
	(0)	(51)	(92)	(102)	(118)	(125)	(132)	(140)	(148)	(149)	(153)	(156)	(160)	(161)	(164)	(164)

—o— BMS-986213 (events: 20/167), median and 95% CI: N.A.
— * - Nivolumab (events: 19/183), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.17 (0.62, 2.19)

NOV 2025 DBL. Symbols represent censored observations.
Unstratified cox proportional hazards model
with baseline PRO score as covariate.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-ttd-ebr2586_b5.sas 13FEB2026:07:01:53

Anhang 4-G 8.1.3: UE − Zeit bis zum ersten Ereignis

Anhang 4-G 8.1.3.1: UE-Hauptkategorien

Anhang 4-G 8.1.3.1.1: Schwere UE (CTCAE-Grad ≥ 3)

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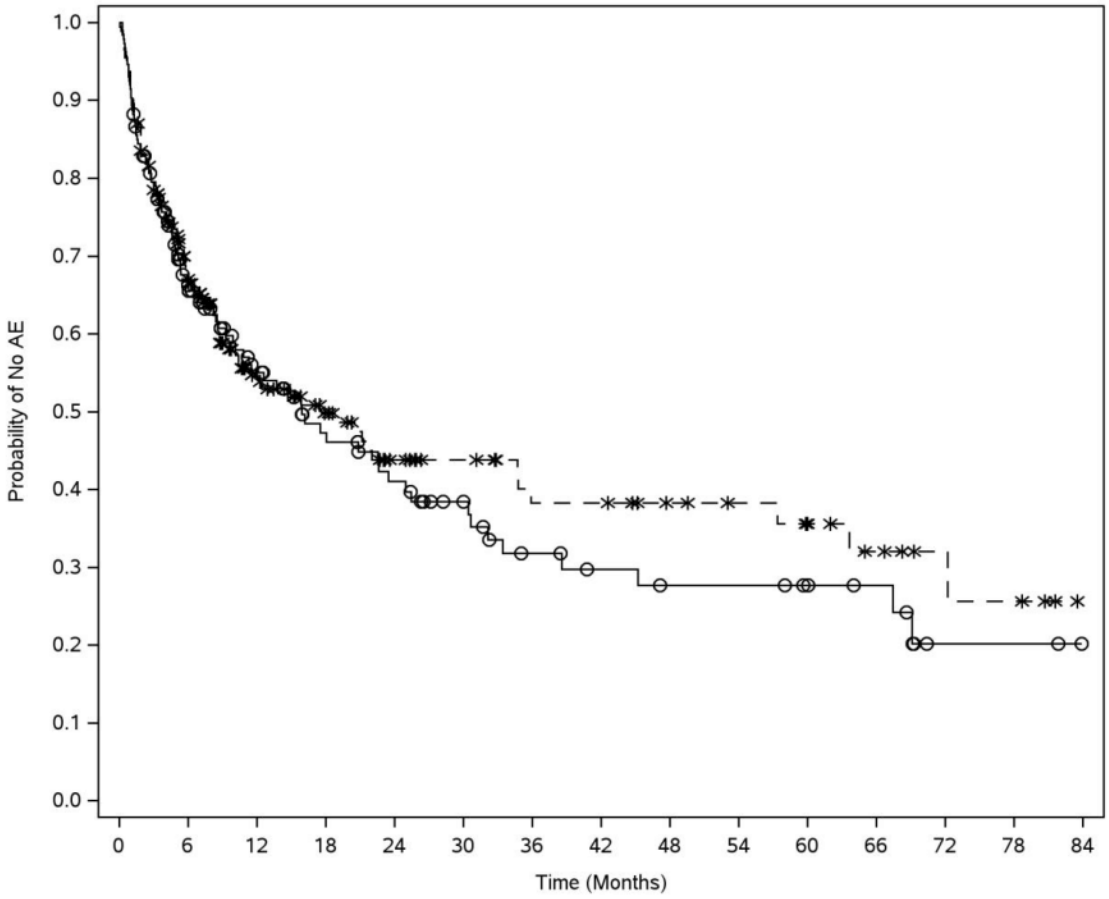
Figure 14.2
Plot of Time to first CTCAE Grade 3-4-5 Adverse Event - Excluding Progression Terms - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	98	56	40	32	24	17	14	12	12	10	8	2	2	0
	(0)	(29)	(58)	(67)	(70)	(76)	(79)	(81)	(82)	(82)	(84)	(86)	(90)	(90)	(92)
Nivolumab	201	117	61	45	32	27	21	21	16	14	11	8	5	4	0
	(0)	(20)	(59)	(70)	(78)	(83)	(86)	(86)	(91)	(93)	(95)	(97)	(100)	(100)	(104)

—o— BMS-986213 (events: 95/187), median and 95% CI: 15.90 (10.15, 23.46)
— * - Nivolumab (events: 97/201), median and 95% CI: 17.64 (10.12, 34.76)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.10 (0.83, 1.46)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-ae-ebr2586_b5.sas 13FEB2026:07:04:14

Anhang 4-G 8.1.3.1.2: SUE

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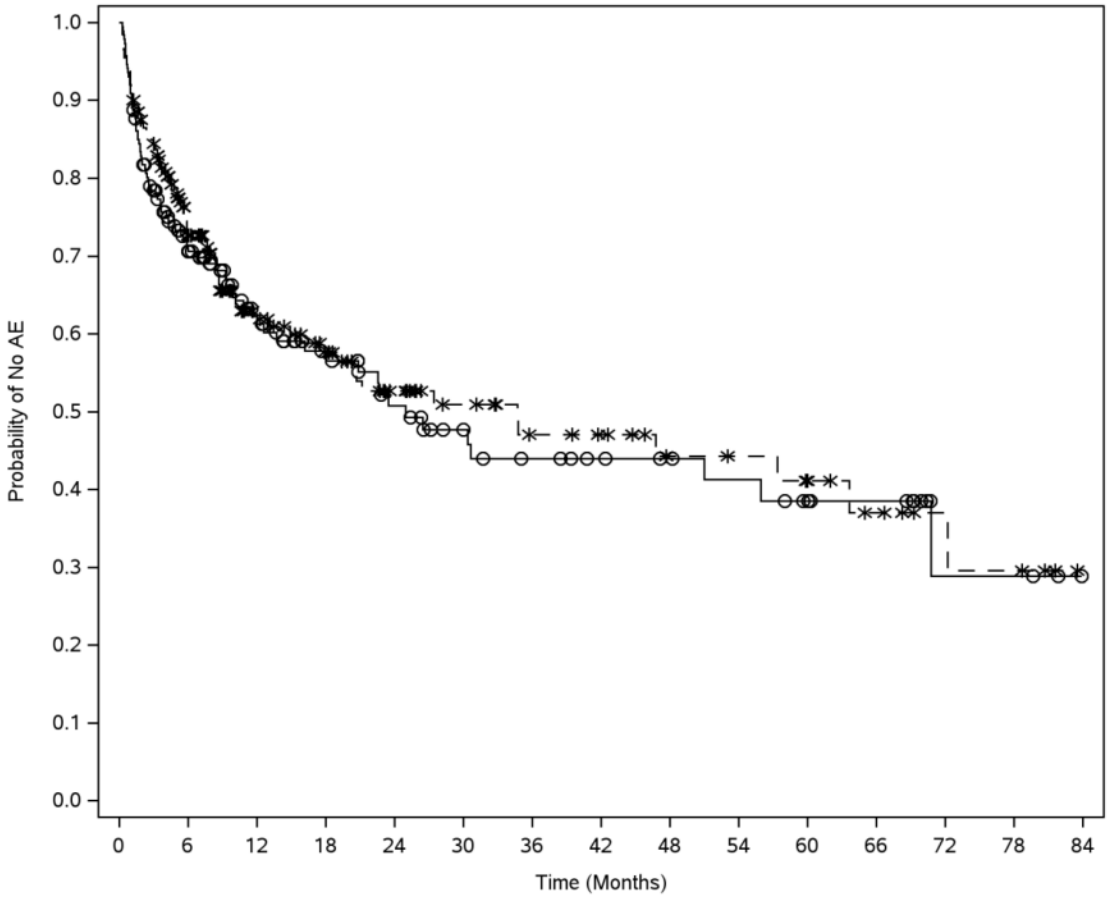
Figure 14.3
Plot of Time to first Serious Adverse Event - Excluding Progression Terms - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	105	61	45	34	26	22	19	17	15	12	10	3	3	0
	(0)	(29)	(64)	(76)	(82)	(88)	(90)	(93)	(95)	(96)	(98)	(100)	(106)	(106)	(109)
Nivolumab	201	119	64	50	37	29	23	21	15	14	11	8	5	4	0
	(0)	(30)	(72)	(82)	(91)	(98)	(102)	(104)	(109)	(110)	(112)	(114)	(117)	(117)	(121)

—o— BMS-986213 (events: 78/187), median and 95% CI: 24.97 (16.16, 55.95)
— * - Nivolumab (events: 80/201), median and 95% CI: 34.73 (17.74, 63.64)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.08 (0.79, 1.47)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-ae-ebr2586_b5.sas 13FEB2026:07:04:38

Anhang 4-G 8.1.3.1.3: Zum Therapieabbruch führende UE

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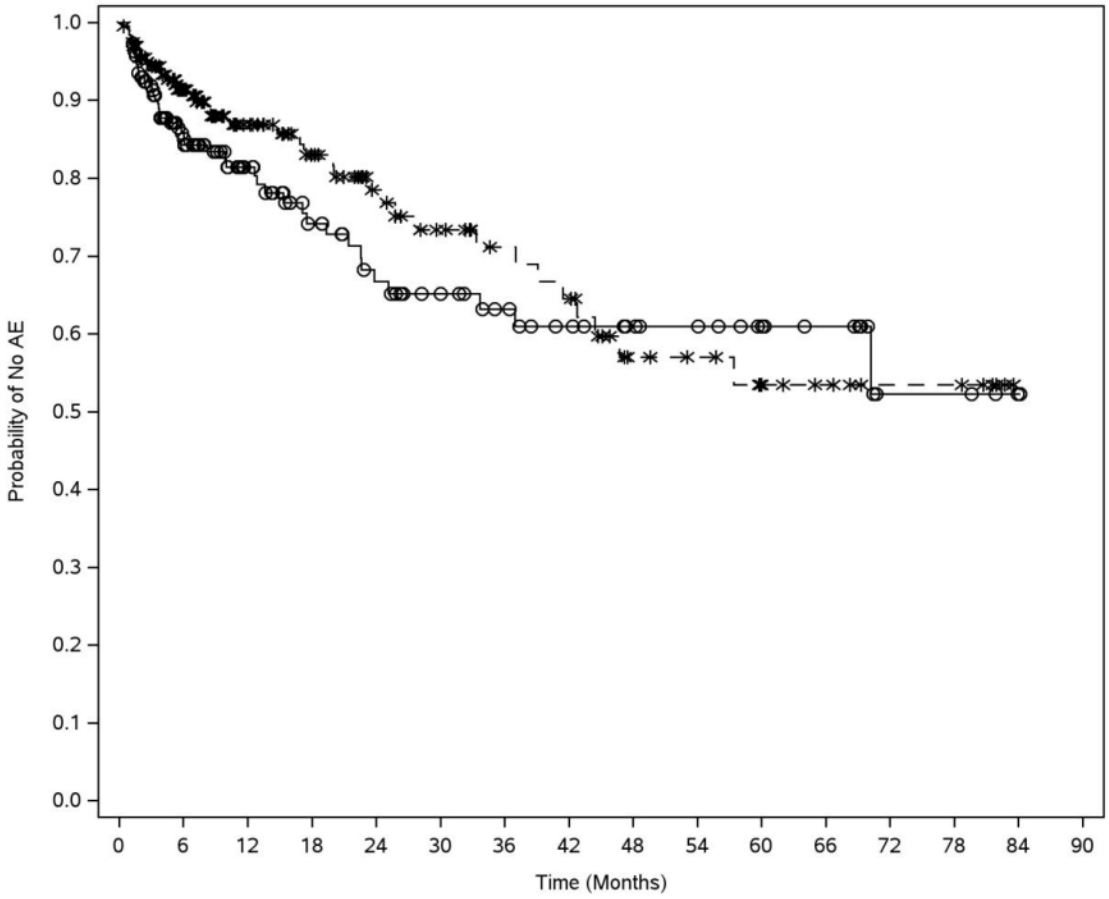
Figure 14.4
Plot of Time to first Adverse Event Leading to Discontinuation of Study Treatment - Excluding Progression Terms - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	120	76	55	43	35	30	25	21	19	15	12	4	4	1	0
	(0)	(42)	(81)	(96)	(103)	(110)	(114)	(118)	(122)	(124)	(128)	(131)	(138)	(138)	(141)	(142)
Nivolumab	201	135	76	60	47	38	32	29	19	17	12	10	7	7	0	0
	(0)	(50)	(104)	(117)	(127)	(133)	(138)	(138)	(145)	(147)	(151)	(153)	(156)	(156)	(163)	(163)

—o— BMS-986213 (events: 45/187), median and 95% CI: N.A. (36.99, N.A.)
— * - Nivolumab (events: 38/201), median and 95% CI: N.A. (42.78, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.28 (0.83, 1.98)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-ae-ebr2586_b5.sas 13FEB2026:07:04:24

Anhang 4-G 8.1.3.2: UE auf Ebene der SOC und PT (nur bei signifikantem Ergebnis)

Anhang 4-G 8.1.3.2.1: Jegliche UE auf Ebene der SOC und PT

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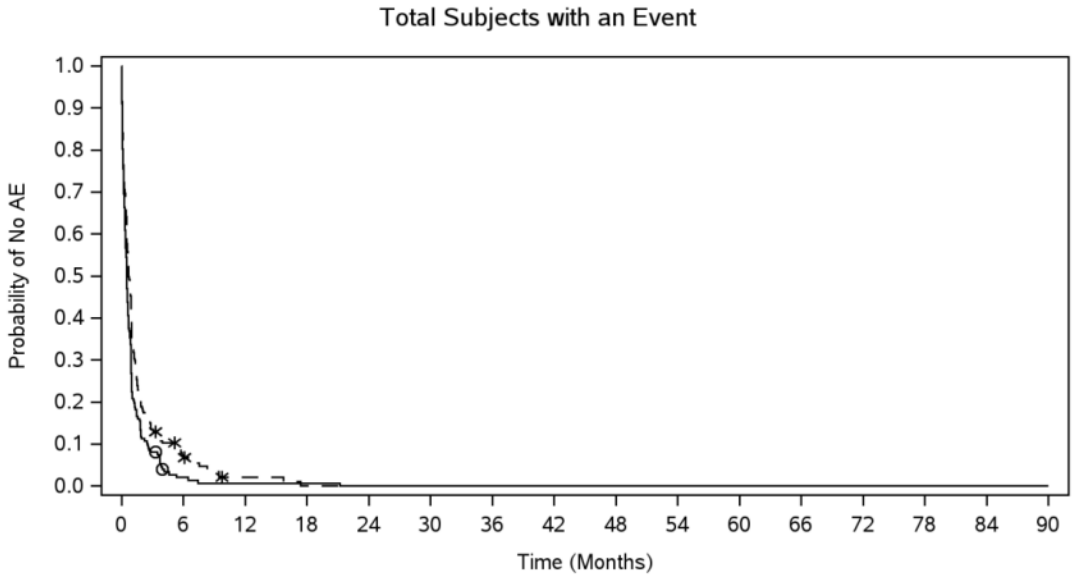
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	3	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)
Nivolumab	201	13	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(3)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)

—o— BMS-986213 (events: 185/187), median and 95% CI: 0.49 (0.39, 0.59)
— ✱ - Nivolumab (events: 195/201), median and 95% CI: 0.69 (0.53, 0.92)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.34 (1.09, 1.64)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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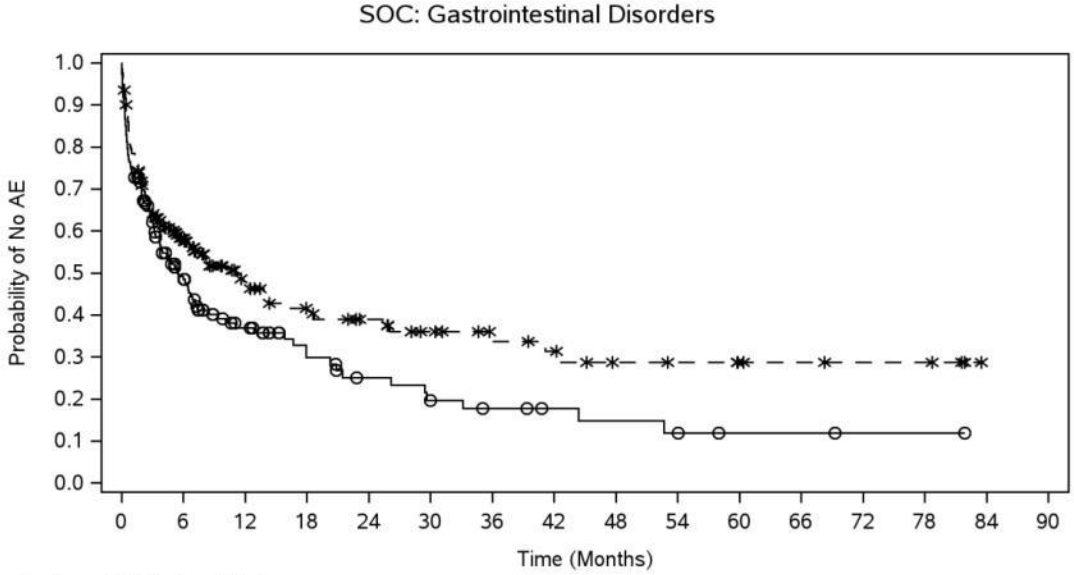
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	65	33	20	14	10	8	6	5	4	2	2	1	1	0	0
	(0)	(31)	(50)	(58)	(61)	(62)	(63)	(65)	(65)	(65)	(67)	(67)	(68)	(68)	(69)	(69)
Nivolumab	201	85	43	33	27	20	15	13	9	8	6	5	4	4	0	0
	(0)	(35)	(65)	(70)	(74)	(79)	(83)	(84)	(87)	(88)	(90)	(91)	(92)	(92)	(96)	(96)

—o— BMS-986213 (events: 118/187), median and 95% CI: 5.42 (3.68, 7.23)
— * · Nivolumab (events: 105/201), median and 95% CI: 11.17 (6.47, 15.90)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.37 (1.05, 1.78)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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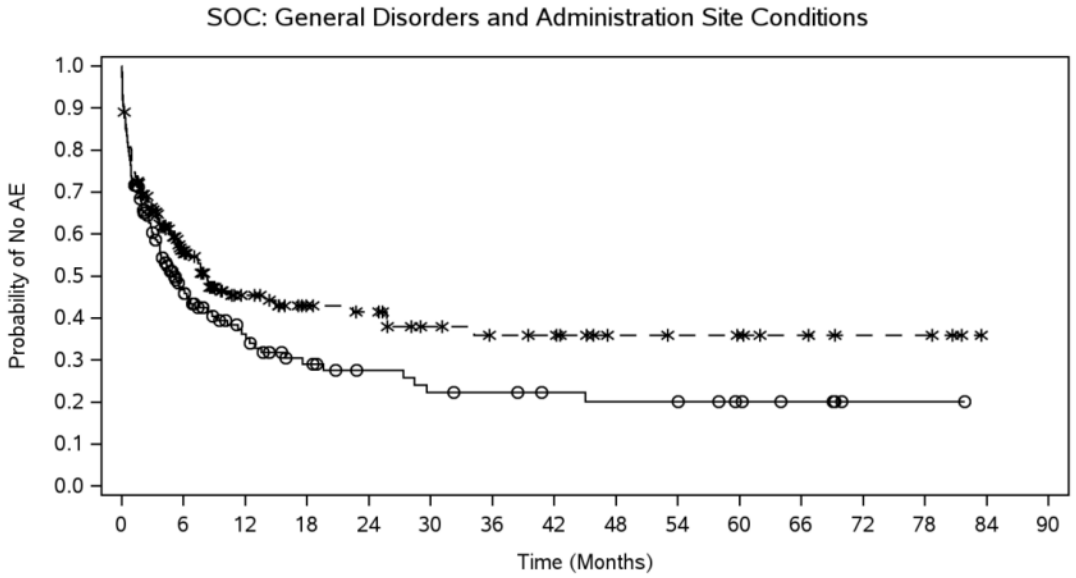
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	59	33	21	16	13	12	10	9	9	6	4	1	1	0	0
	(0)	(34)	(49)	(55)	(59)	(59)	(60)	(62)	(62)	(62)	(65)	(67)	(70)	(70)	(71)	(71)
Nivolumab	201	82	40	29	26	19	16	15	10	9	8	6	4	4	0	0
	(0)	(35)	(64)	(73)	(75)	(80)	(82)	(83)	(88)	(89)	(90)	(92)	(94)	(94)	(98)	(98)

—o— BMS-986213 (events: 116/187), median and 95% CI: 5.13 (3.68, 8.31)
— * - Nivolumab (events: 103/201), median and 95% CI: 8.21 (5.55, 22.44)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.32 (1.02, 1.73)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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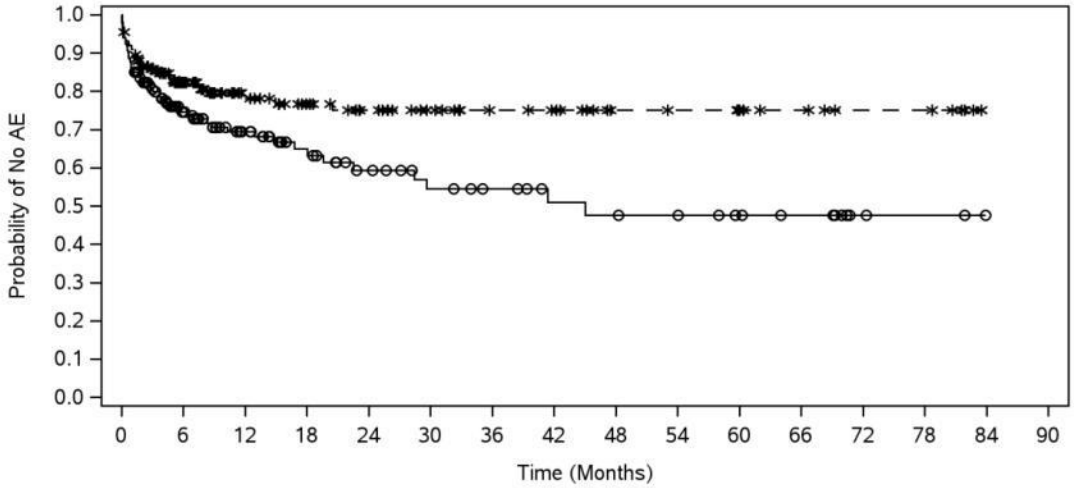
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

PT: Fatigue



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	95	55	38	28	22	19	15	14	13	10	8	3	2	0	0
(0)	(47)	(82)	(96)	(103)	(107)	(110)	(113)	(113)	(114)	(117)	(119)	(124)	(125)	(127)	(127)

Nivolumab

201	115	59	48	40	32	26	24	16	15	12	10	7	7	0	0
(0)	(52)	(104)	(114)	(121)	(129)	(135)	(137)	(145)	(146)	(149)	(151)	(154)	(154)	(161)	(161)

—o— BMS-986213 (events: 60/187), median and 95% CI: 45.01 (22.51, N.A.)

