Dossier zur Nutzenbewertung gemäß § 35a SGB V

Blinatumomab (BLINCYTO®)

Amgen GmbH

Separater Anhang 4-G: Ergänzende Unterlagen

Behandlung von Erwachsenen mit einer Philadelphia-Chromosom-negativen, CD19-positiven, rezidivierten oder refraktären B-Vorläufer akuten lymphatischen Leukämie

Stand: 26.05.2026

Anhang 4-G: Ergänzende Daten zur Studie TOWER

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Anhang 4-G1: Ergänzende Darstellung der Studien- und Patientencharakteristika

Anhang 4-G1.1: Disposition

Table 14-1.1. Subject Disposition with Discontinuation Reason (Full Analysis Set)

	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)	Total (N = 405) n (%)
Subjects randomized	134 (100.0)	271 (100.0)	405 (100.0)
Investigational product accounting			
Subjects who never received investigational product	25 (18.7)	4 (1.5)	29 (7.2)
Adverse event	2 (1.5)	0 (0.0)	2 (0.5)
Subject request	22 (16.4)	1 (0.4)	23 (5.7)
Death	1 (0.7)	2 (0.7)	3 (0.7)
Protocol-specified criteria	0 (0.0)	1 (0.4)	1 (0.2)
Premature end of induction due to progression without prior CR/CRh*/Cri	0 (0.0)	1 (0.4)	1 (0.2)
Subjects who received investigational product	109 (81.3)	267 (98.5)	376 (92.8)
Subjects continuing investigational product[a]	0 (0.0)	22 (8.1)	22 (5.4)
Subjects who discontinued investigational product	109 (81.3)	245 (90.4)	354 (87.4)
Adverse event	5 (3.7)	33 (12.2)	38 (9.4)
Subject request	4 (3.0)	6 (2.2)	10 (2.5)
Death	17 (12.7)	20 (7.4)	37 (9.1)
Protocol-specified criteria	83 (61.9)	186 (68.6)	269 (66.4)
Premature end of induction due to progression without prior CR/CRh*/Cri	24 (17.9)	60 (22.1)	84 (20.7)
Failure to achieve CR/CRh*/CRi within 2 cycles	2 (1.5)	13 (4.8)	15 (3.7)
Relapse subsequent to CR/CRh*/CRi on treatment	3 (2.2)	33 (12.2)	36 (8.9)
Intention to receive allogeneic HSCT	31 (23.1)	59 (21.8)	90 (22.2)
Intention to receive additional therapy other than allogeneic HSCT	23 (17.2)	18 (6.6)	41 (10.1)
Reached end of maintenance period	0 (0.0)	3 (1.1)	3 (0.7)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Study completion accounting			
Subjects continuing study	33 (24.6)	93 (34.3)	126 (31.1)
Subjects who discontinued study	101 (75.4)	178 (65.7)	279 (68.9)
Withdrawal of consent from study	15 (11.2)	14 (5.2)	29 (7.2)
Decision by sponsor	1 (0.7)	3 (1.1)	4 (1.0)
Lost to follow-up	0 (0.0)	1 (0.4)	1 (0.2)
Death	85 (63.4)	160 (59.0)	245 (60.5)

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[a]Continuing investigational product at time of data cutoff for the analysis.
Number of subjects screened: 468
First subject enrolled: 03JAN2014 Data cutoff: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ds-sum-eoip.sas
Output: t14-01-001-ds-sum-discont-reason.rtf (Date Generated: 04MAY16:02:14:21) Source: adam.adsl

Anhang 4-G1.2: Behandlungs- und Beobachtungszeiten

Table 14-5.1. Blinatumomab Exposure Summarized Across All Cycles (Safety Analysis Set)

	Blinatumomab (N = 267)
Number of cycles started - n (%)	
1	116 (43.4)
2	65 (24.3)
3	26 (9.7)
4	20 (7.5)
5	13 (4.9)
6 or more	27 (10.1)
Number of cycles started	
n	267
Mean	2.5
SD	1.9
Median	2.0
Q1, Q3	1.0, 3.0
Min, Max	1, 9
Number of cycles completed - n (%)	
0	70 (26.2)
1	62 (23.2)
2	59 (22.1)
3	22 (8.2)
4	20 (7.5)
5	10 (3.7)
6 or more	24 (9.0)
Number of cycles completed	
n	267
Mean	2.0
SD	2.1
Median	2.0
Q1, Q3	0.0, 3.0
Min, Max	0, 9

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[a] Restarted cycles occur for dose interruptions lasting more than 7 days but less than 14 (due to AEs) or 21 (due to logisitical difficulties) days
[b] Relative treatment duration is the actual duration divided by intended duration
[c]Cumulative dose is the sum of (duration of each infusion)x(dose of each infusion)
[d]Percent of intended dose is the cumulative dose divided by the planned intended cumulative dose
[e] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')
All exposure records with the start date before the data-cut off were included.