—✳- Nivolumab (events: 40/201), median and 95% CI: N.A.

Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.72 (1.16, 2.57)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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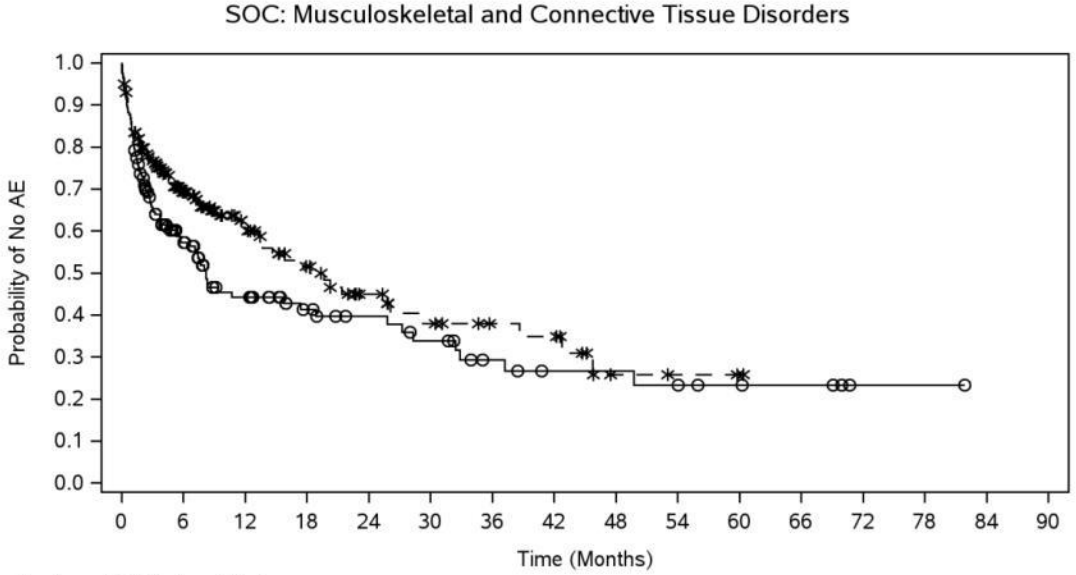
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	76	39	26	21	17	11	8	8	7	5	4	1	1	0	0
	(0)	(35)	(59)	(70)	(74)	(75)	(79)	(81)	(81)	(81)	(83)	(84)	(87)	(87)	(88)	(88)
Nivolumab	201	97	49	33	22	16	12	11	3	2	1	0	0	0	0	0
	(0)	(46)	(86)	(95)	(102)	(105)	(109)	(109)	(115)	(116)	(117)	(118)	(118)	(118)	(118)	(118)

—o— BMS-986213 (events: 99/187), median and 95% CI: 8.21 (5.75, 17.38)
—✱— Nivolumab (events: 83/201), median and 95% CI: 18.30 (13.34, 29.14)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.38 (1.03, 1.84)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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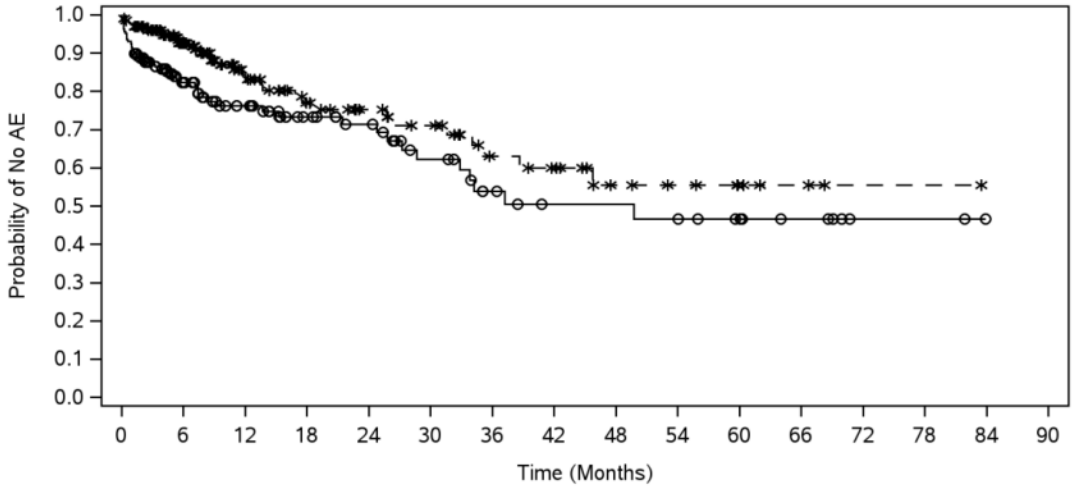
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

PT: Arthralgia



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	106	61	43	35	25	17	13	13	12	9	6	2	2	0	0
	(0)	(50)	(89)	(105)	(112)	(118)	(123)	(126)	(126)	(126)	(129)	(132)	(136)	(136)	(138)	(138)
Nivolumab	201	128	64	46	38	31	21	18	10	8	5	3	1	1	0	0
	(0)	(60)	(116)	(129)	(136)	(141)	(148)	(150)	(157)	(159)	(162)	(164)	(166)	(166)	(167)	(167)

—o— BMS-986213 (events: 49/187), median and 95% CI: 49.74 (28.65, N.A.)
— * - Nivolumab (events: 34/201), median and 95% CI: N.A. (34.73, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.65 (1.06, 2.55)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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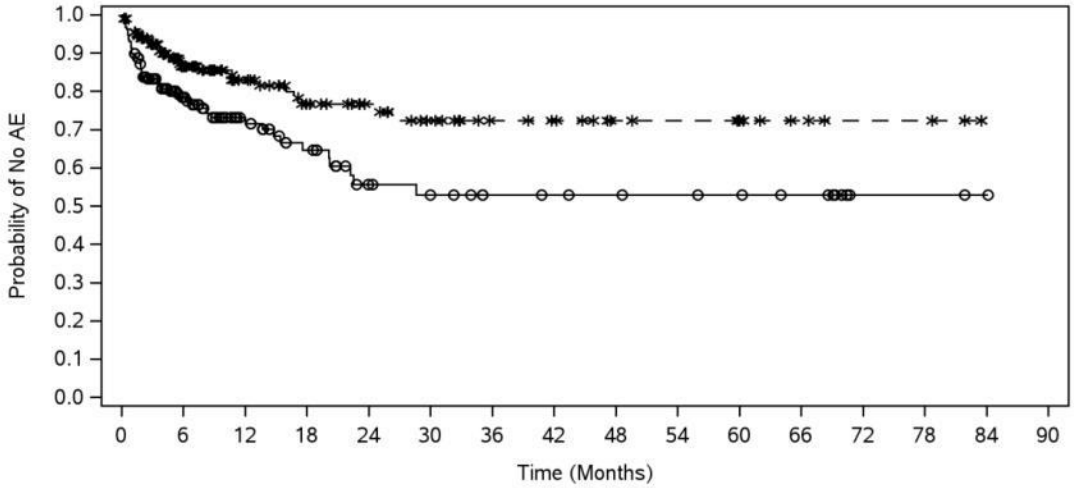
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders

PT: Pruritus



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	96	49	34	21	18	14	13	12	11	10	8	2	2	1	0
(0)	(53)	(95)	(105)	(114)	(116)	(120)	(121)	(122)	(123)	(124)	(126)	(132)	(132)	(133)	(134)

Nivolumab

201	115	61	45	37	28	21	19	14	12	9	6	4	4	0	0
(0)	(62)	(113)	(125)	(133)	(140)	(147)	(149)	(154)	(156)	(159)	(162)	(164)	(164)	(168)	(168)

—o— BMS-986213 (events: 53/187), median and 95% CI: N.A. (20.21, N.A.)

—✳— Nivolumab (events: 33/201), median and 95% CI: N.A.

Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.93 (1.25, 2.98)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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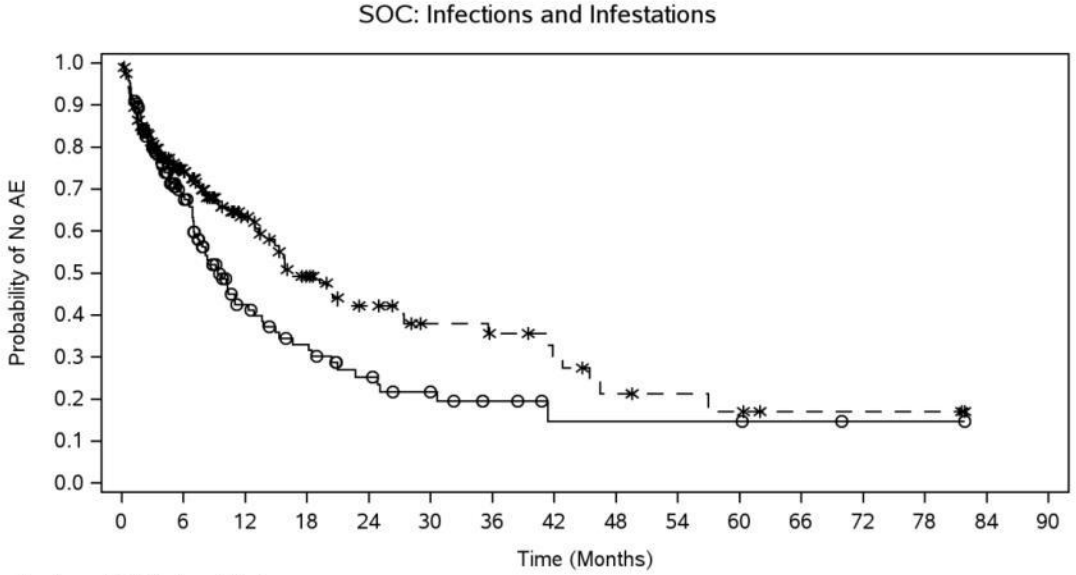
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	88	33	23	15	10	6	3	3	3	3	2	1	1	0	0
	(0)	(44)	(73)	(76)	(79)	(82)	(85)	(87)	(87)	(87)	(87)	(88)	(89)	(89)	(90)	(90)
Nivolumab	201	104	49	31	22	16	14	11	7	5	4	2	2	2	0	0
	(0)	(48)	(92)	(100)	(105)	(109)	(110)	(111)	(112)	(114)	(114)	(116)	(116)	(116)	(118)	(118)

—o— BMS-986213 (events: 97/187), median and 95% CI: 9.30 (7.39, 12.85)
—✱— Nivolumab (events: 83/201), median and 95% CI: 16.39 (13.70, 27.43)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.44 (1.07, 1.94)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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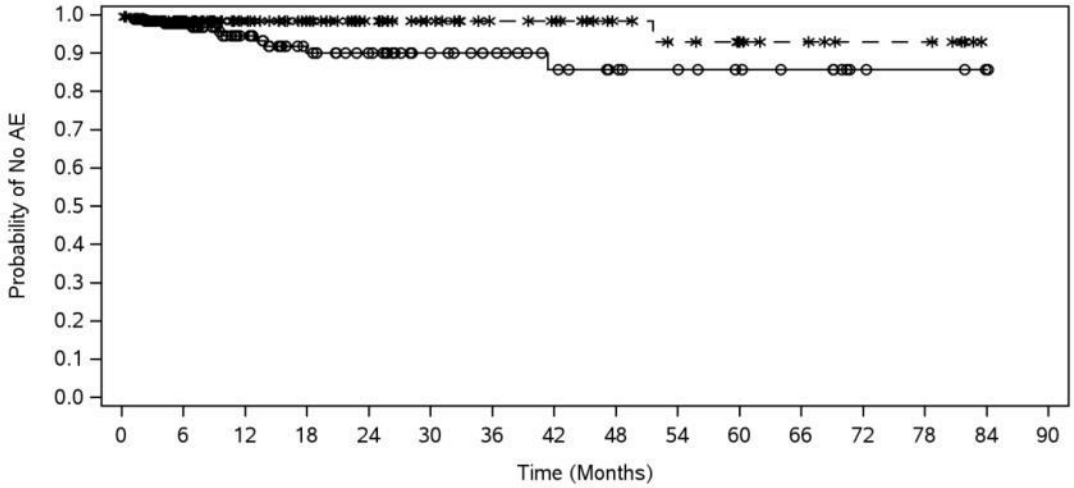
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

PT: Influenza



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	125	75	52	42	31	26	20	16	14	11	9	4	3	1	0
	(0)	(58)	(105)	(125)	(135)	(146)	(151)	(156)	(160)	(162)	(165)	(167)	(172)	(173)	(175)	(176)
Nivolumab	201	135	74	61	48	38	31	29	20	16	12	10	7	7	0	0
	(0)	(63)	(124)	(137)	(150)	(160)	(167)	(169)	(178)	(181)	(185)	(187)	(190)	(190)	(197)	(197)

—o— BMS-986213 (events: 11/187), median and 95% CI: N.A.
—✳— Nivolumab (events: 4/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 3.03 (0.96, 9.53)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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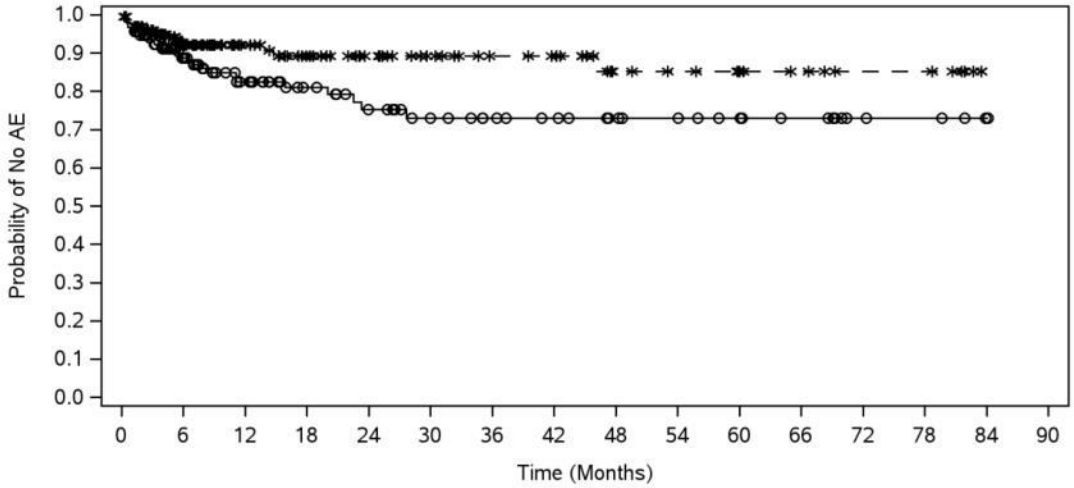
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders

PT: Decreased Appetite



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	114	66	48	37	29	25	22	18	16	13	10	5	4	1	0
	(0)	(54)	(96)	(113)	(121)	(128)	(132)	(135)	(139)	(141)	(144)	(147)	(152)	(153)	(156)	(157)
Nivolumab	201	128	70	56	46	37	31	29	18	16	12	10	7	7	0	0
	(0)	(59)	(117)	(129)	(139)	(148)	(154)	(156)	(166)	(168)	(172)	(174)	(177)	(177)	(184)	(184)

—o— BMS-986213 (events: 30/187), median and 95% CI: N.A.
—✱— Nivolumab (events: 17/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.95 (1.07, 3.53)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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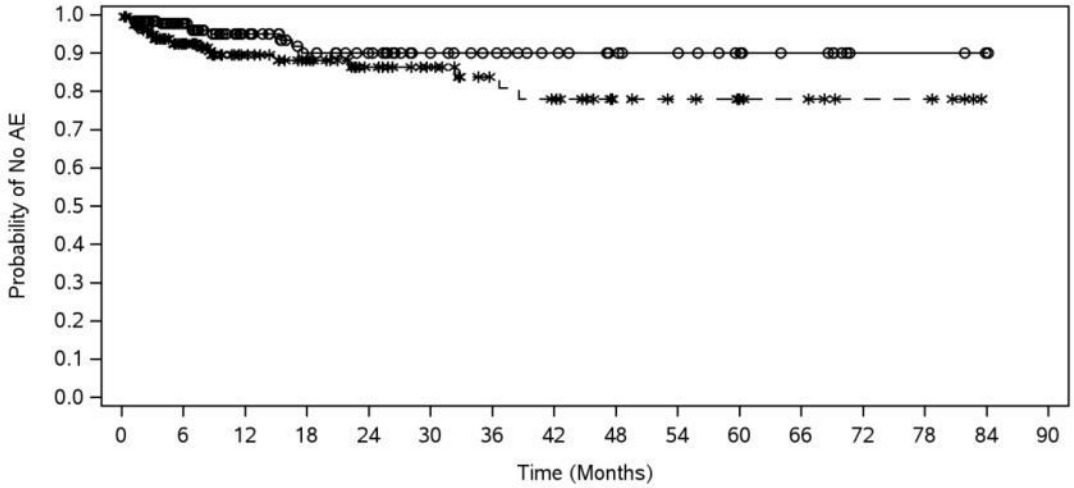
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Metabolism and Nutrition Disorders

PT: Hyperglycaemia



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	126	75	52	42	32	27	22	18	16	12	9	3	3	1	0
(0)	(57)	(105)	(125)	(135)	(145)	(150)	(155)	(159)	(161)	(165)	(168)	(174)	(174)	(176)	(177)

Nivolumab

201	130	69	56	44	37	29	26	17	14	10	9	6	6	0	0
(0)	(57)	(115)	(127)	(138)	(145)	(152)	(153)	(162)	(165)	(169)	(170)	(173)	(173)	(179)	(179)

—o— BMS-986213 (events: 10/187), median and 95% CI: N.A.

— * - Nivolumab (events: 22/201), median and 95% CI: N.A.

Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.47 (0.22, 1.00)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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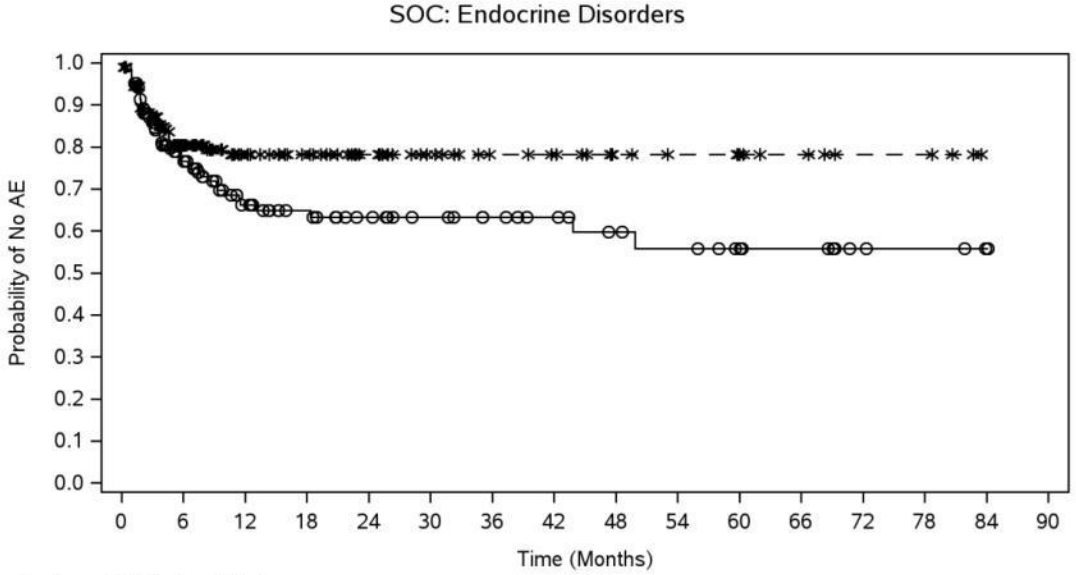
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	99	54	41	32	27	23	20	16	14	11	9	4	3	1	0
	(0)	(48)	(83)	(95)	(103)	(108)	(112)	(115)	(118)	(119)	(122)	(124)	(129)	(130)	(132)	(133)
Nivolumab	201	112	59	50	39	29	23	21	14	12	9	7	4	4	0	0
	(0)	(53)	(104)	(113)	(124)	(134)	(140)	(142)	(149)	(151)	(154)	(156)	(159)	(159)	(163)	(163)

—o— BMS-986213 (events: 54/187), median and 95% CI: N.A. (43.86, N.A.)
—✱— Nivolumab (events: 38/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.54 (1.01, 2.33)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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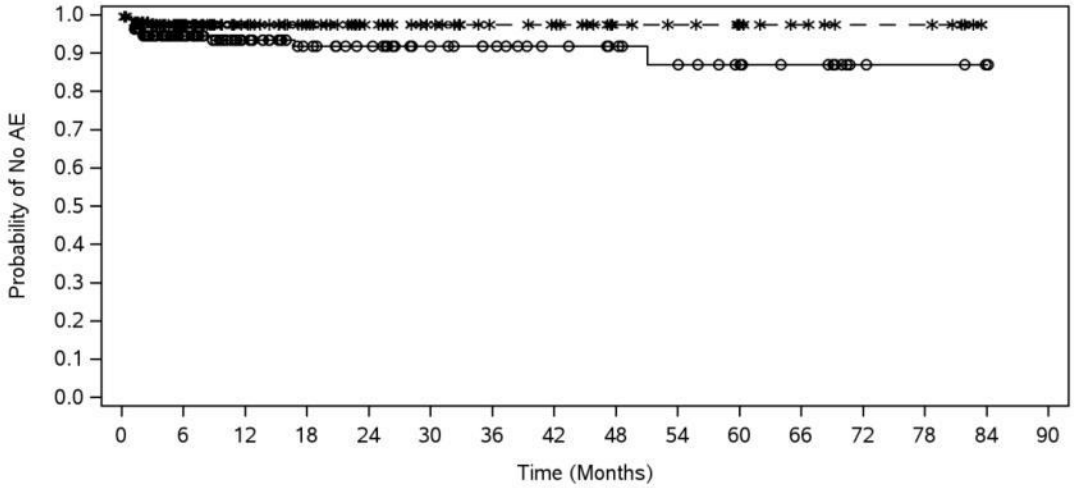
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Injury, Poisoning and Procedural Complications

PT: Infusion Related Reaction



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	120	71	51	43	33	29	24	21	18	14	11	4	3	1	0
(0)	(57)	(105)	(124)	(132)	(142)	(146)	(151)	(154)	(156)	(160)	(163)	(170)	(171)	(173)	(174)

Nivolumab

201	135	75	61	48	39	32	30	20	17	13	10	7	7	0	0
(0)	(61)	(121)	(135)	(148)	(157)	(164)	(166)	(176)	(179)	(183)	(186)	(189)	(189)	(196)	(196)

—o— BMS-986213 (events: 13/187), median and 95% CI: N.A.

—✱— Nivolumab (events: 5/201), median and 95% CI: N.A.

Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.81 (1.00, 7.89)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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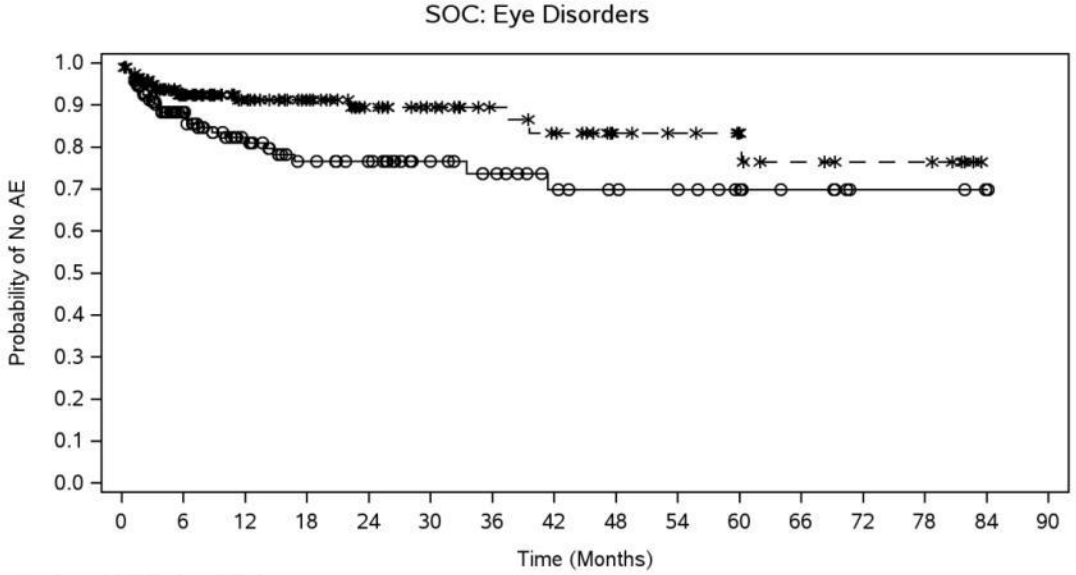
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	112	63	46	39	29	24	18	15	14	10	7	3	3	1	0
(0)	(54)	(97)	(110)	(117)	(127)	(131)	(136)	(139)	(140)	(144)	(147)	(151)	(151)	(153)	(154)

Nivolumab

201	129	73	59	45	37	30	26	18	16	12	9	7	7	0	0
(0)	(58)	(113)	(127)	(140)	(148)	(155)	(157)	(165)	(167)	(171)	(173)	(175)	(175)	(182)	(182)

—o— BMS-986213 (events: 33/187), median and 95% CI: N.A.
—✱— Nivolumab (events: 19/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.97 (1.12, 3.47)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

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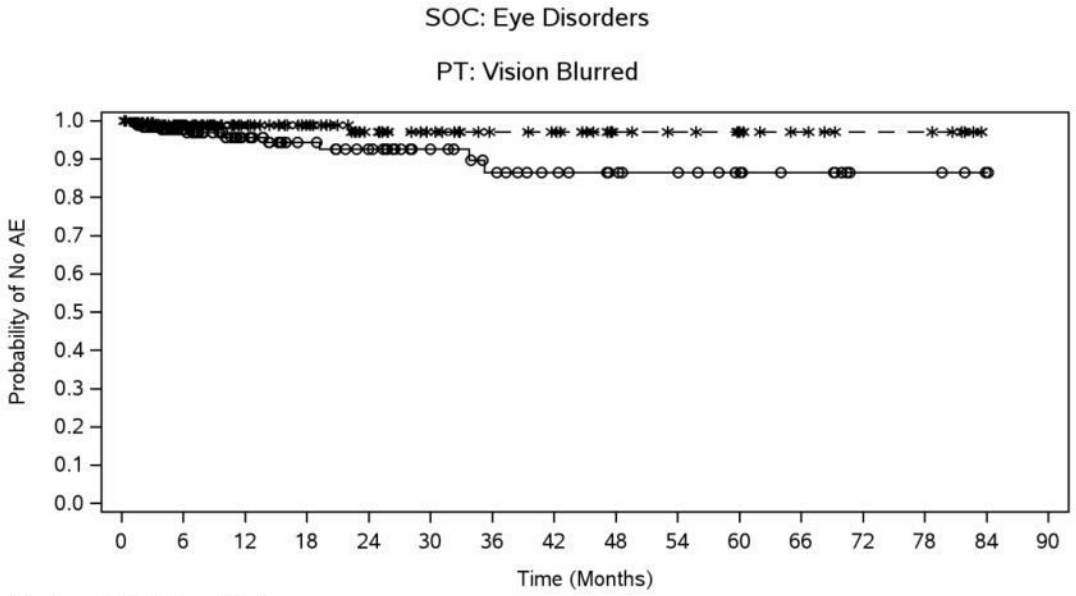
Figure 16.1
Plot of Time to Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	187	125	75	54	44	34	27	22	18	16	12	9	4	4	1	0
	(0)	(58)	(106)	(126)	(135)	(145)	(150)	(155)	(159)	(161)	(165)	(168)	(173)	(173)	(176)	(177)
Nivolumab	201	137	76	62	48	39	32	30	20	17	13	10	7	7	0	0
	(0)	(62)	(123)	(137)	(150)	(159)	(166)	(168)	(178)	(181)	(185)	(188)	(191)	(191)	(198)	(198)

—o— BMS-986213 (events: 10/187), median and 95% CI: N.A.
—✱— Nivolumab (events: 3/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 3.61 (0.99, 13.12)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:25

Anhang 4-G 8.1.3.2.2: Schwere UE (CTCAE-Grad ≥ 3) auf Ebene der SOC und PT

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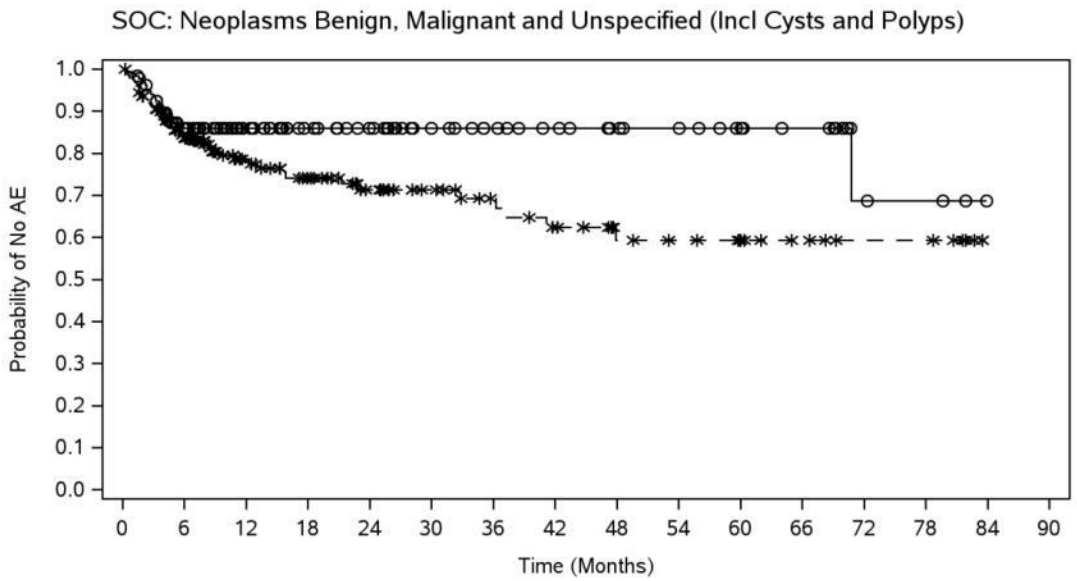
Figure 16.2
Plot of Time to CTCAE Grade 3-4-5 Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	125	76	56	45	34	29	25	21	19	15	12	4	3	0	0
(0)	(37)	(86)	(106)	(117)	(128)	(133)	(137)	(141)	(143)	(147)	(150)	(157)	(158)	(161)	(161)

Nivolumab

201	135	75	60	47	38	31	26	19	17	13	10	7	7	0	0
(0)	(35)	(89)	(100)	(111)	(120)	(126)	(128)	(134)	(136)	(140)	(143)	(146)	(146)	(153)	(153)

—o— BMS-986213 (events: 26/187), median and 95% CI: N.A. (70.77, N.A.)
— * - Nivolumab (events: 48/201), median and 95% CI: N.A. (47.90, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.57 (0.35, 0.92)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:50

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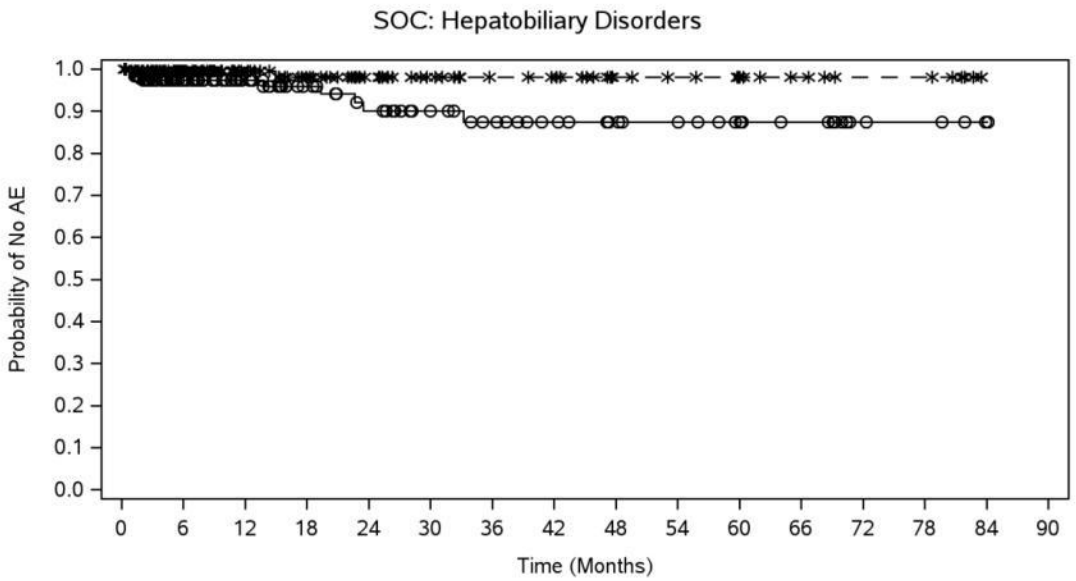
Figure 16.2
Plot of Time to CTCAE Grade 3-4-5 Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	126	78	56	44	35	30	25	21	19	15	12	5	4	1	0
(0)	(56)	(104)	(125)	(134)	(143)	(147)	(152)	(156)	(158)	(162)	(165)	(172)	(173)	(176)	(177)

Nivolumab

201	138	76	61	48	38	32	30	20	17	13	10	7	7	0	0
(0)	(62)	(124)	(138)	(151)	(161)	(167)	(169)	(179)	(182)	(186)	(189)	(192)	(192)	(199)	(199)

—o— BMS-986213 (events: 10/187), median and 95% CI: N.A.
— * - Nivolumab (events: 2/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 5.33 (1.17, 24.32)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:50

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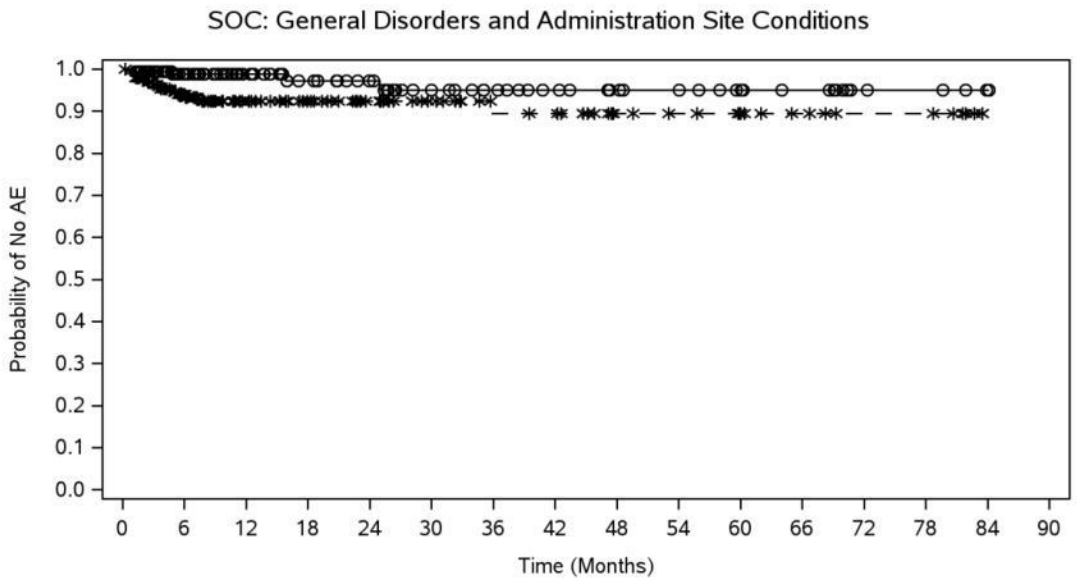
Figure 16.2
Plot of Time to CTCAE Grade 3-4-5 Adverse Event - Including Significant SOC/PT - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213

187	128	78	57	46	35	30	25	21	19	15	12	5	4	1	0
(0)	(57)	(107)	(127)	(138)	(148)	(153)	(158)	(162)	(164)	(168)	(171)	(178)	(179)	(182)	(183)

Nivolumab

201	136	74	60	48	38	30	29	19	17	13	10	7	7	0	0
(0)	(54)	(114)	(128)	(140)	(150)	(157)	(158)	(168)	(170)	(174)	(177)	(180)	(180)	(187)	(187)

—o— BMS-986213 (events: 4/187), median and 95% CI: N.A.
— * - Nivolumab (events: 14/201), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.30 (0.10, 0.91)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between the first dose and 100 days after the last dose of the study therapy.
Unstratified cox proportional hazards model.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsocsig-ebr2586_b5.sas 23FEB2026:06:18:50

Anhang 4-G 8.2: Kaplan-Meier-Kurven auf Subgruppenebene (nur bei signifikantem Interaktionsterm)

Anhang 4-G 8.2.1: EQ-5D-VAS − Zeit bis zur bestätigten Verschlechterung

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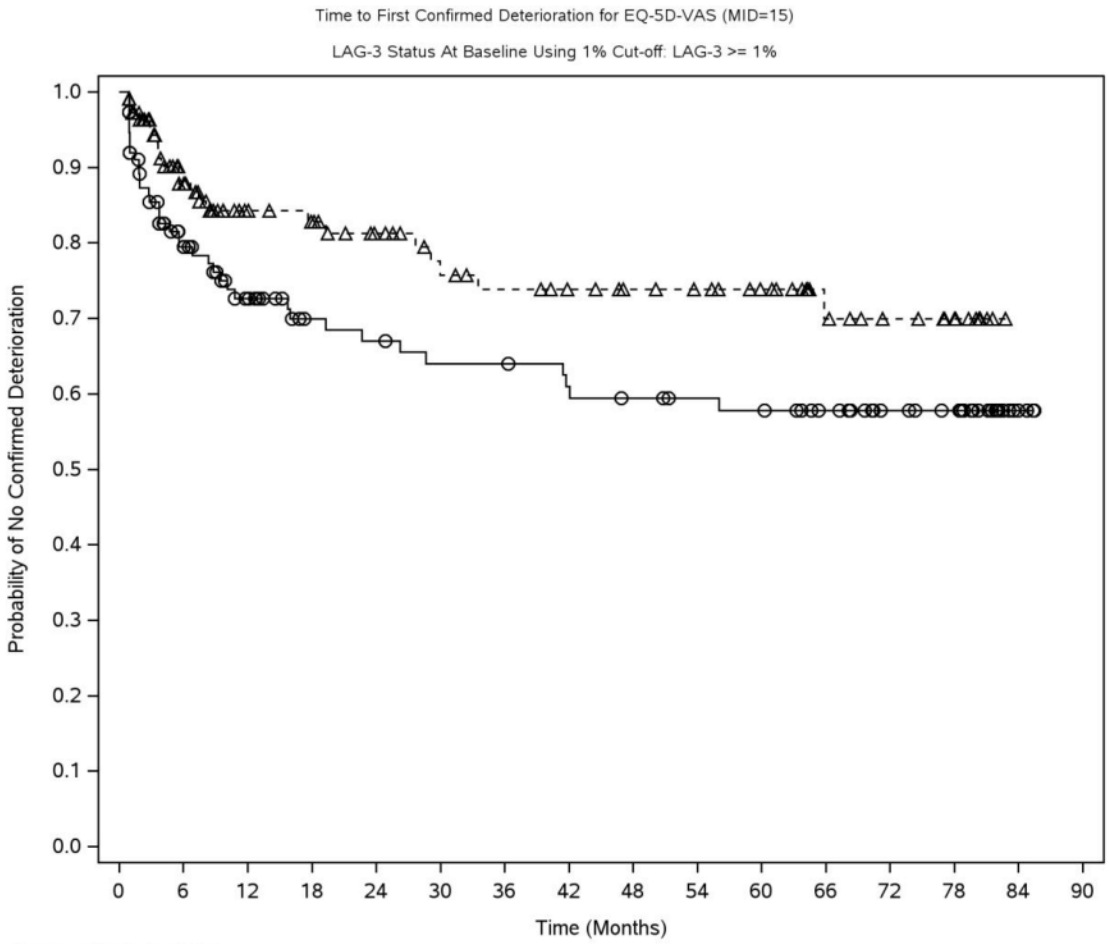
Figure 7.4
Subgroup Plots of EQ-5D VAS Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	113	76	60	48	46	43	43	40	38	36	35	30	23	20	3	0
	(0)	(15)	(25)	(35)	(35)	(36)	(36)	(37)	(38)	(40)	(40)	(45)	(52)	(55)	(72)	(75)
Nivolumab	112	78	59	55	48	41	38	35	32	30	26	18	14	10	0	0
	(0)	(22)	(38)	(41)	(47)	(51)	(53)	(56)	(59)	(61)	(65)	(72)	(76)	(80)	(90)	(90)

—o— BMS-986213 (events: 38/113), median and 95% CI: N.A. (41.76, N.A.)
- -Δ- - Nivolumab (events: 22/112), median and 95% CI: N.A.