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-exp.sas
Output: t14-05-001-ex-sum-exp.rtf (Date Generated: 28JUN16:02:46:33) Source: adam.adsl, adam.adex, adam.adexcyc

Table 14-5.1. Blinatumomab Exposure Summarized Across All Cycles (Safety Analysis Set)

	Blinatumomab (N = 267)
Number of cycles ≥25 days - n (%)	
0	66 (24.7)
1	65 (24.3)
2	59 (22.1)
3	21 (7.9)
4	22 (8.2)
5	8 (3.0)
6 or more	26 (9.7)
Number of cycles ≥25 days	
n	267
Mean	2.1
SD	2.1
Median	2.0
Q1, Q3	1.0, 3.0
Min, Max	0, 9
Number of cycles restarted[a] - n (%)	
0	255 (95.5)
1	12 (4.5)
2	0 (0.0)
3	0 (0.0)
4	0 (0.0)
5	0 (0.0)
6 or more	0 (0.0)

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[a] Restarted cycles occur for dose interruptions lasting more than 7 days but less than 14 (due to AEs) or 21 (due to logisitical difficulties) days
[b] Relative treatment duration is the actual duration divided by intended duration
[c]Cumulative dose is the sum of (duration of each infusion)x(dose of each infusion)
[d]Percent of intended dose is the cumulative dose divided by the planned intended cumulative dose
[e] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')
All exposure records with the start date before the data-cut off were included.

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-exp.sas
Output: t14-05-001-ex-sum-exp.rtf (Date Generated: 28JUN16:02:46:33) Source: adam.adsl, adam.adex, adam.adexcyc

Table 14-5.1. Blinatumomab Exposure Summarized Across All Cycles (Safety Analysis Set)

	Blinatumomab (N = 267)
Number of cycles restarted[a]	
n	267
Mean	0.0
SD	0.2
Median	0.0
Q1, Q3	0.0, 0.0
Min, Max	0, 1
Duration of treatment (days)	
n	267
Mean	64.2
SD	56.2
Median	54.1
Q1, Q3	25.5, 84.0
Min, Max	0, 258
Duration of treatment - n (%)	
<25 days	66 (24.7)
25 - <50 days	61 (22.8)
≥50 - <75 days	60 (22.5)
≥75 - <126 days	43 (16.1)
≥126 days	37 (13.9)
Relative treatment duration[b] - n (%)	
<50%	28 (10.5)
50 - <80%	46 (17.2)
80 - 100%	135 (50.6)
>100%	58 (21.7)

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[a] Restarted cycles occur for dose interruptions lasting more than 7 days but less than 14 (due to AEs) or 21 (due to logisitical difficulties) days
[b] Relative treatment duration is the actual duration divided by intended duration
[c]Cumulative dose is the sum of (duration of each infusion)x(dose of each infusion)
[d]Percent of intended dose is the cumulative dose divided by the planned intended cumulative dose
[e] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')
All exposure records with the start date before the data-cut off were included.

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-exp.sas
Output: t14-05-001-ex-sum-exp.rtf (Date Generated: 28JUN16:02:46:33) Source: adam.adsl, adam.adex, adam.adexcyc

Table 14-5.1. Blinatumomab Exposure Summarized Across All Cycles (Safety Analysis Set)

	Blinatumomab (N = 267)
Relative treatment duration[b] (%)	
n	267
Mean	85.1
SD	23.9
Median	98.5
Q1, Q3	75.2, 100.0
Min, Max	2, 107
Cumulative dose[c] (µg)	
n	267
Mean	1591.0
SD	1543.5
Median	1264.9
Q1, Q3	564.4, 2204.3
Min, Max	4, 6935
Percent of intended dose[d] - n (%)	
<50%	50 (18.7)
50 - <80%	42 (15.7)
80 - 100%	123 (46.1)
>100%	52 (19.5)
Percent of intended dose[d] (%)	
n	267
Mean	80.0
SD	28.6
Median	96.9
Q1, Q3	62.5, 100.0
Min, Max	1, 109

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[a] Restarted cycles occur for dose interruptions lasting more than 7 days but less than 14 (due to AEs) or 21 (due to logisitical difficulties) days
[b] Relative treatment duration is the actual duration divided by intended duration
[c]Cumulative dose is the sum of (duration of each infusion)x(dose of each infusion)
[d]Percent of intended dose is the cumulative dose divided by the planned intended cumulative dose
[e] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')
All exposure records with the start date before the data-cut off were included.

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-exp.sas
Output: t14-05-001-ex-sum-exp.rtf (Date Generated: 28JUN16:02:46:33) Source: adam.adsl, adam.adex, adam.adexcyc

Table 14-5.1. Blinatumomab Exposure Summarized Across All Cycles (Safety Analysis Set)

	Blinatumomab (N = 267)
Drug interruptions[e] - n (%)	
None	117 (43.8)
Adverse event	80 (30.0)
Noncompliance	1 (0.4)
Dose administration error	5 (1.9)
Weight change	0 (0.0)
Subject request	4 (1.5)
Dose reinstated	5 (1.9)
Device complaint	12 (4.5)
Compromised IP	0 (0.0)
PI decision	12 (4.5)
Withdrew from IP	19 (7.1)
Infusion bag emptied prematurely	13 (4.9)
Other	46 (17.2)

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[a] Restarted cycles occur for dose interruptions lasting more than 7 days but less than 14 (due to AEs) or 21 (due to logisitical difficulties) days
[b] Relative treatment duration is the actual duration divided by intended duration
[c]Cumulative dose is the sum of (duration of each infusion)x(dose of each infusion)
[d]Percent of intended dose is the cumulative dose divided by the planned intended cumulative dose
[e] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')
All exposure records with the start date before the data-cut off were included.

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-exp.sas
Output: t14-05-001-ex-sum-exp.rtf (Date Generated: 28JUN16:02:46:33) Source: adam.adsl, adam.adex, adam.adexcyc

Table 14-8.4. SOC Chemotherapy Exposure (Safety Analysis Set)

	SOC Chemotherapy (N=109) n (%)
FLAG ± anthracycline	49 (45.0)
FLAG	9 (8.3)
FLAG-AMSA	1 (0.9)
FLAG-IDA	35 (32.1)
GMALL 07/03	1 (0.9)
IDARUBICIN+CYTARABINE	1 (0.9)
ST. JUDE	1 (0.9)
VANDEVOL	1 (0.9)
HiDAC	19 (17.4)
ARACYTINE+NOVANTRONE	1 (0.9)
CALGB 9111	1 (0.9)
FLAG	1 (0.9)
GRASPALL VANDA	1 (0.9)
HIDAC	3 (2.8)
HIDAC+MITOXANTRONE	1 (0.9)
HIDAC-MITOX	1 (0.9)
HIDACBASED REGIMEN	1 (0.9)
HIGH DOSE ARA C	1 (0.9)
HYPERCHIDAM	1 (0.9)
HYPERCVAD	3 (2.8)
HYPERCVAD II - (MTX/ARA-C)	1 (0.9)
MEC345	1 (0.9)
NOVANTRONE+ARACYTINE	1 (0.9)
VANDA	1 (0.9)

[a] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-soc.sas Output: t14-08-004-ex-sum-soc-saf.rtf (Date generated: 25APR2016:23:54) Source data: adam.adsl, adam.adex, adam.adexcyc

Table 14-8.4. SOC Chemotherapy Exposure (Safety Analysis Set)

	SOC Chemotherapy (N=109) n (%)
High-dose methotrexate	22 (20.2)
ARACYTINE+NOVANTRONE	1 (0.9)
BFM ALL REZ - BLOCK R1M	1 (0.9)
CALGB 10002	1 (0.9)
CAPIZZI	1 (0.9)
CLIMBING THE DOSE METHOTREXATE	1 (0.9)
CLOFARABINE	1 (0.9)
CLOFARBINE BASED COMBINATION REGIMEN	1 (0.9)
GMALL	1 (0.9)
HD-MTX	1 (0.9)
HDMTX + BORTEZOMIB + VINCRESTINE + CYCLOPHOSPHAMIDE	1 (0.9)
HIGH DOSE METHOTREXATE	1 (0.9)
HIGH-DOSE METHOTREXATE	3 (2.8)
HYPERCVAD	3 (2.8)
METHOTREXATE+IT	1 (0.9)
METHOTREXATE+IFOSFAMIDE+VINCRISTINE+CYTARABINE+ETOPOSIDE	
METHOTREXATE+VINCRISTIN+ PREDNOL	1 (0.9)
MOAD	1 (0.9)
PALG	1 (0.9)
VELCADE FOR ALL	1 (0.9)
Clofarabine or clofarabine	19 (17.4)
CLOFARABINE	3 (2.8)
CLOFARBINE BASED COMBINATION REGIMEN	15 (13.8)
FLAG-IDA	1 (0.9)