Hazard Ratio (BMS-986213 vs Nivolumab) and 95% CI: 1.83 (1.08, 3.10),
p-value: 0.0238

NOV 2025 DBL. Symbols represent censored observations.
Unstratified Cox proportional hazard model
with baseline PRO score as covariate.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-tfdsub-ebr2586_b5.sas 13FEB2026:07:03:52

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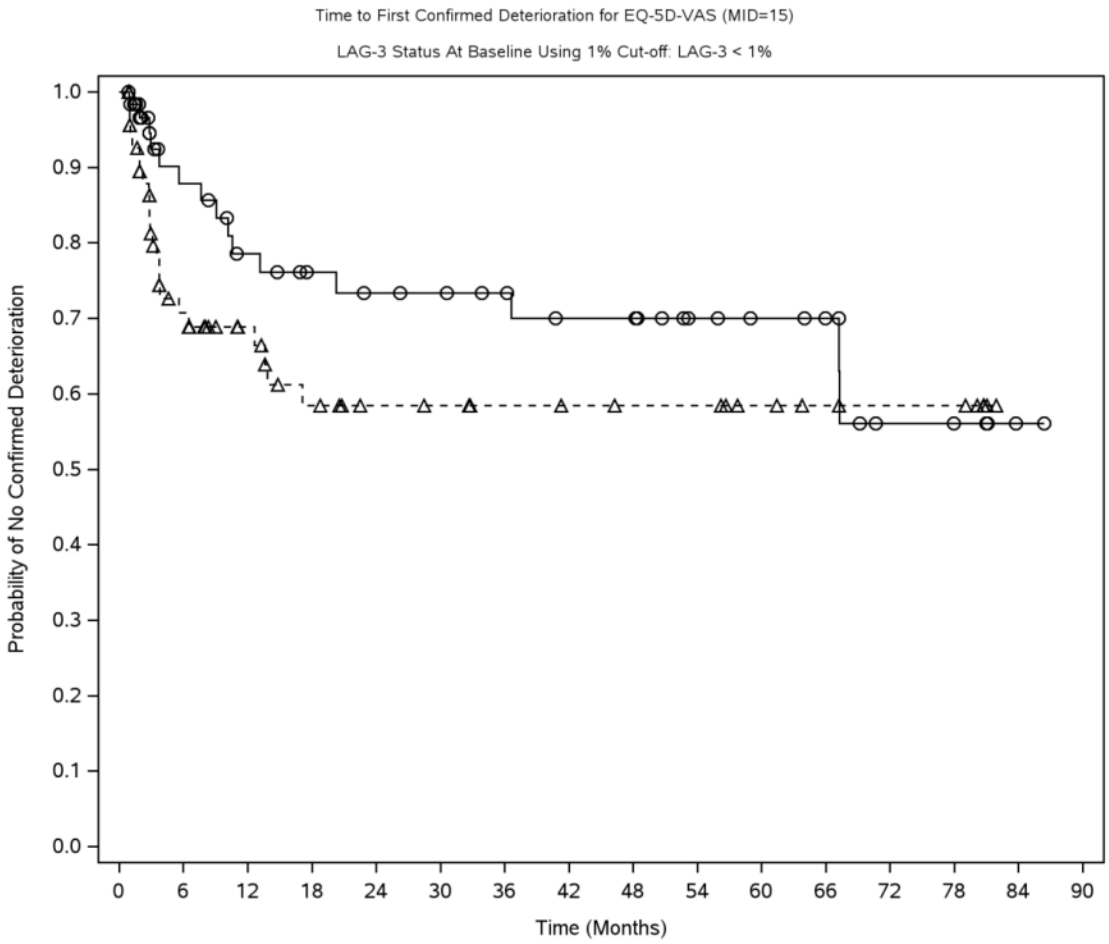
Figure 7.4
Subgroup Plots of EQ-5D VAS Time to First Confirmed Deterioration - All Randomized Subjects with Quantifiable PD-L1 < 1% (CRF) - Only Subjects with Baseline and >=1 Post-Baseline Value of the PRO Score Non-Missing



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	61	39	32	28	26	25	23	20	20	15	13	11	6	5	1	0
	(0)	(16)	(19)	(22)	(23)	(24)	(26)	(28)	(28)	(33)	(35)	(37)	(40)	(41)	(45)	(46)
Nivolumab	71	38	28	21	17	16	14	13	12	12	9	7	6	6	0	0
	(0)	(15)	(24)	(27)	(31)	(32)	(34)	(35)	(36)	(36)	(39)	(41)	(42)	(42)	(48)	(48)

—o— BMS-986213 (events: 15/61), median and 95% CI: N.A. (67.22, N.A.)
- -Δ- - Nivolumab (events: 23/71), median and 95% CI: N.A. (13.60, N.A.)
Hazard Ratio (BMS-986213 vs Nivolumab) and 95% CI: 0.59 (0.31, 1.14),
p-value: 0.1196

NOV 2025 DBL. Symbols represent censored observations.
Unstratified Cox proportional hazard model
with baseline PRO score as covariate.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-sy-tfdsub-ebr2586_b5.sas 13FEB2026:07:03:52

Anhang 4-G 8.2.2: UE − Zeit bis zum ersten Ereignis

Anhang 4-G 8.2.2.1: UE-Hauptkategorien

Anhang 4-G 8.2.2.1.1: SUE

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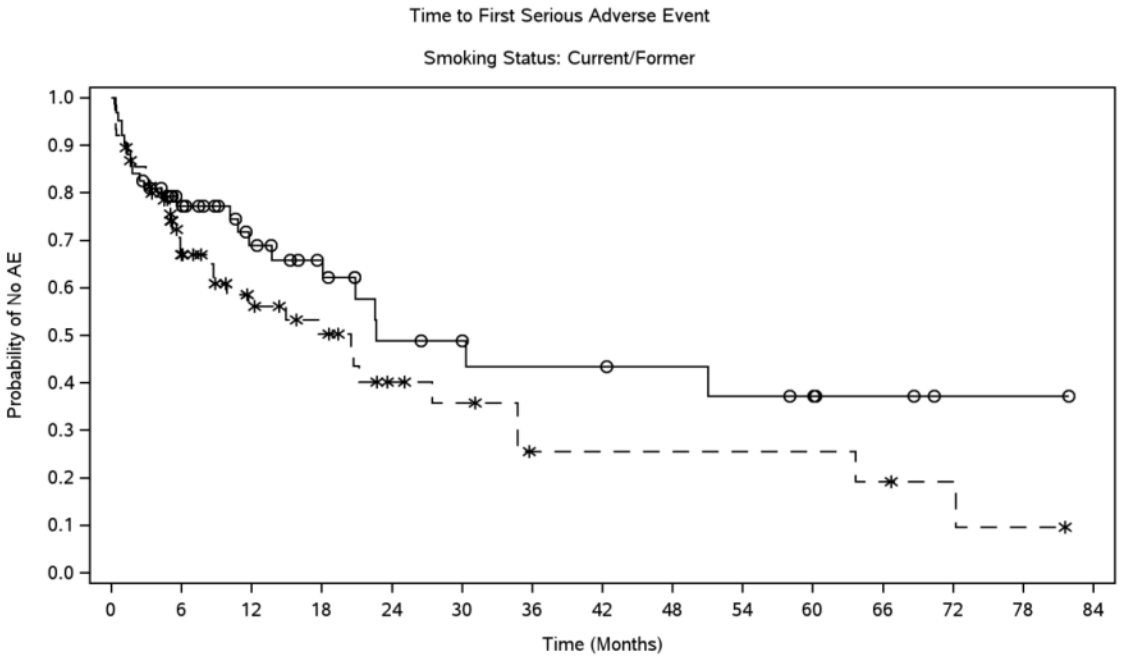
Figure 15.2
Subgroup Plots of Time to first Serious Adverse Event - Excluding Progression Terms - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	63	38	24	18	11	9	8	8	7	6	5	3	1	1	0
	(0)	(11)	(22)	(27)	(30)	(32)	(32)	(32)	(33)	(33)	(34)	(36)	(38)	(38)	(39)
Nivolumab	76	38	22	17	10	8	4	4	4	4	4	3	2	1	0
	(0)	(15)	(26)	(29)	(33)	(34)	(36)	(36)	(36)	(36)	(36)	(36)	(37)	(37)	(38)

—o— BMS-986213 (events: 24/63), median and 95% CI: 22.64 (18.07, N.A.)
— * - Nivolumab (events: 38/76), median and 95% CI: 20.50 (8.71, 34.73)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.67 (0.40, 1.13)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of the study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsig-ebr2586_b5.sas 23FEB2026:06:18:01

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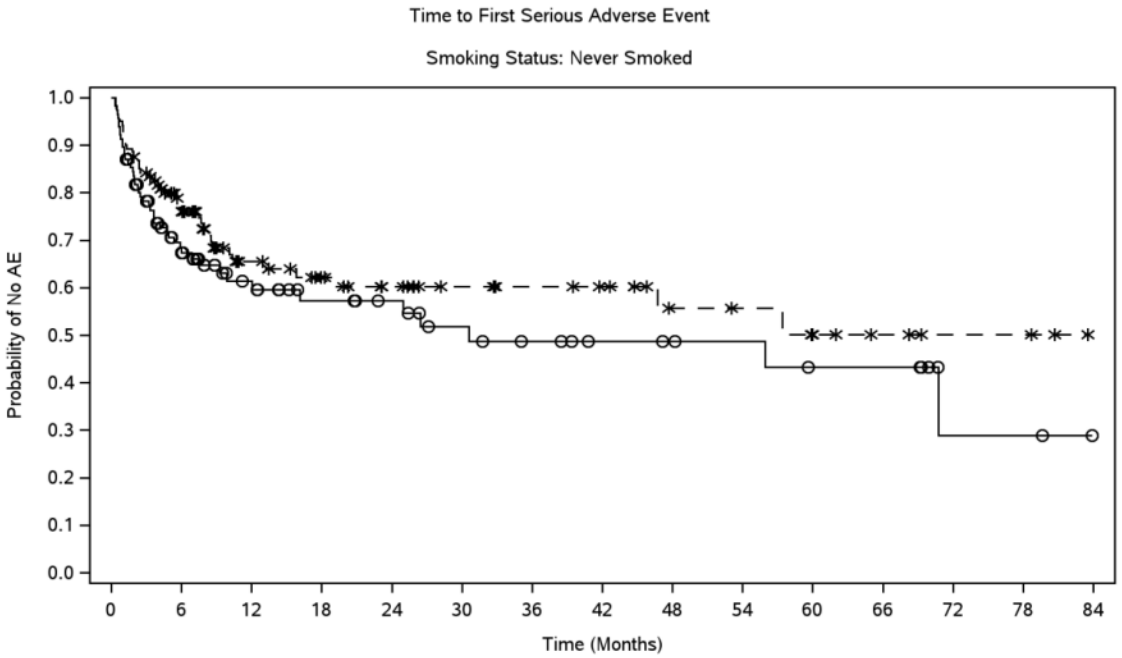
Figure 15.2
Subgroup Plots of Time to first Serious Adverse Event - Excluding Progression Terms - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	116	62	34	25	22	17	14	11	10	9	7	7	2	2	0
	(0)	(18)	(42)	(49)	(52)	(55)	(57)	(60)	(61)	(62)	(63)	(63)	(67)	(67)	(69)
Nivolumab	121	79	42	33	27	21	19	17	11	10	7	5	3	3	0
	(0)	(14)	(43)	(50)	(55)	(61)	(63)	(65)	(70)	(71)	(73)	(75)	(77)	(77)	(80)

—o— BMS-986213 (events: 47/116), median and 95% CI: 30.62 (12.02, N.A.)
— * - Nivolumab (events: 41/121), median and 95% CI: N.A. (19.25, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.33 (0.88, 2.03)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of the study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsig-ebr2586_b5.sas 23FEB2026:06:18:01

Anhang 4-G 8.2.2.2: UE auf Ebene der SOC und PT

Anhang 4-G 8.2.2.2.1: Jegliche UE auf Ebene der SOC und PT

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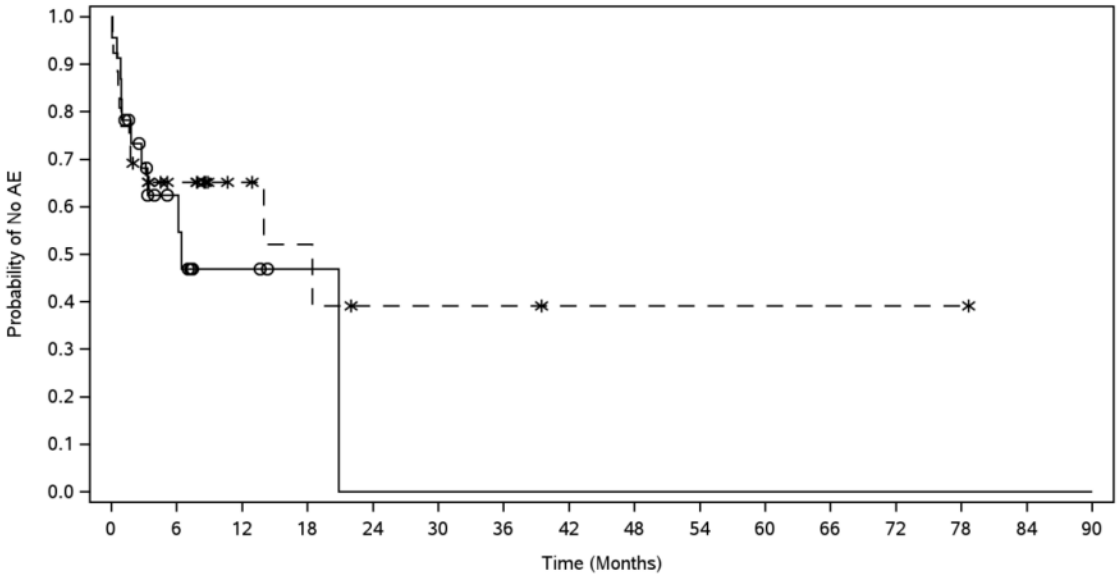
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

Histology (Disease Subtype): Cutaneous Acral



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	23	8	3	1	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(7)	(10)	(12)	(12)	(12)	(12)	(12)	(12)	(12)	(12)	(12)	(12)	(12)	(12)	(12)
Nivolumab	26	12	6	4	2	2	2	1	1	1	1	1	1	1	0	0
	(0)	(5)	(11)	(12)	(13)	(13)	(13)	(14)	(14)	(14)	(14)	(14)	(14)	(14)	(15)	(15)

—o— BMS-986213 (events: 11/23), median and 95% CI: 6.41 (1.81, N.A.)
— * - Nivolumab (events: 11/26), median and 95% CI: 18.46 (1.74, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.33 (0.57, 3.11)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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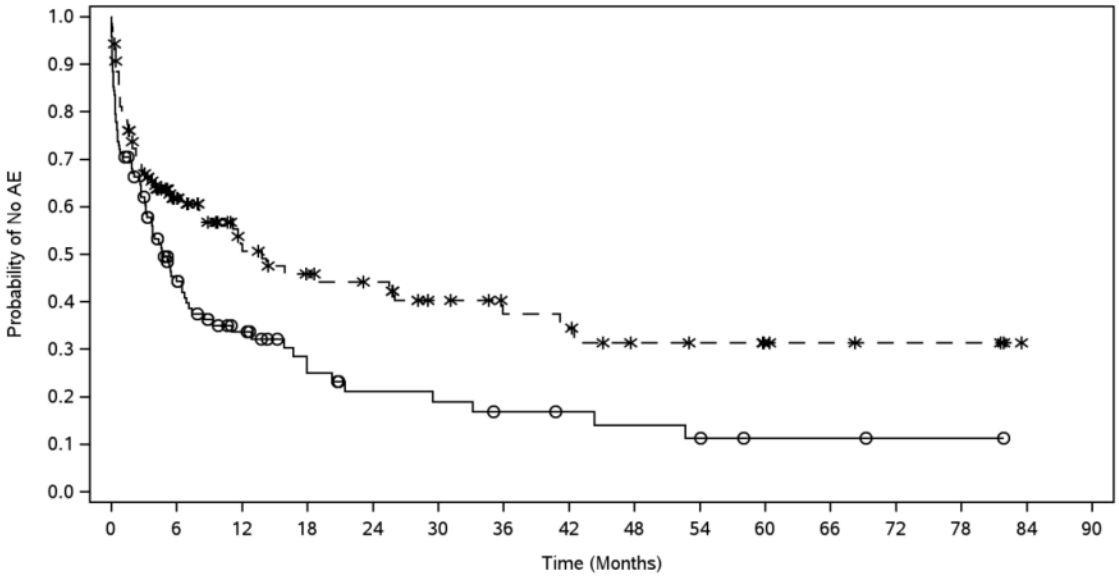
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

Histology (Disease Subtype): Cutaneous Non-Acral



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	122	42	24	14	10	9	7	6	5	4	2	2	1	1	0	0
	(0)	(15)	(24)	(29)	(31)	(31)	(32)	(33)	(33)	(33)	(35)	(35)	(36)	(36)	(37)	(37)
Nivolumab	139	60	34	27	24	17	13	12	8	7	5	4	3	3	0	0
	(0)	(28)	(47)	(50)	(52)	(57)	(60)	(60)	(63)	(64)	(66)	(67)	(68)	(68)	(71)	(71)