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[a] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-soc.sas
Output: t14-08-004-ex-sum-soc-saf.rtf (Date generated: 25APR2016:23:54) Source data: adam.adsl, adam.adex, adam.adexcyc

Table 14-8.4. SOC Chemotherapy Exposure (Safety Analysis Set)

	SOC Chemotherapy (N=109) n (%)
Number of cycles – n (%)	
1	81 (74.3)
2	25 (22.9)
3	1 (0.9)
4	2 (1.8)
Number of cycles	
n	109
Mean	1.3
SD	0.6
Median	1.0
Q1, Q3	1.0, 2.0
Min, Max	1, 4
Drug interruptions[a] – n (%)	
None	106 (97.2)
Adverse event	5 (4.6)
PI decision	3 (2.8)
Other	1 (0.9)

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[a] Dose Interruption reasons may not be mutually exclusive (except if a subject indicates 'none')

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ex-sum-soc.sas Output: t14-08-004-ex-sum-soc-saf.rtf (Date generated: 25APR2016:23:54) Source data: adam.adsl, adam.adex, adam.adexcyc

Table 14-8.1.1. Summary of Duration of Observation for OS and EFS Endpoints (Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Overall (N=405)
Overall survival (months)[a]			
n	134	271	405
Mean	4.99	6.60	6.07
SD	4.95	5.43	5.33
Median	3.33	5.48	4.43
Min, Max	0.0, 21.4	0.1, 23.1	0.0, 23.1
Event-free survival (months)[b]			
n	134	271	405
Mean	1.42	2.99	2.47
SD	3.43	4.40	4.17
Median	0.03	0.03	0.03
Min, Max	0.0, 20.2	0.0, 21.0	0.0, 21.0

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
[a] Months are calculated as days from randomization to death or last observation on study in absence of death, divided by 30.5.
[b] Months are calculated as days from randomization to relapse/death or last disease assessment date in absence of relapse/death, divided by 30.5. Subjects who fail to achieve a CR following treatment with investigational product or who died before the disease assessment at the end of treatment will be considered treatment failures and assigned an EFS duration of 1, divided by 30.5.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-sum-dur-os-efs-fas.sas
Output: t14-08-001-001-sum-dur-os-efs-fas.rtf (Date generated: 22MAY2025:23:49) Source data: adam_pa.adsl, adam_pa.adtteeff

Table 14-8.1.2. Summary of Duration of Observation for CR and MRD response (Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Overall (N=405)
CR/CRh*/CRi response (months)[a]			
n	33	119	152
Mean	4.63	5.36	5.20
SD	4.91	4.45	4.55
Median	1.90	4.20	4.16
Min, Max	0.0, 19.0	0.0, 20.1	0.0, 20.1
MRD response (months)[b]			
n	109	267	376
Mean	0.71	3.16	2.45
SD	0.85	3.31	3.04
Median	0.26	2.33	1.18
Min, Max	0.1, 5.5	0.1, 18.0	0.1, 18.0

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
MRD = Minimal residual disease.
[a] Months are calculated as days from CR/CRh*/CRi is first achieved within first 2 cycles to relapse/death or last disease assessment date in absence of relapse/death, divided by 30.5.
[b] Months are calculated as days from randomization to treatment end date, divided by 30.5.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-sum-dur-resp-fas.sas
Output: t14-08-001-002-sum-dur-resp-fas.rtf (Date generated: 23MAY2025:05:55) Source data: adam_pa.adsl, adam_pa.adtteeff

Table 14-8.1.3. Summary of Duration of Observation for Treatment-emergent Adverse Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Overall (N=376)
Treatment-emergent adverse events (months)[a]			
n	108	263	371
Mean	1.52	3.82	3.15
SD	0.88	3.39	3.07
Median	1.15	3.25	1.93
Min, Max	0.1, 5.5	0.1, 18.9	0.1, 18.9

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
[a] Months are calculated as days from start of treatment to end of treatment + 30 days or last observation on study whichever occurs first, divided by 30.5.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-sum-dur-teae-saf.sas
Output: t14-08-001-003-sum-dur-teae-saf.rtf (Date generated: 29MAY2025:23:15) Source data: adam_pa.adsl, adam_pa.adae

Table 14-8.2.1. Summary of Completion Rate for EORTC QLQ C30 (Full Analysis Set)

	SOC Chemotherapy (N=134)		Blinatumomab (N=271)	
EORTC QLQ C30	n/N1	Completion Rate	n/N1	Completion Rate
Baseline	90/112	80.4	226/267	84.6
Cycle 1 Day 8	73/106	68.9	209/258	81.0
Cycle 1 Day 15	69/102	67.6	208/243	85.6
Cycle 1 Day 29	53/90	58.9	152/218	69.7
Cycle 2 Day 1	25/32	78.1	136/153	88.9
Cycle 2 Day 15	20/27	74.1	113/143	79.0
Cycle 2 Day 29	15/23	65.2	107/138	77.5
Cycle 3 Day 1	7/7	100.0	81/90	90.0
Cycle 3 Day 15	3/3	100.0	75/85	88.2
Cycle 3 Day 29	3/5	60.0	66/81	81.5
Cycle 4 Day 1	4/4	100.0	60/65	92.3
Cycle 4 Day 15	4/4	100.0	55/63	87.3
Cycle 4 Day 29	1/1	100.0	53/61	86.9
Cycle 5 Day 1	0/0	-	40/46	87.0
Cycle 5 Day 15	0/0	-	37/43	86.0
Cycle 5 Day 29	0/0	-	33/40	82.5
Safety Follow Up	40/72	55.6	86/162	53.1

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects who completed the forms.
N1 = Number of subjects expected to complete the forms. EORTC QLQ= European organization for research and treatment of cancer quality of life questionnaire.
The completion rate at each assessment time is defined as the number of received forms divided by the number of expected forms at each assessment time.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-sum-cr-eortc-qlq-fas.sas
Output: t14-08-002-001-sum-cr-eortc-qlq-fas.rtf (Date generated: 29MAY2025:23:01) Source data: adam_pa.adsl, adam_pa.adqs

Table 14-8.2.2. Summary of Completion Rate for ALLSS sum score (Full Analysis Set)

	SOC Chemotherapy (N=134)		Blinatumomab (N=271)	
ALLSS sum score	n/N1	Completion Rate	n/N1	Completion Rate
Baseline	98/112	87.5	231/267	86.5
Cycle 1 Day 8	77/106	72.6	228/258	88.4
Cycle 1 Day 15	72/102	70.6	221/243	90.9
Cycle 1 Day 29	55/90	61.1	160/218	73.4
Cycle 2 Day 1	27/32	84.4	142/153	92.8
Cycle 2 Day 15	21/27	77.8	119/143	83.2
Cycle 2 Day 29	15/23	65.2	114/138	82.6
Cycle 3 Day 1	7/7	100.0	80/90	88.9
Cycle 3 Day 15	3/3	100.0	78/85	91.8
Cycle 3 Day 29	3/5	60.0	66/81	81.5
Cycle 4 Day 1	4/4	100.0	57/65	87.7
Cycle 4 Day 15	4/4	100.0	54/63	85.7
Cycle 4 Day 29	1/1	100.0	49/61	80.3
Cycle 5 Day 1	0/0	-	36/46	78.3
Cycle 5 Day 15	0/0	-	33/43	76.7
Cycle 5 Day 29	0/0	-	32/40	80.0
Safety Follow Up	42/72	58.3	84/162	51.9

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects who completed the forms.
N1 = Number of subjects expected to complete the forms. ALLSS= Acute lymphoblastic leukemia symptom scale.
The completion rate at each assessment time is defined as the number of received forms divided by the number of expected forms at each assessment time.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-sum-cr-allss-fas.sas
Output: t14-08-002-002-sum-cr-allss-fas.rtf (Date generated: 29MAY2025:23:00) Source data: adam_pa.adsl, adam_pa.adqs

Anhang 4-G1.3: Erste Folgetherapien

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
Number of subjects reporting first subsequent anti-cancer therapy during long-term follow-up	34 (25.4)	51 (18.8)
CYCLOPHOSPHAMIDE	1 (0.7)	5 (1.8)
FLAG-IDA	0 (0.0)	5 (1.8)
CLOFARBINE BASED COMBINATION REGIMEN	1 (0.7)	4 (1.5)
FLUDARABINE	2 (1.5)	3 (1.1)
ETOPOSIDE	1 (0.7)	3 (1.1)
CLOFARABINE	0 (0.0)	2 (0.7)
CYTARABINE	0 (0.0)	2 (0.7)
FLAG	0 (0.0)	2 (0.7)
INOTUZUMAB	0 (0.0)	2 (0.7)
PURINETHOL	0 (0.0)	2 (0.7)
VINCRISTINE SULPHATE LIPOSOME INJECTION (MARQUIBO)	0 (0.0)	2 (0.7)
BLINATUMOMAB	3 (2.2)	1 (0.4)
DEXAMETHASONE	2 (1.5)	1 (0.4)
BUSULFAN	1 (0.7)	1 (0.4)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:20:55) Source data: adam_pa.adsl, adam_pa.adcm