—o— BMS-986213 (events: 85/122), median and 95% CI: 4.80 (3.19, 6.70)
— * - Nivolumab (events: 68/139), median and 95% CI: 13.80 (8.21, 35.91)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.68 (1.22, 2.32)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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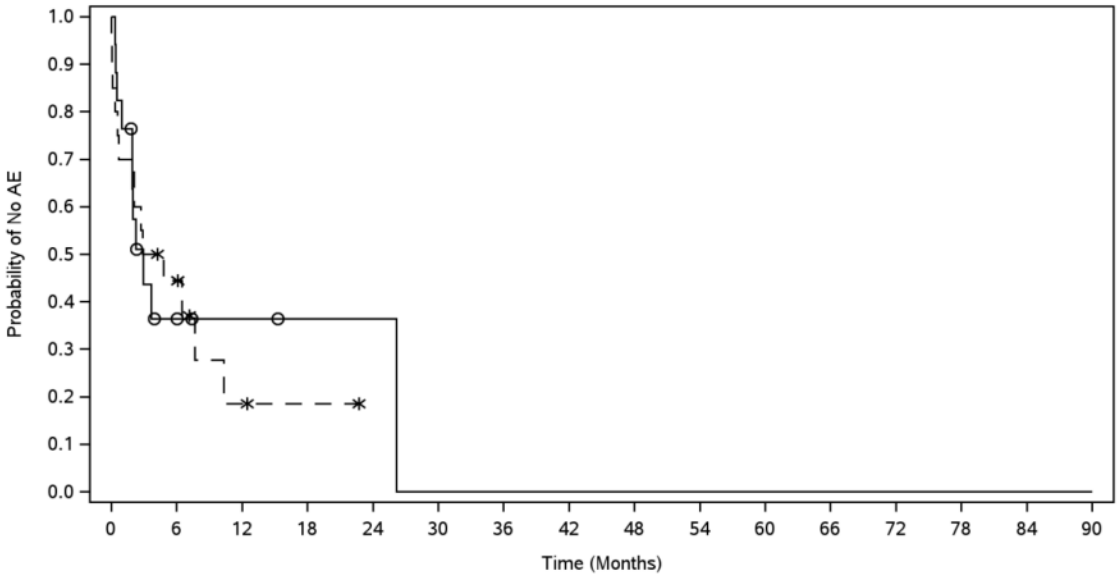
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

Histology (Disease Subtype): Mucosal



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	17	4	2	1	1	0	0	0	0	0	0	0	0	0	0	0
	(0)	(3)	(5)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)
Nivolumab	20	8	2	1	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(1)	(4)	(5)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)

—o— BMS-986213 (events: 11/17), median and 95% CI: 2.96 (0.99, N.A.)
— * - Nivolumab (events: 14/20), median and 95% CI: 3.83 (0.59, 10.35)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.95 (0.42, 2.14)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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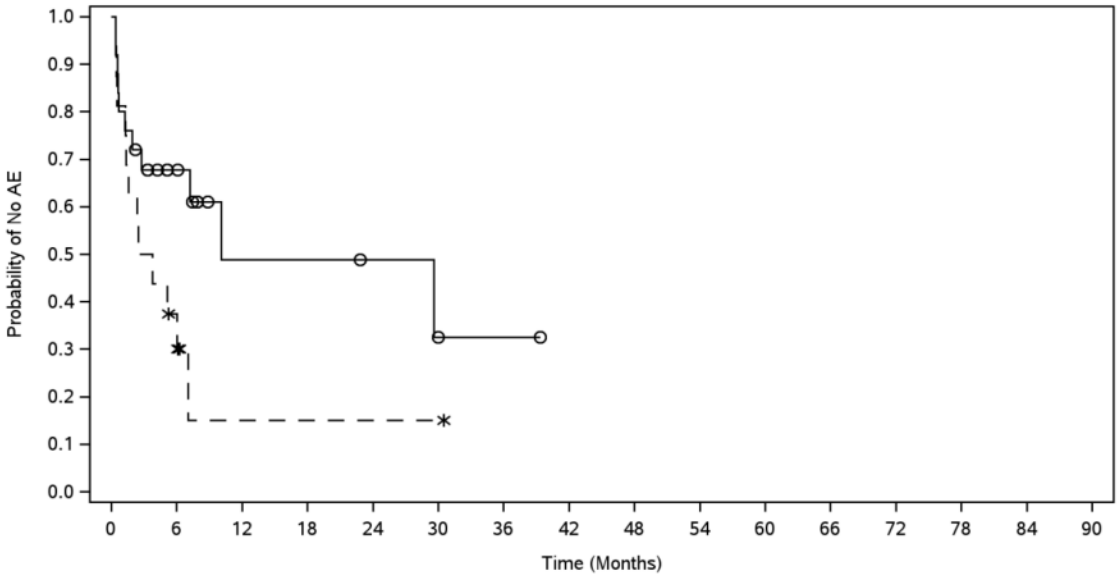
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Gastrointestinal Disorders

Histology (Disease Subtype): Other



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	25	11	4	4	3	1	1	0	0	0	0	0	0	0	0	0
	(0)	(6)	(11)	(11)	(12)	(13)	(13)	(14)	(14)	(14)	(14)	(14)	(14)	(14)	(14)	(14)
Nivolumab	16	5	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	(0)	(1)	(3)	(3)	(3)	(3)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)

—o— BMS-986213 (events: 11/25), median and 95% CI: 10.12 (2.79, N.A.)
— * - Nivolumab (events: 12/16), median and 95% CI: 3.14 (1.31, 7.03)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.44 (0.19, 1.03)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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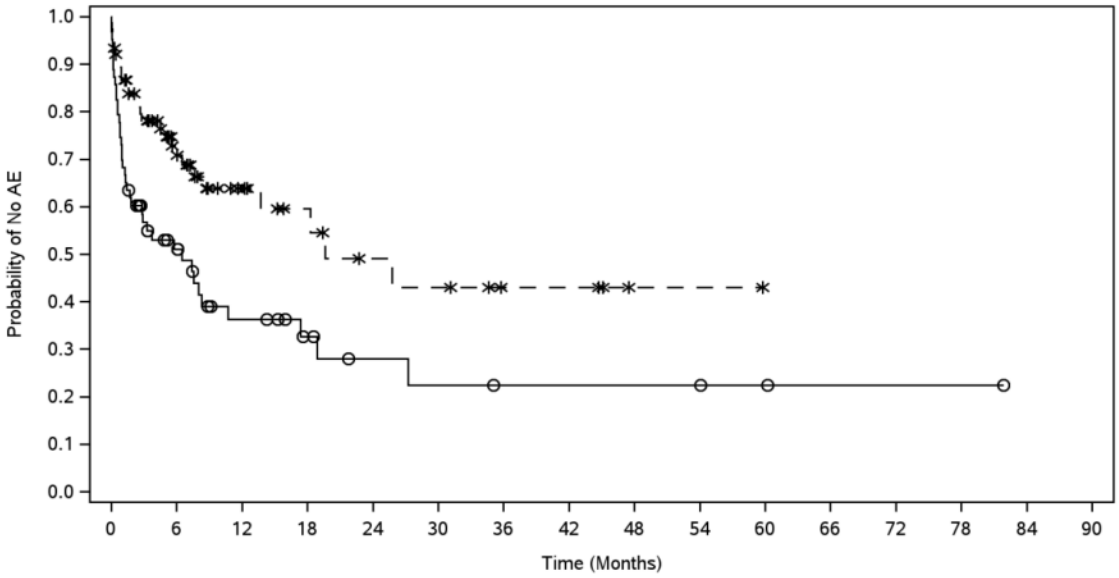
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

Smoking Status: Current/Former



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	63	25	13	8	5	4	3	3	3	3	2	1	1	1	0	0
	(0)	(8)	(14)	(18)	(20)	(20)	(21)	(21)	(21)	(21)	(22)	(23)	(23)	(23)	(24)	(24)
Nivolumab	76	35	17	12	8	7	4	4	1	1	0	0	0	0	0	0
	(0)	(21)	(36)	(40)	(42)	(42)	(45)	(45)	(48)	(48)	(49)	(49)	(49)	(49)	(49)	(49)

—o— BMS-986213 (events: 39/63), median and 95% CI: 6.47 (1.71, 10.71)
— * - Nivolumab (events: 27/76), median and 95% CI: 19.65 (8.57, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.05 (1.26, 3.36)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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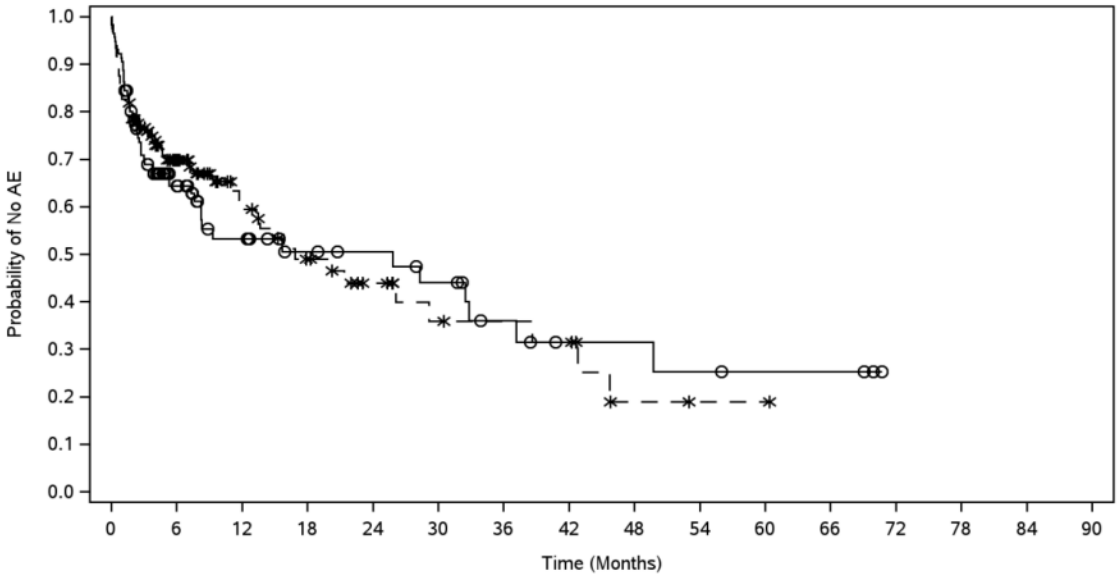
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders

Smoking Status: Never Smoked



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	116	50	26	18	16	13	8	5	5	4	3	3	0	0	0	0
	(0)	(27)	(45)	(52)	(54)	(55)	(58)	(60)	(60)	(60)	(61)	(61)	(64)	(64)	(64)	(64)
Nivolumab	121	62	32	21	14	9	8	7	2	1	1	0	0	0	0	0
	(0)	(24)	(49)	(54)	(59)	(62)	(63)	(63)	(66)	(67)	(67)	(68)	(68)	(68)	(68)	(68)

—o— BMS-986213 (events: 52/116), median and 95% CI: 25.82 (8.21, 37.19)
— * - Nivolumab (events: 53/121), median and 95% CI: 16.85 (12.02, 38.64)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.04 (0.71, 1.53)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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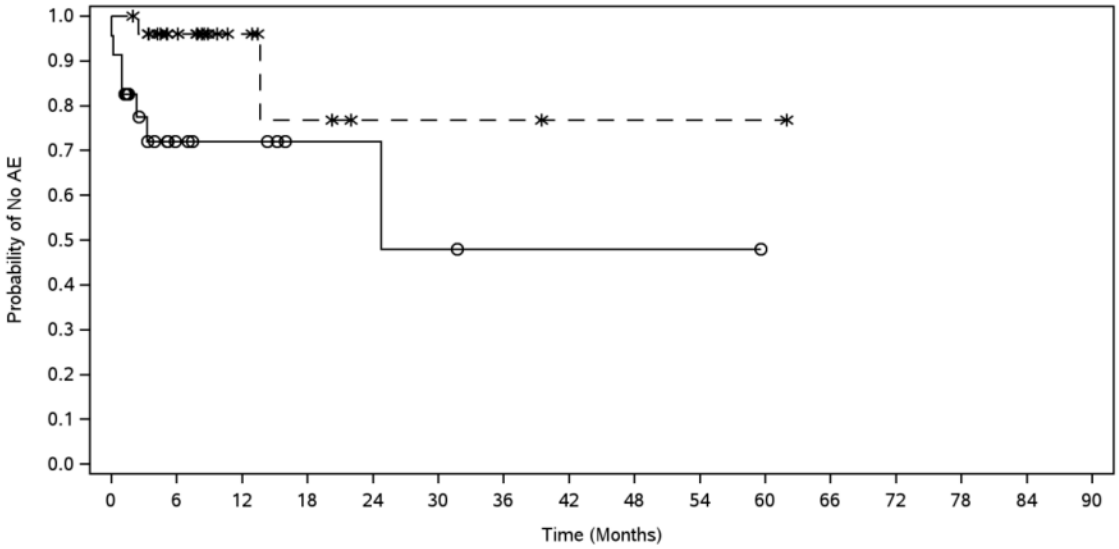
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Histology (Disease Subtype): Cutaneous Acral



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	23	8	6	3	3	2	1	1	1	1	0	0	0	0	0	0
	(0)	(9)	(11)	(14)	(14)	(14)	(15)	(15)	(15)	(15)	(16)	(16)	(16)	(16)	(16)	(16)
Nivolumab	26	17	7	4	2	2	2	1	1	1	1	0	0	0	0	0
	(0)	(8)	(18)	(20)	(22)	(22)	(22)	(23)	(23)	(23)	(23)	(24)	(24)	(24)	(24)	(24)

—o— BMS-986213 (events: 7/23), median and 95% CI: 24.77 (3.25, N.A.)
— * - Nivolumab (events: 2/26), median and 95% CI: N.A. (13.63, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 4.32 (0.89, 21.01)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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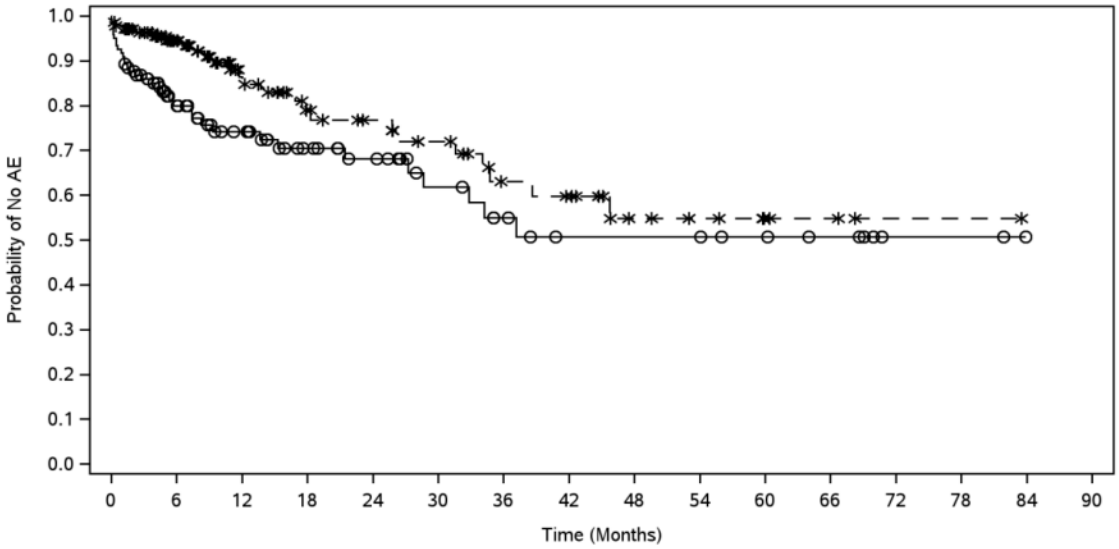
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Histology (Disease Subtype): Cutaneous Non-Acral



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	122	72	46	33	27	19	14	10	10	10	8	6	2	2	0	0
	(0)	(27)	(49)	(60)	(65)	(71)	(74)	(77)	(77)	(77)	(79)	(81)	(85)	(85)	(87)	(87)
Nivolumab	139	91	52	38	33	27	19	17	9	7	4	3	1	1	0	0
	(0)	(41)	(74)	(84)	(88)	(92)	(97)	(98)	(105)	(107)	(110)	(111)	(113)	(113)	(114)	(114)

—o— BMS-986213 (events: 35/122), median and 95% CI: N.A. (28.65, N.A.)
— * - Nivolumab (events: 25/139), median and 95% CI: N.A. (34.73, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.73 (1.04, 2.90)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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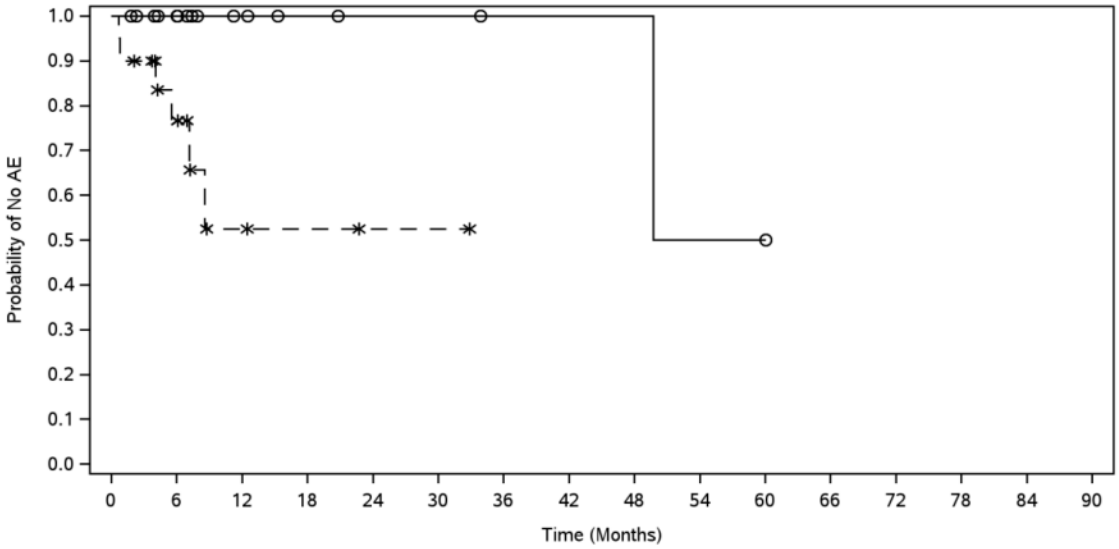
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Histology (Disease Subtype): Mucosal



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	17	13	6	4	3	3	2	2	2	1	1	0	0	0	0	0
	(0)	(4)	(11)	(13)	(14)	(14)	(15)	(15)	(15)	(15)	(15)	(16)	(16)	(16)	(16)	(16)
Nivolumab	20	11	3	2	1	1	0	0	0	0	0	0	0	0	0	0
	(0)	(5)	(11)	(12)	(13)	(13)	(14)	(14)	(14)	(14)	(14)	(14)	(14)	(14)	(14)	(14)

—o— BMS-986213 (events: 1/17), median and 95% CI: N.A. (49.74, N.A.)
— * - Nivolumab (events: 6/20), median and 95% CI: N.A. (5.52, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: <0.01 (<0.01, N.A.)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
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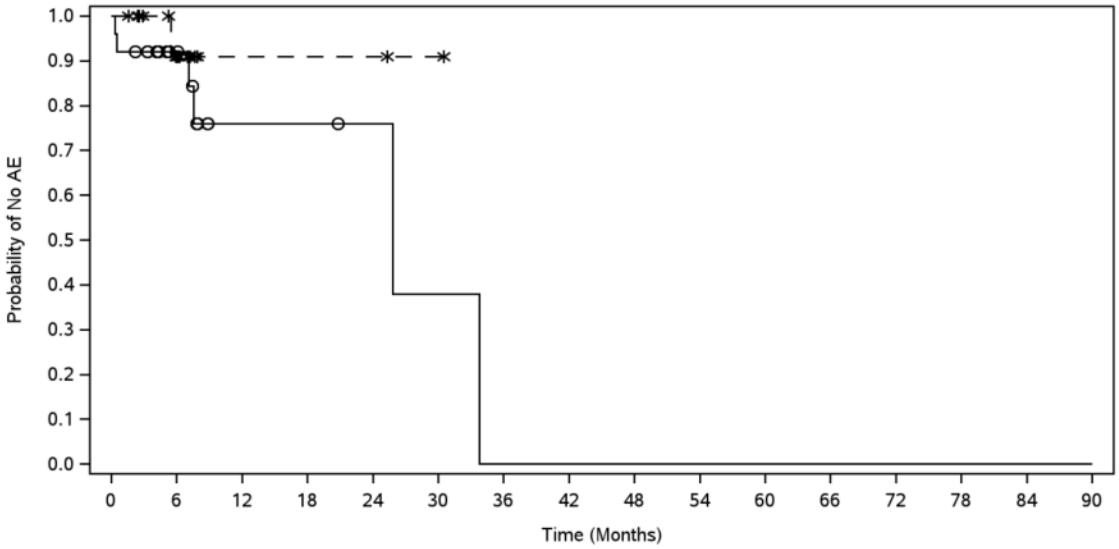
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Musculoskeletal and Connective Tissue Disorders
PT: Arthralgia

Histology (Disease Subtype): Other



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	25	13	3	3	2	1	0	0	0	0	0	0	0	0	0	0
	(0)	(10)	(18)	(18)	(19)	(19)	(19)	(19)	(19)	(19)	(19)	(19)	(19)	(19)	(19)	(19)
Nivolumab	16	9	2	2	2	1	0	0	0	0	0	0	0	0	0	0
	(0)	(6)	(13)	(13)	(13)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)