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
DONOR LYMPHOCYTE INFUSION	1 (0.7)	1 (0.4)
FTBI	1 (0.7)	1 (0.4)
HYPERCVAD	1 (0.7)	1 (0.4)
METHOTREXATE	1 (0.7)	1 (0.4)
TOTAL BODY IRRADIATION	1 (0.7)	1 (0.4)
ADRIAMYCIN, CYTARABINE, ONCOVIN, PREDNISONE	0 (0.0)	1 (0.4)
ASPARAGINASE CYTARABINE METHOTREXATE	0 (0.0)	1 (0.4)
CVAD	0 (0.0)	1 (0.4)
CYCLOPHOSPHAMIDE AND TBI ALLOGENIC CONDITIONING PROTOCOL	0 (0.0)	1 (0.4)
DAY +8 POST CD22 CAR T CELLS TRANSPLANT	0 (0.0)	1 (0.4)
DOXORUBICIN	0 (0.0)	1 (0.4)
ERWINAZE	0 (0.0)	1 (0.4)
FLUDARABINE AND CYTARABINE	0 (0.0)	1 (0.4)
HIDROXIUREA	0 (0.0)	1 (0.4)
HOVAD B	0 (0.0)	1 (0.4)
HYDROXYUREA	0 (0.0)	1 (0.4)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:20:55) Source data: adam_pa.adsl, adam_pa.adcm

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
IDARUBICIN	0 (0.0)	1 (0.4)
METHOTREXAT, PEG-ASPARAGINASE	0 (0.0)	1 (0.4)
OTHER CLINICAL TRIAL	0 (0.0)	1 (0.4)
PALLIATIVE TREATMENT	0 (0.0)	1 (0.4)
POMP	0 (0.0)	1 (0.4)
PREDNISONE 20 MG	0 (0.0)	1 (0.4)
PURINETHOL 50 MG	0 (0.0)	1 (0.4)
SALVAGE THERAPY OF UNKNOWN NATURE	0 (0.0)	1 (0.4)
THYMOGLOBULIN	0 (0.0)	1 (0.4)
VINBLASTINE	0 (0.0)	1 (0.4)
MERCAPTOPURINE	3 (2.2)	0 (0.0)
INOTUZUMAB OZOGAMICIN (CMC-544)	2 (1.5)	0 (0.0)
PREDNISONE	2 (1.5)	0 (0.0)
6-MERCAPTOPURINE	1 (0.7)	0 (0.0)
ARA-C	1 (0.7)	0 (0.0)
CY-TBI	1 (0.7)	0 (0.0)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:20:55) Source data: adam_pa.adsl, adam_pa.adcm

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
DAUNORUBICINE	1 (0.7)	0 (0.0)
DECITABINE	1 (0.7)	0 (0.0)
FLUDARABINE+TREOSULFAN	1 (0.7)	0 (0.0)
HYPERCHIDAM	1 (0.7)	0 (0.0)
MELPHALAN	1 (0.7)	0 (0.0)
METOTREXATE	1 (0.7)	0 (0.0)
RADIOACTIVE MONOCLONAL ANTIBODY	1 (0.7)	0 (0.0)
RITUXIMAB	1 (0.7)	0 (0.0)
SCT ALLO MUD FOR ALL -TREOSULFAN/FLUDARABINE/THYMOGLOBULIN	1 (0.7)	0 (0.0)
SGN-CD19A IV (INVESTIGATIONAL SUPPLY) 400 MG INTRAVENOUS	1 (0.7)	0 (0.0)
UKALL60	1 (0.7)	0 (0.0)
VINCRISTINE	1 (0.7)	0 (0.0)
VINCRISTINE +DEXAMETHASONE+DASATINIB+PURINETHOL	1 (0.7)	0 (0.0)
VINCRISTINE, PEG-ASPARGINASE, DEXAMETHASONE, DOXORUBICIN, ARA-C, METHOTREXATE, M	1 (0.7)	0 (0.0)