—o— BMS-986213 (events: 6/25), median and 95% CI: 25.82 (7.56, N.A.)
— * - Nivolumab (events: 1/16), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.86 (0.33, 24.71)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
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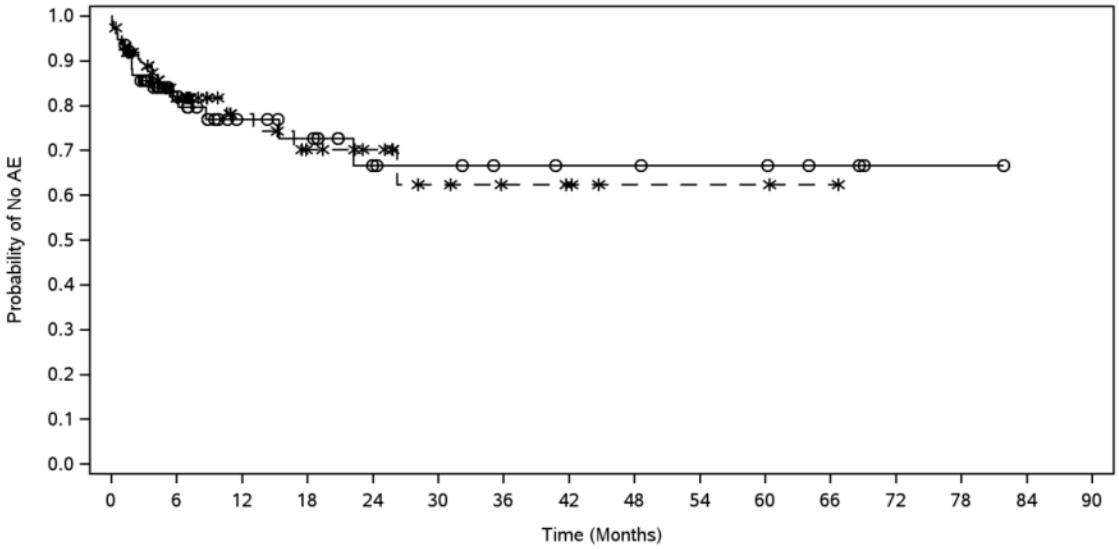
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders
PT: Pruritus

BRAF Mutation Status: BRAF Mutant



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	77	42	20	17	10	9	7	6	6	5	5	3	1	1	0	0
	(0)	(22)	(42)	(44)	(50)	(51)	(53)	(54)	(54)	(55)	(55)	(57)	(59)	(59)	(60)	(60)
Nivolumab	75	38	20	15	12	7	5	4	2	2	2	1	0	0	0	0
	(0)	(25)	(42)	(45)	(48)	(52)	(54)	(55)	(57)	(57)	(57)	(58)	(59)	(59)	(59)	(59)

—o— BMS-986213 (events: 17/77), median and 95% CI: N.A. (22.24, N.A.)
— * - Nivolumab (events: 16/75), median and 95% CI: N.A. (26.25, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.04 (0.52, 2.05)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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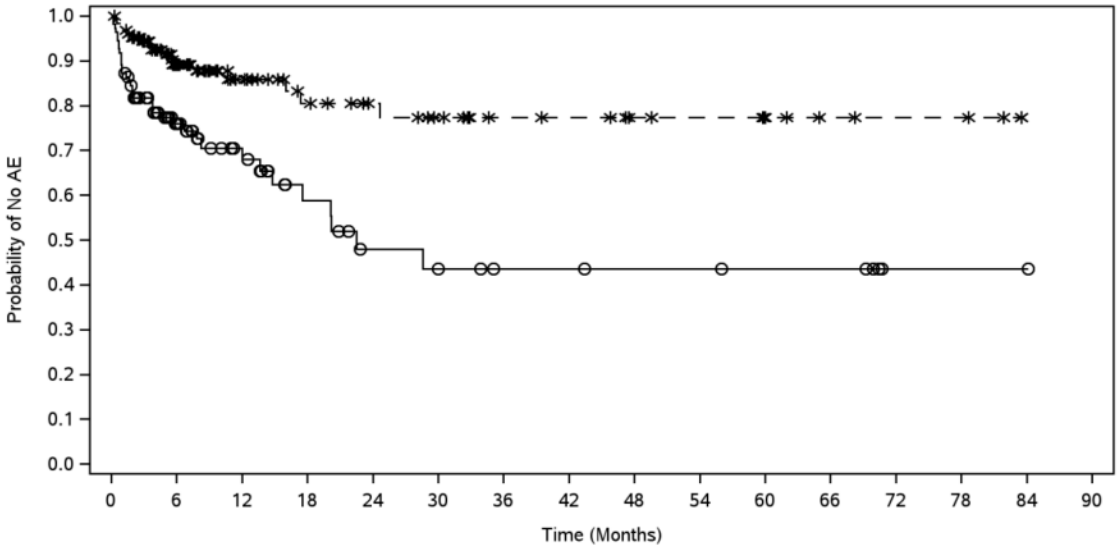
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Skin and Subcutaneous Tissue Disorders
PT: Pruritus

BRAF Mutation Status: BRAF Wildtype



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	110	54	29	17	11	9	7	7	6	6	5	5	1	1	1	0
	(0)	(31)	(53)	(61)	(64)	(65)	(67)	(67)	(68)	(68)	(69)	(69)	(73)	(73)	(73)	(74)
Nivolumab	126	77	41	30	25	21	16	15	12	10	7	5	4	4	0	0
	(0)	(37)	(71)	(80)	(85)	(88)	(93)	(94)	(97)	(99)	(102)	(104)	(105)	(105)	(109)	(109)

—o— BMS-986213 (events: 36/110), median and 95% CI: 22.51 (14.78, N.A.)
— * - Nivolumab (events: 17/126), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.92 (1.64, 5.21)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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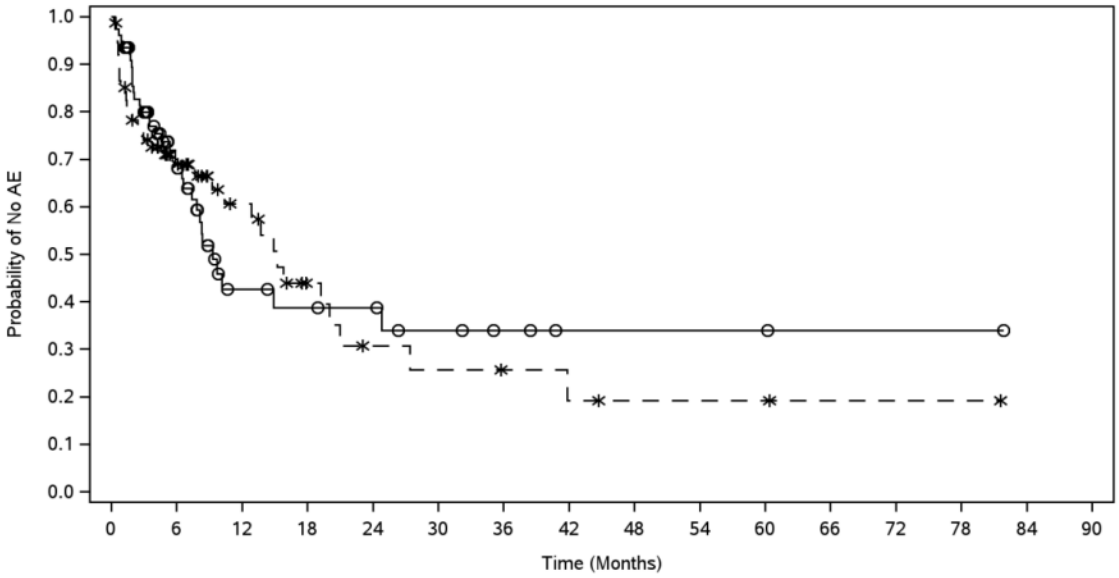
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

BRAF Mutation Status: BRAF Mutant



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	77	37	12	10	9	6	4	2	2	2	2	1	1	1	0	0
	(0)	(19)	(33)	(34)	(35)	(37)	(39)	(41)	(41)	(41)	(41)	(42)	(42)	(42)	(43)	(43)
Nivolumab	75	35	19	10	6	5	4	3	2	2	2	1	1	1	0	0
	(0)	(18)	(31)	(35)	(36)	(36)	(37)	(37)	(38)	(38)	(38)	(39)	(39)	(39)	(40)	(40)

—o— BMS-986213 (events: 34/77), median and 95% CI: 9.30 (7.39, 24.84)
— * - Nivolumab (events: 35/75), median and 95% CI: 15.21 (9.23, 20.99)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.98 (0.61, 1.57)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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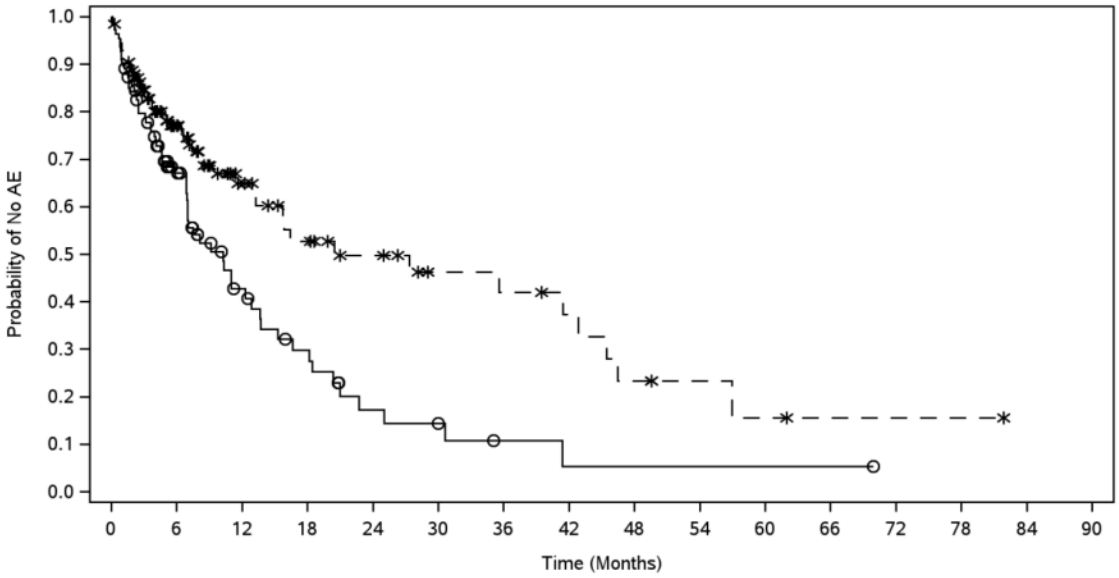
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

BRAF Mutation Status: BRAF Wildtype



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	110	51	21	13	6	4	2	1	1	1	1	1	0	0	0	0
	(0)	(25)	(40)	(42)	(44)	(45)	(46)	(46)	(46)	(46)	(46)	(46)	(47)	(47)	(47)	(47)
Nivolumab	126	69	30	21	16	11	10	8	5	3	2	1	1	1	0	0
	(0)	(30)	(61)	(65)	(69)	(73)	(73)	(74)	(74)	(76)	(76)	(77)	(77)	(77)	(78)	(78)

—o— BMS-986213 (events: 63/110), median and 95% CI: 10.25 (7.00, 13.63)
— * - Nivolumab (events: 48/126), median and 95% CI: 20.50 (13.27, 42.84)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.89 (1.29, 2.78)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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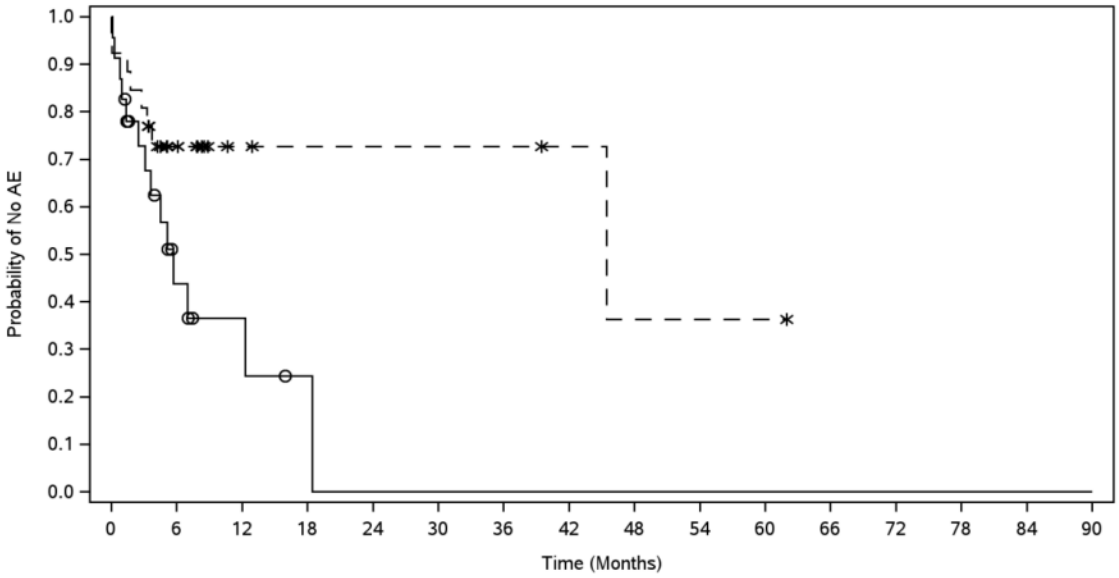
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

Histology (Disease Subtype): Cutaneous Acral



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	23	6	3	1	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(6)	(8)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)
Nivolumab	26	12	4	3	3	3	3	2	1	1	1	0	0	0	0	0
	(0)	(7)	(15)	(16)	(16)	(16)	(16)	(17)	(17)	(17)	(17)	(18)	(18)	(18)	(18)	(18)

—o— BMS-986213 (events: 14/23), median and 95% CI: 5.72 (2.50, N.A.)
— * - Nivolumab (events: 8/26), median and 95% CI: 45.44 (45.44, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.85 (1.14, 7.10)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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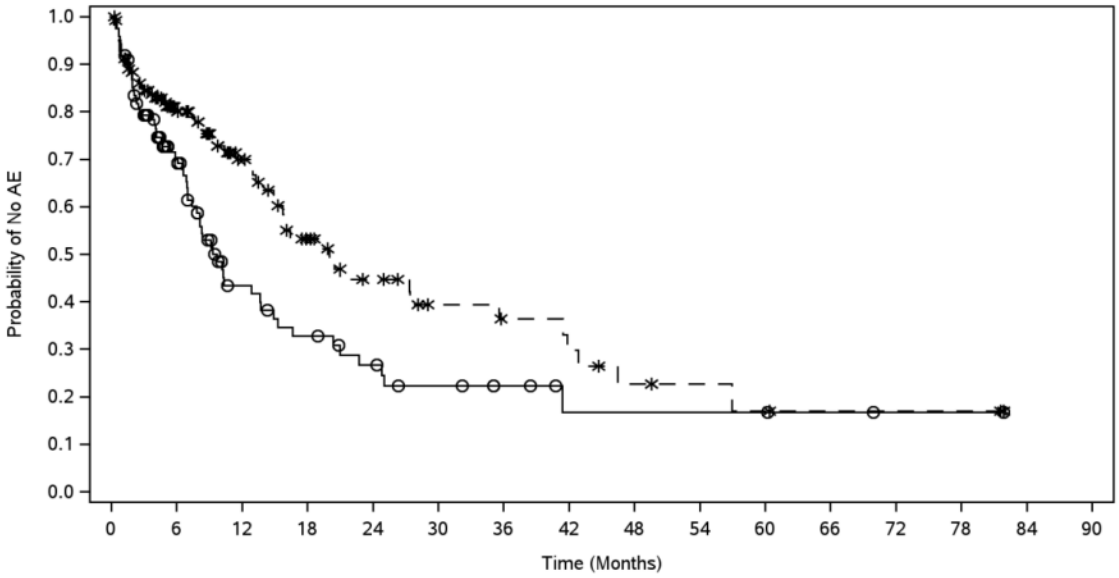
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

Histology (Disease Subtype): Cutaneous Non-Acral



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	122	61	25	18	13	9	6	3	3	3	3	2	1	1	0	0
	(0)	(27)	(44)	(45)	(47)	(49)	(52)	(54)	(54)	(54)	(54)	(55)	(56)	(56)	(57)	(57)
Nivolumab	139	79	45	28	19	13	11	9	6	4	3	2	2	2	0	0
	(0)	(34)	(60)	(67)	(72)	(76)	(77)	(77)	(78)	(80)	(80)	(81)	(81)	(81)	(83)	(83)

—o— BMS-986213 (events: 65/122), median and 95% CI: 9.30 (7.39, 13.73)
— * - Nivolumab (events: 56/139), median and 95% CI: 20.04 (15.21, 35.58)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.65 (1.15, 2.36)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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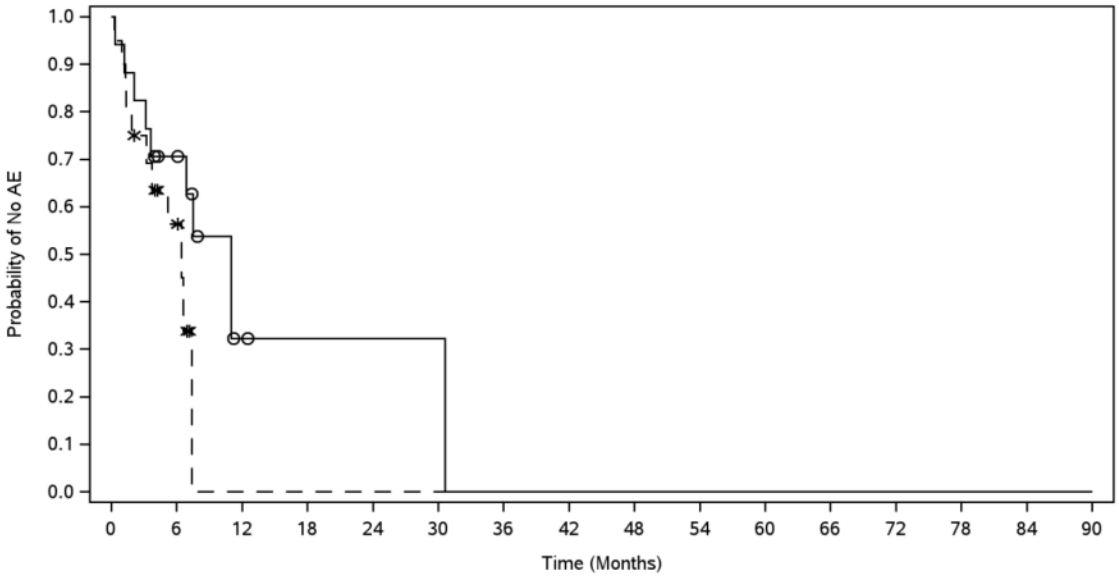
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

Histology (Disease Subtype): Mucosal



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	17	10	2	1	1	1	0	0	0	0	0	0	0	0	0	0
	(0)	(2)	(6)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)
Nivolumab	20	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	(0)	(4)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)

—o— BMS-986213 (events: 10/17), median and 95% CI: 10.97 (3.19, N.A.)
— * - Nivolumab (events: 11/20), median and 95% CI: 6.41 (1.84, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.42 (0.15, 1.19)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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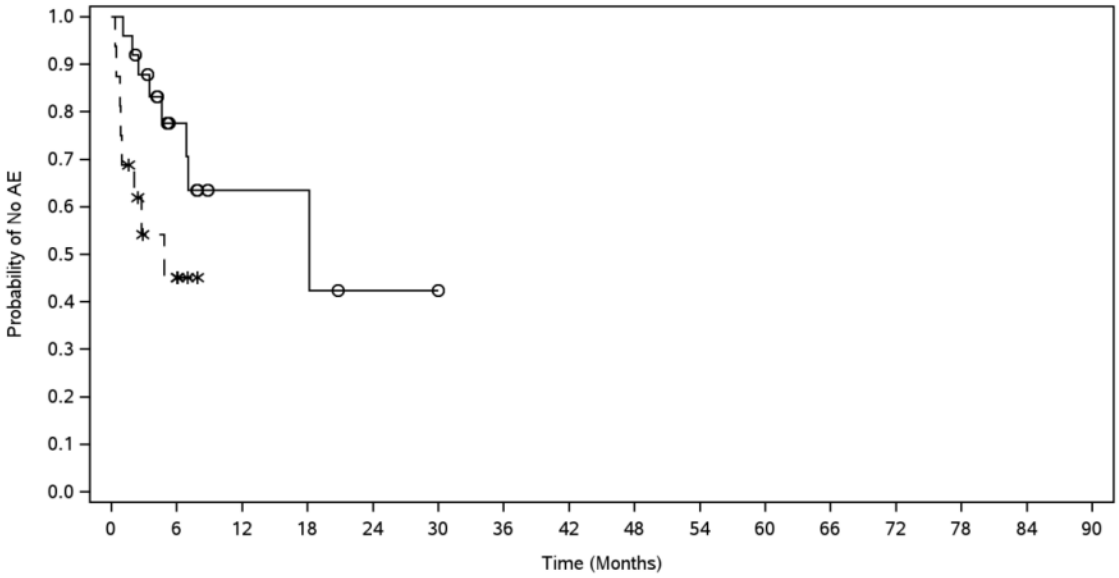
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Infections and Infestations