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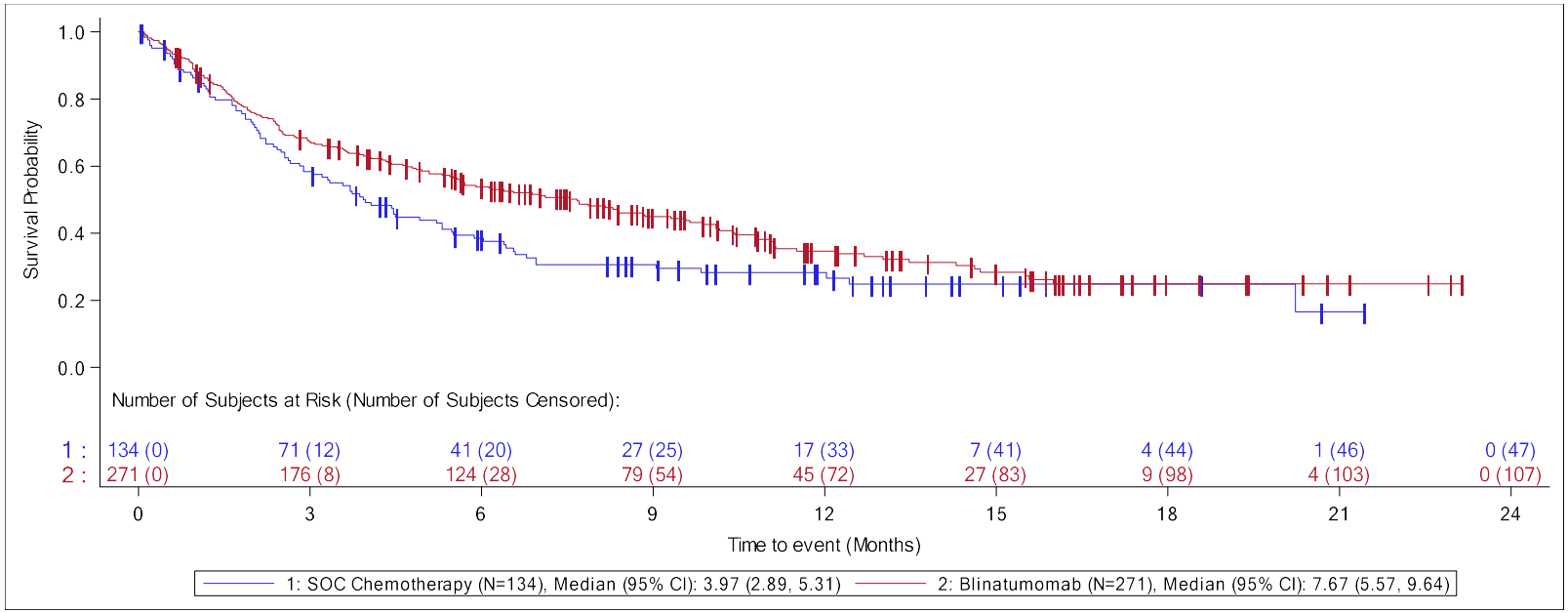
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:20:55) Source data: adam_pa.adsl, adam_pa.adcm

Anhang 4-G2: Ergänzende Ergebnisdarstellung des primären Datenschnitts

Anhang 4-G2.1: Gesamtüberleben

Figure 14-4.5.3. Kaplan-Meier plot for Overall Survival (Full Analysis Set)