Histology (Disease Subtype): Other



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	25 (0)	11 (9)	3 (15)	3 (15)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Nivolumab	16 (0)	5 (3)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

—o— BMS-986213 (events: 8/25), median and 95% CI: 18.14 (6.90, N.A.)
— * - Nivolumab (events: 8/16), median and 95% CI: 4.86 (0.85, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.34 (0.12, 0.96)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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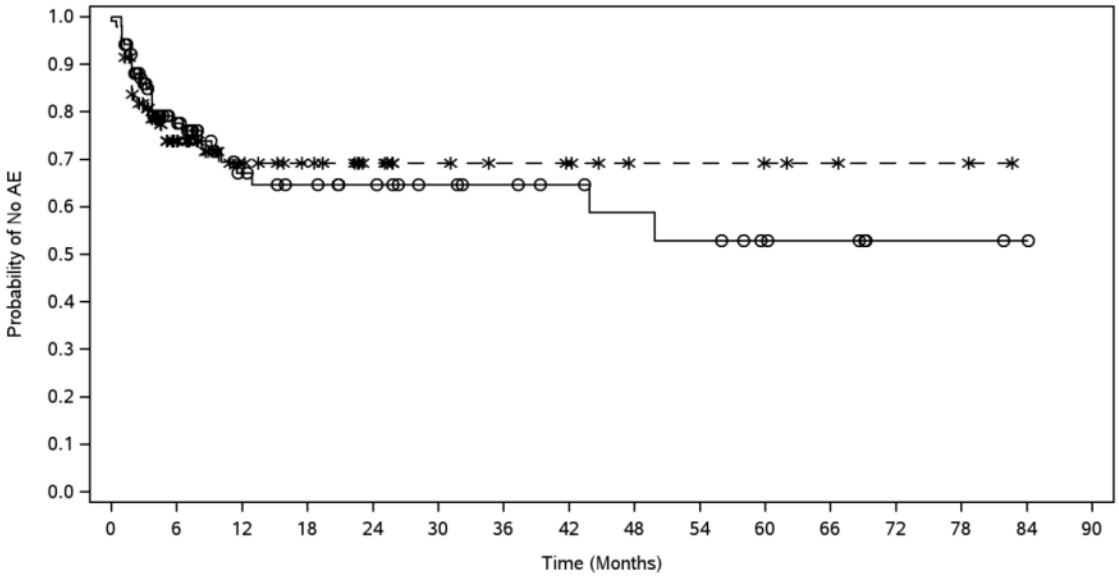
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

Age Categorization II: < 65



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	102	53	28	24	20	16	14	12	10	9	6	5	2	2	1	0
	(0)	(28)	(48)	(51)	(55)	(59)	(61)	(63)	(64)	(64)	(67)	(68)	(71)	(71)	(72)	(73)
Nivolumab	105	54	26	21	15	11	9	8	5	5	4	3	2	2	0	0
	(0)	(25)	(51)	(56)	(62)	(66)	(68)	(69)	(72)	(72)	(73)	(74)	(75)	(75)	(77)	(77)

—o— BMS-986213 (events: 29/102), median and 95% CI: N.A. (43.86, N.A.)
— * - Nivolumab (events: 28/105), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.01 (0.60, 1.70)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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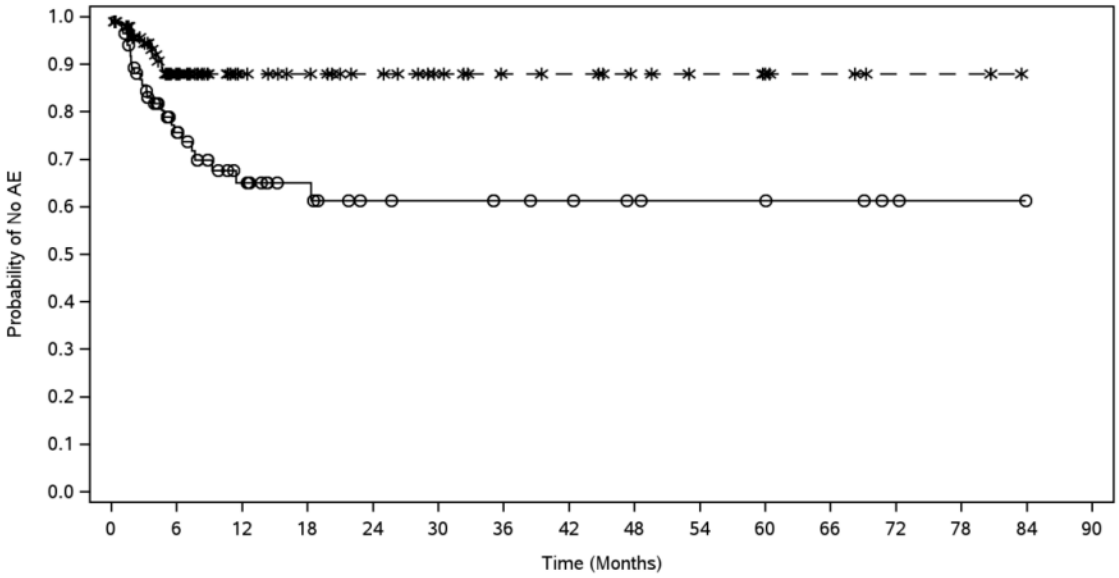
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Endocrine Disorders

Age Categorization II: >= 65



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	85	46	26	17	12	11	9	8	6	5	5	4	2	1	0	0
	(0)	(20)	(35)	(44)	(48)	(49)	(51)	(52)	(54)	(55)	(55)	(56)	(58)	(59)	(60)	(60)
Nivolumab	96	58	33	29	24	18	14	13	9	7	5	4	2	2	0	0
	(0)	(28)	(53)	(57)	(62)	(68)	(72)	(73)	(77)	(79)	(81)	(82)	(84)	(84)	(86)	(86)

—o— BMS-986213 (events: 25/85), median and 95% CI: N.A. (18.33, N.A.)
— * - Nivolumab (events: 10/96), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.97 (1.42, 6.18)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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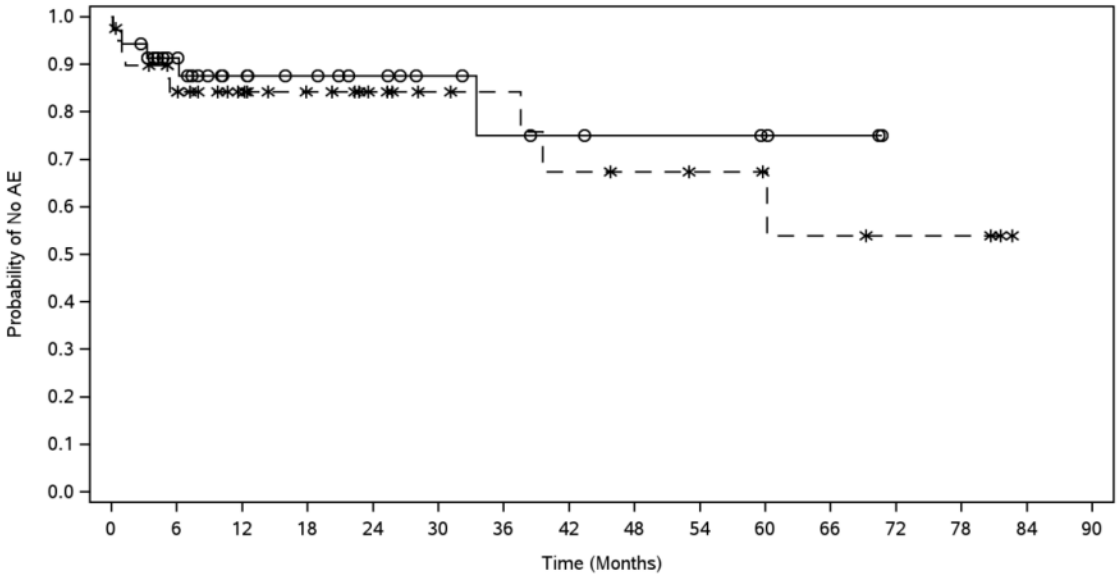
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

LAG-3 Status At Baseline Using 5% Cut-off: LAG-3 >= 5%



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	35	25	17	14	11	8	6	5	4	4	3	2	0	0	0	0
	(0)	(7)	(14)	(17)	(20)	(23)	(24)	(25)	(26)	(26)	(27)	(28)	(30)	(30)	(30)	(30)
Nivolumab	40	30	22	18	14	11	10	8	7	6	5	4	3	3	0	0
	(0)	(4)	(12)	(16)	(20)	(23)	(24)	(24)	(25)	(26)	(27)	(27)	(28)	(28)	(31)	(31)

—o— BMS-986213 (events: 5/35), median and 95% CI: N.A. (33.51, N.A.)
— * - Nivolumab (events: 9/40), median and 95% CI: N.A. (39.59, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.70 (0.23, 2.09)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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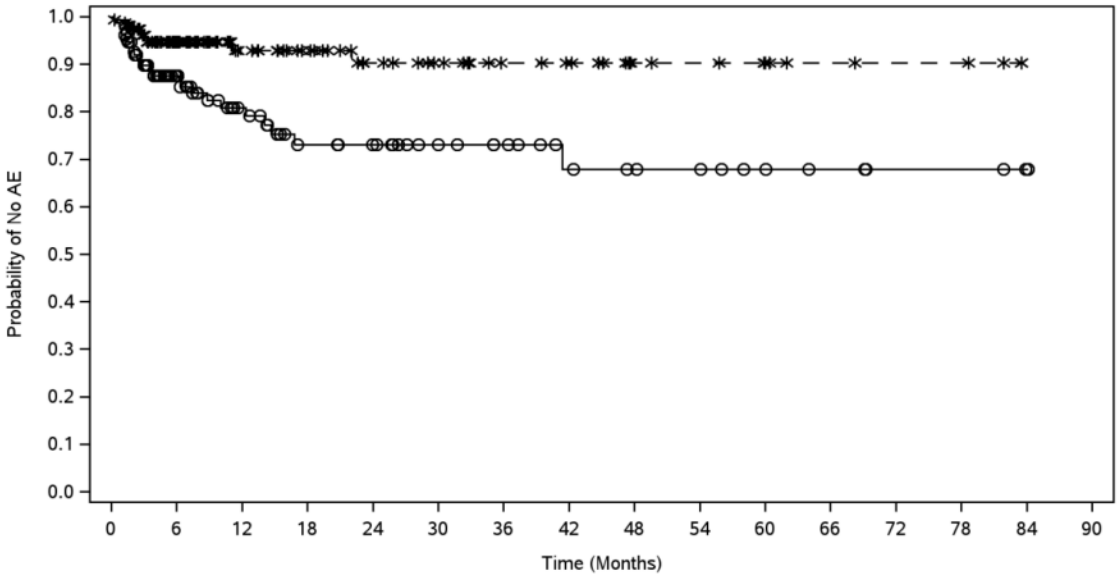
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

LAG-3 Status At Baseline Using 5% Cut-off: LAG-3 < 5%



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	152	87	46	32	28	21	18	13	11	10	7	5	3	3	1	0
	(0)	(47)	(83)	(93)	(97)	(104)	(107)	(111)	(113)	(114)	(117)	(119)	(121)	(121)	(123)	(124)
Nivolumab	161	99	51	41	31	26	20	18	11	10	7	5	4	4	0	0
	(0)	(54)	(101)	(111)	(120)	(125)	(131)	(133)	(140)	(141)	(144)	(146)	(147)	(147)	(151)	(151)

—o— BMS-986213 (events: 28/152), median and 95% CI: N.A.
— * - Nivolumab (events: 10/161), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 3.12 (1.51, 6.42)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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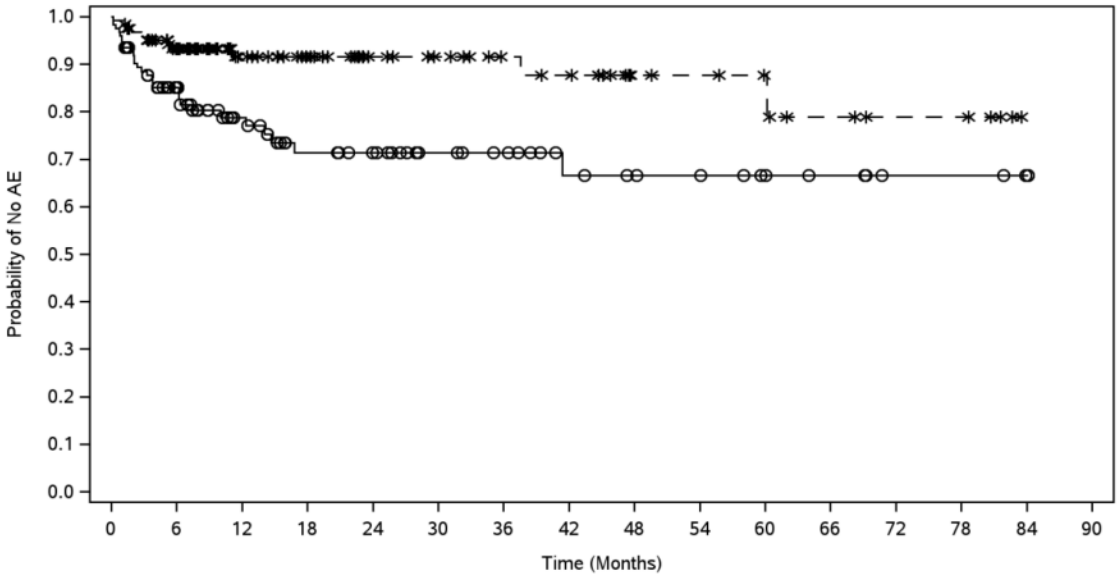
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

AJCC Stage: M0/M1any[0]



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	123	82	47	35	30	23	20	14	12	11	8	6	3	3	1	0
	(0)	(23)	(53)	(61)	(66)	(73)	(76)	(81)	(83)	(84)	(87)	(89)	(92)	(92)	(94)	(95)
Nivolumab	125	97	53	43	32	28	23	21	13	12	10	7	5	5	0	0
	(0)	(20)	(63)	(73)	(84)	(88)	(93)	(94)	(102)	(103)	(105)	(107)	(109)	(109)	(114)	(114)

—o— BMS-986213 (events: 28/123), median and 95% CI: N.A.
— * - Nivolumab (events: 11/125), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.89 (1.44, 5.80)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

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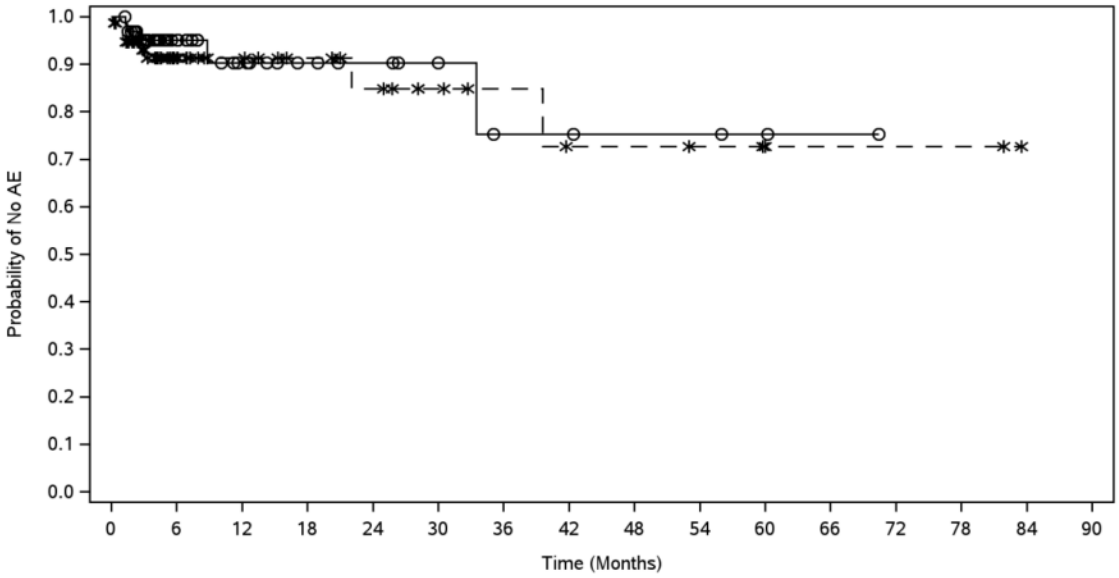
Figure 17.1
Subgroup Plots of Time to Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Eye Disorders

AJCC Stage: M1any[1]



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	64	30	16	11	9	6	4	4	3	3	2	1	0	0	0	0
	(0)	(31)	(44)	(49)	(51)	(54)	(55)	(55)	(56)	(56)	(57)	(58)	(59)	(59)	(59)	(59)
Nivolumab	76	32	20	16	13	9	7	5	5	4	2	2	2	2	0	0
	(0)	(38)	(50)	(54)	(56)	(60)	(62)	(63)	(63)	(64)	(66)	(66)	(66)	(66)	(68)	(68)

—o— BMS-986213 (events: 5/64), median and 95% CI: N.A. (33.51, N.A.)
— * - Nivolumab (events: 8/76), median and 95% CI: N.A. (39.59, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.74 (0.24, 2.27)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:18

Anhang 4-G 8.2.2.2.2: Schwere UE (CTCAE-Grad ≥ 3) auf Ebene der SOC und PT

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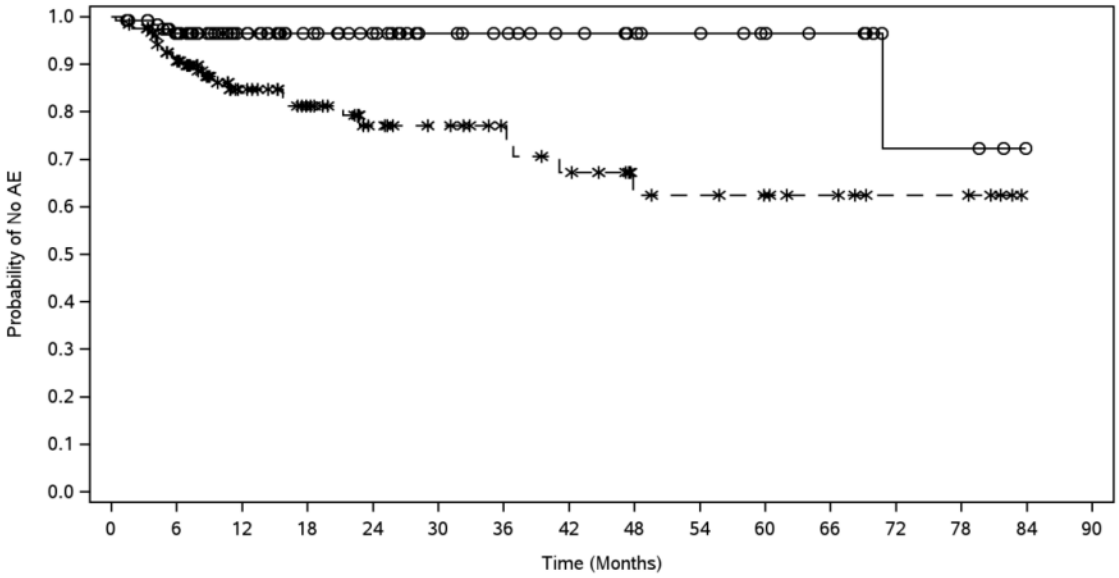
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

AJCC Stage: M0/M1any[0]



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	123	96	59	43	34	26	23	19	16	14	11	9	3	3	0	0
	(0)	(23)	(60)	(76)	(85)	(93)	(96)	(100)	(103)	(105)	(108)	(110)	(115)	(115)	(118)	(118)
Nivolumab	125	101	55	44	33	29	24	20	13	12	10	8	5	5	0	0
	(0)	(13)	(54)	(63)	(72)	(76)	(81)	(82)	(88)	(89)	(91)	(93)	(96)	(96)	(101)	(101)

—o— BMS-986213 (events: 5/123), median and 95% CI: N.A. (70.77, N.A.)
— * - Nivolumab (events: 24/125), median and 95% CI: N.A. (47.90, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.21 (0.08, 0.56)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56

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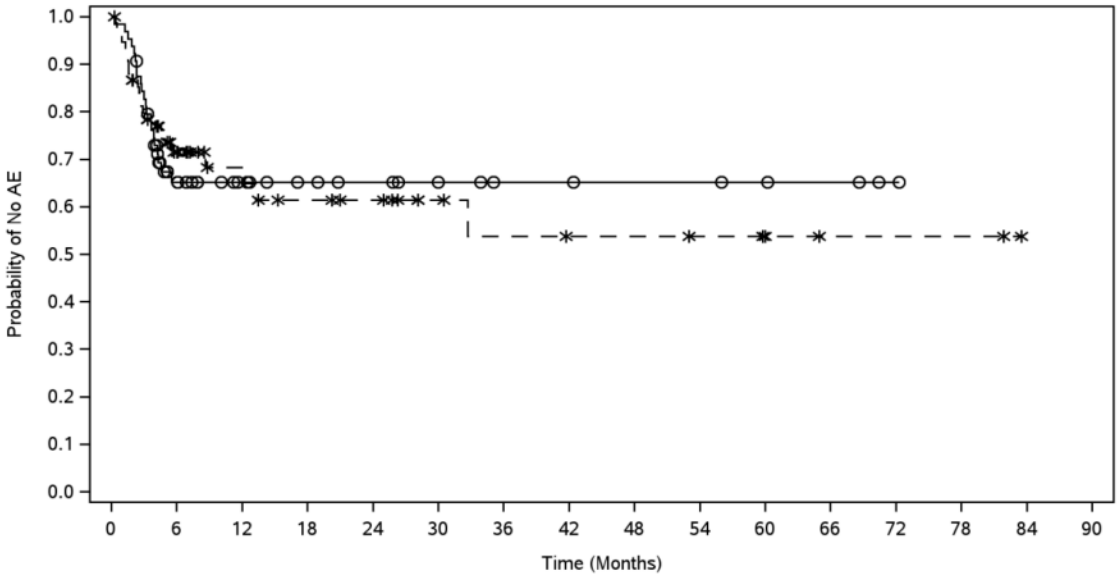
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

AJCC Stage: M1any[1]



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	64	29	17	13	11	8	6	6	5	5	4	3	1	0	0	0
	(0)	(14)	(26)	(30)	(32)	(35)	(37)	(37)	(38)	(38)	(39)	(40)	(42)	(43)	(43)	(43)
Nivolumab	76	34	20	16	14	9	7	6	6	5	3	2	2	2	0	0
	(0)	(22)	(35)	(37)	(39)	(44)	(45)	(46)	(46)	(47)	(49)	(50)	(50)	(50)	(52)	(52)

—o— BMS-986213 (events: 21/64), median and 95% CI: N.A.
— * - Nivolumab (events: 24/76), median and 95% CI: N.A. (13.24, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.99 (0.55, 1.79)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
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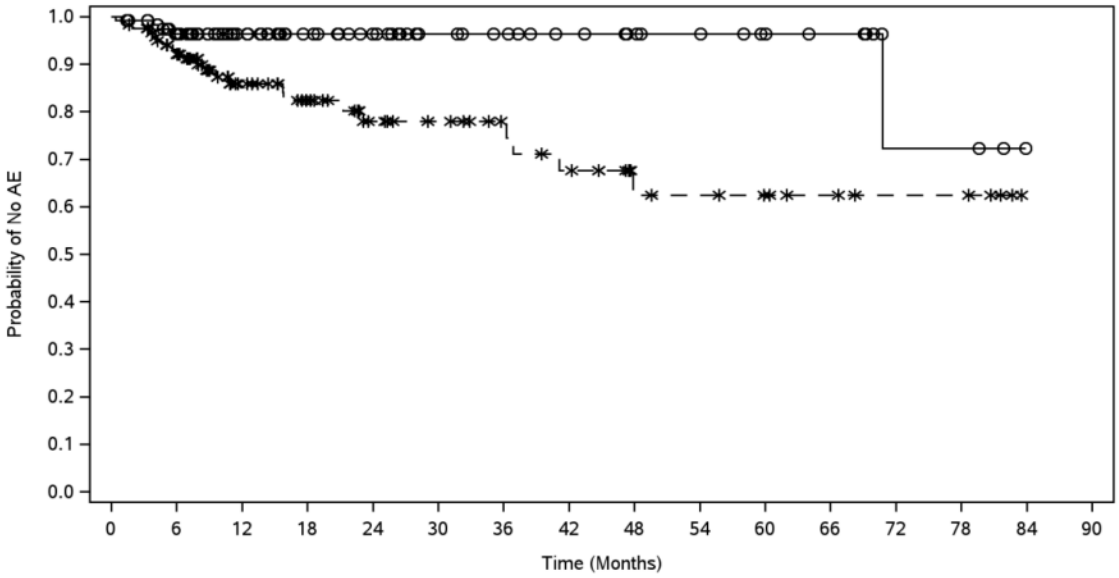
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Baseline LDH I: <= ULN



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	120	93	57	42	33	25	22	18	15	13	10	8	3	3	0	0
	(0)	(23)	(59)	(74)	(83)	(91)	(94)	(98)	(101)	(103)	(106)	(108)	(112)	(112)	(115)	(115)
Nivolumab	121	99	54	43	32	28	23	19	12	11	9	7	5	5	0	0
	(0)	(13)	(53)	(62)	(71)	(75)	(80)	(81)	(87)	(88)	(90)	(92)	(94)	(94)	(99)	(99)

—o— BMS-986213 (events: 5/120), median and 95% CI: N.A. (70.77, N.A.)
— * - Nivolumab (events: 22/121), median and 95% CI: N.A. (47.90, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.23 (0.09, 0.62)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56

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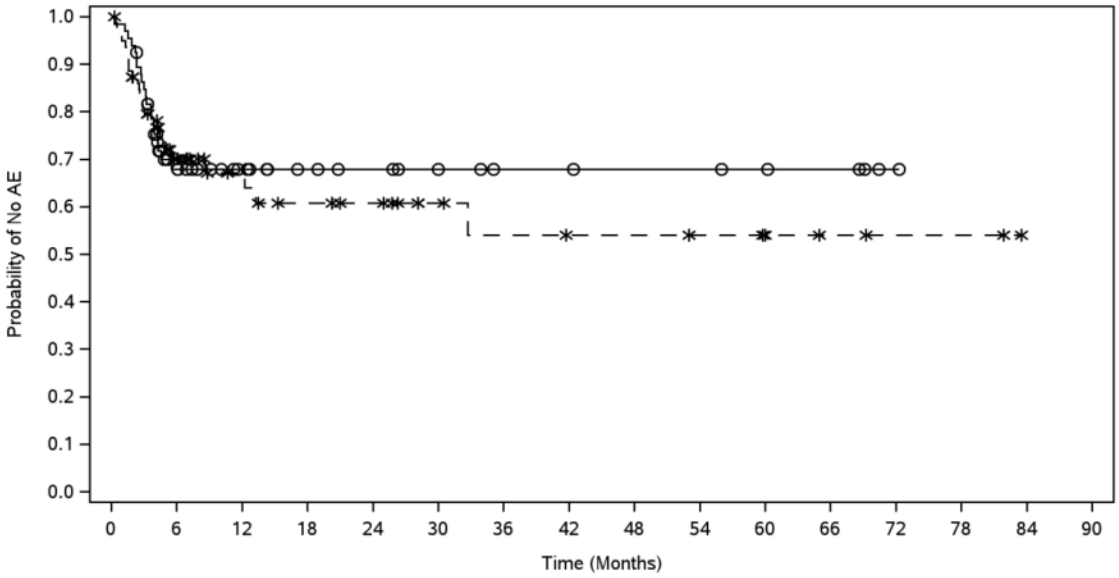
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Baseline LDH I: > ULN



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	66	32	19	14	12	9	7	7	6	6	5	4	1	0	0	0
	(0)	(14)	(27)	(32)	(34)	(37)	(39)	(39)	(40)	(40)	(41)	(42)	(45)	(46)	(46)	(46)
Nivolumab	80	36	21	17	15	10	8	7	7	6	4	3	2	2	0	0
	(0)	(22)	(36)	(38)	(40)	(45)	(46)	(47)	(47)	(48)	(50)	(51)	(52)	(52)	(54)	(54)

—o— BMS-986213 (events: 20/66), median and 95% CI: N.A.
— * - Nivolumab (events: 26/80), median and 95% CI: N.A. (12.25, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.88 (0.49, 1.58)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56

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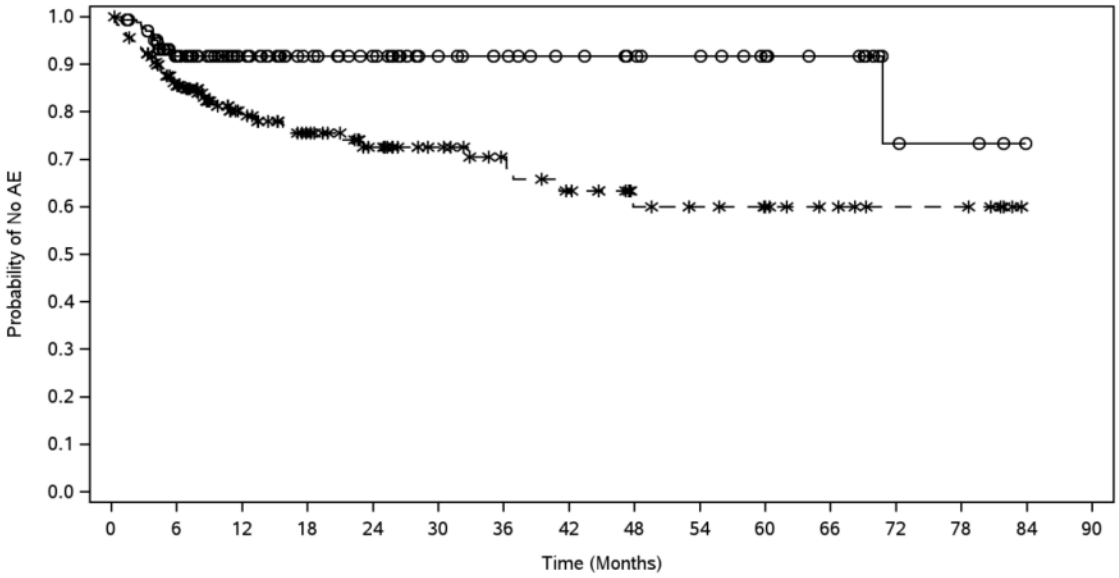
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Baseline LDH II: <= 2 x ULN



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	168	120	73	53	43	32	28	24	21	19	15	12	4	3	0	0
	(0)	(35)	(82)	(102)	(112)	(123)	(127)	(131)	(134)	(136)	(140)	(143)	(150)	(151)	(154)	(154)
Nivolumab	181	130	73	58	46	37	30	25	18	16	13	10	7	7	0	0
	(0)	(26)	(77)	(88)	(98)	(107)	(113)	(115)	(121)	(123)	(126)	(129)	(132)	(132)	(139)	(139)

—o— BMS-986213 (events: 14/168), median and 95% CI: N.A. (70.77, N.A.)
— * - Nivolumab (events: 42/181), median and 95% CI: N.A. (47.90, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.35 (0.19, 0.65)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56

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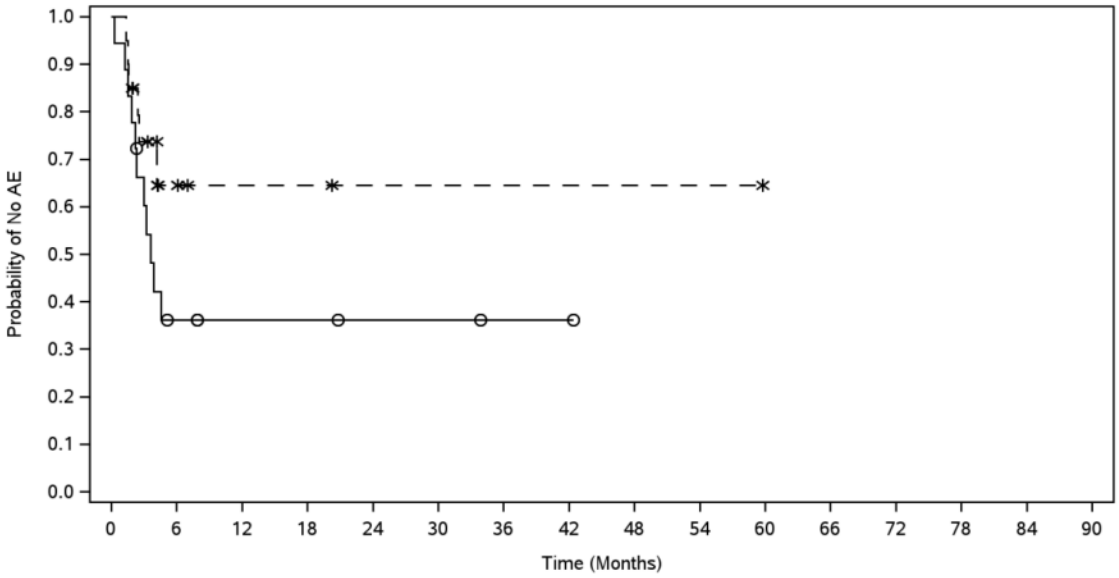
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Baseline LDH II: > 2 x ULN



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	18	5	3	3	2	2	1	1	0	0	0	0	0	0	0	0
	(0)	(2)	(4)	(4)	(5)	(5)	(6)	(6)	(7)	(7)	(7)	(7)	(7)	(7)	(7)	(7)
Nivolumab	20	5	2	2	1	1	1	1	1	1	0	0	0	0	0	0
	(0)	(9)	(12)	(12)	(13)	(13)	(13)	(13)	(13)	(13)	(14)	(14)	(14)	(14)	(14)	(14)

—o— BMS-986213 (events: 11/18), median and 95% CI: 3.61 (2.20, N.A.)
— * - Nivolumab (events: 6/20), median and 95% CI: N.A. (2.56, N.A.)
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 2.11 (0.78, 5.72)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56

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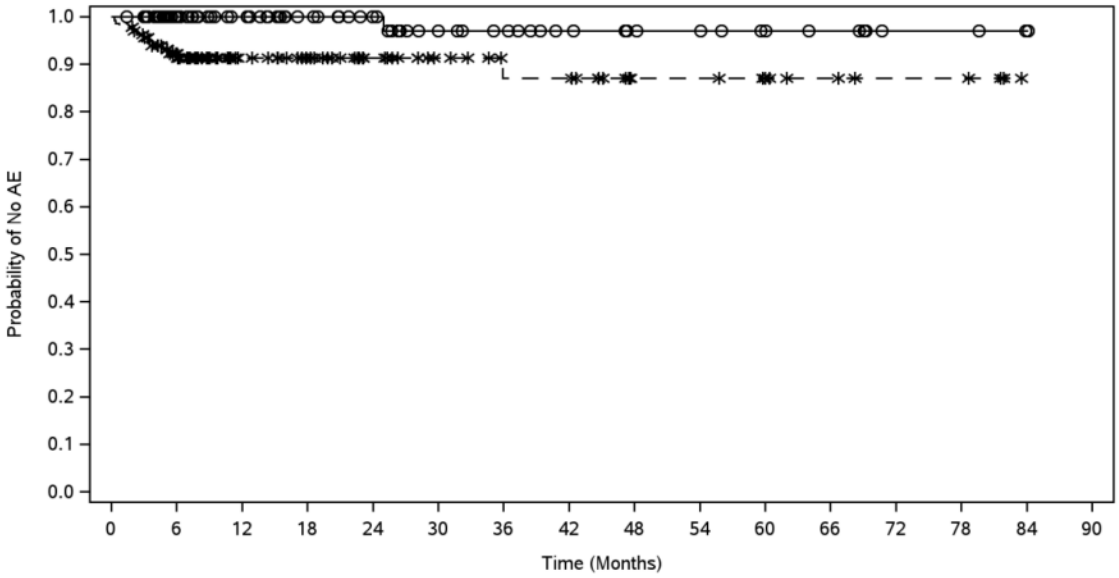
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

Baseline ECOG PS: 0



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	121	89	57	42	34	24	21	16	13	12	9	7	3	3	1	0
	(0)	(32)	(64)	(79)	(87)	(96)	(99)	(104)	(107)	(108)	(111)	(113)	(117)	(117)	(119)	(120)
Nivolumab	136	101	53	44	33	25	20	20	11	11	8	6	4	4	0	0
	(0)	(25)	(72)	(81)	(92)	(100)	(104)	(104)	(113)	(113)	(116)	(118)	(120)	(120)	(124)	(124)

—o— BMS-986213 (events: 1/121), median and 95% CI: N.A.
— * - Nivolumab (events: 12/136), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 0.09 (0.01, 0.69)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56

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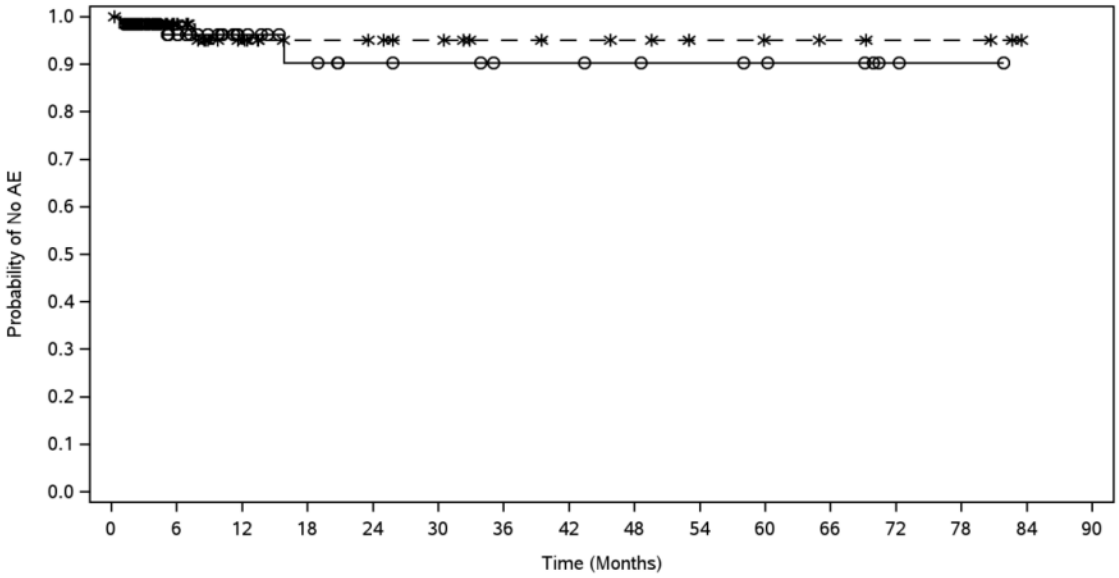
Figure 17.2
Subgroup Plots of Time to CTCAE Grade 3-4-5 Adverse Event - All Treated Subjects with Quantifiable PD-L1 < 1% (CRF)

SOC: General Disorders and Administration Site Conditions

Baseline ECOG PS: 1



Number of Subjects at Risk
(Number of Censored Subjects)

BMS-986213	66	39	21	15	12	11	9	9	8	7	6	5	2	1	0	0
	(0)	(25)	(43)	(48)	(51)	(52)	(54)	(54)	(55)	(56)	(57)	(58)	(61)	(62)	(63)	(63)
Nivolumab	65	35	21	16	15	13	10	9	8	6	5	4	3	3	0	0
	(0)	(29)	(42)	(47)	(48)	(50)	(53)	(54)	(55)	(57)	(58)	(59)	(60)	(60)	(63)	(63)

—o— BMS-986213 (events: 3/66), median and 95% CI: N.A.
— * - Nivolumab (events: 2/65), median and 95% CI: N.A.
Hazard Ratio (BMS-986213 vs. Nivolumab) and 95% CI: 1.42 (0.24, 8.51)

NOV 2025 DBL. Symbols represent censored observations.
Based on events reported between first dose and 100 days after last dose of study therapy.
Unstratified Cox proportional hazard model.
Includes subgroups from subgroup factors showing a significant interaction with treatment.
Program Path: /projects/bms214671/stats/market/ma224047_202511/prog/figures
Program Name: rg-ae-tsubsocaehr-ebr2586_b5.sas 23FEB2026:06:19:56