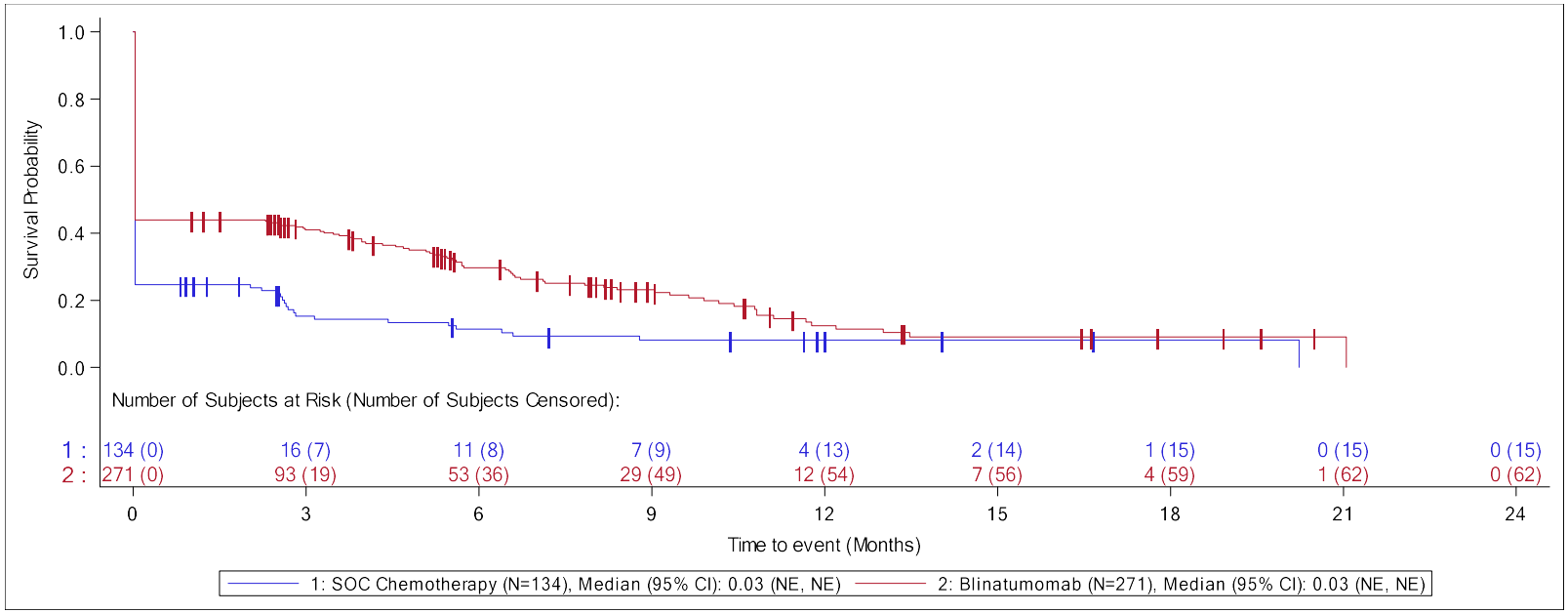


Censor indicated by vertical bar |. CI = Confidence interval.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-os-fas.sas
Output: f14-04-005-003-km-os-fas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adtteeff

Anhang 4-G2.2: Ereignisfreies Überleben

Figure 14-4.5.4. Kaplan-Meier plot for Event Free Survival (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-efs-fas.sas
Output: f14-04-005-004-km-efs-fas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adtteeff

Anhang 4-G2.3: Komplette Remission

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete Remission (CR)			
Number of subjects assessed[c]	72	204	
Events - n (%)	21 (29.2)	91 (44.6)	15.4
Unstratified odds ratio[b]			1.96
(95% CI)			(1.10, 3.49)
p-value			0.0230
Stratified odds ratio[a, b]			2.23
(95% CI)			(1.23, 4.04)
p-value			0.0081
Unstratified risk ratio[b]			1.53
(95% CI)			(1.03, 2.26)
p-value			0.0332
Stratified risk ratio[a, b]			1.55
(95% CI)			(1.06, 2.27)
p-value			0.0249
Absolute risk reduction			0.15
(95% CI)			(0.03, 0.28)
p-value			0.0156

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 29MAY2025:03:07) Source data: adam_pa.adsl, adam_pa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete remission with partial hematological recovery (CRh*)			
Number of subjects assessed[c]	72	204	
Events - n (%)	6 (8.3)	24 (11.8)	3.4
Unstratified odds ratio[b]			1.47
(95% CI)			(0.57, 3.75)
p-value			0.4236
Stratified odds ratio[a, b]			1.38
(95% CI)			(0.54, 3.52)
p-value			0.5056
Unstratified risk ratio[b]			1.41
(95% CI)			(0.60, 3.31)
p-value			0.4283
Stratified risk ratio[a, b]			1.34
(95% CI)			(0.57, 3.11)
p-value			0.5021
Absolute risk reduction			0.03
(95% CI)			(-0.04, 0.11)
p-value			0.3865

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 29MAY2025:03:07) Source data: adam_pa.adsl, adam_pa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete remission with incomplete hematological recovery (CRi)			
Number of subjects assessed[c]	72	204	
Events - n (%)	6 (8.3)	4 (2.0)	-6.4
Unstratified odds ratio[b]			0.22
(95% CI)			(0.06, 0.80)
p-value			0.0220
Stratified odds ratio[a, b]			0.24
(95% CI)			(0.07, 0.85)
p-value			0.0274
Unstratified risk ratio[b]			0.24
(95% CI)			(0.07, 0.81)
p-value			0.0218
Stratified risk ratio[a, b]			0.24
(95% CI)			(0.07, 0.84)
p-value			0.0250
Absolute risk reduction			-0.06
(95% CI)			(-0.13, 0.00)
p-value			0.0608

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 29MAY2025:03:07) Source data: adam_pa.adsl, adam_pa.adrs

Anhang 4-G2.4: Komplette Remission - Sensitivitätsanalyse

Table 14-4.1.2. Best Response Within 12 Weeks of Treatment Initiation (Subjects in Full Analysis Set Who Were Dosed)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject Status			
CR - n (%)	21 (19.3)	91 (34.1)	14.8
(95% CI)	(12.3, 27.9)	(28.4, 40.1)	(5.5, 24.2)
p-value [a]			0.002
CRh* - n (%)	6 (5.5)	24 (9.0)	
(95% CI)	(2.0, 11.6)	(5.8, 13.1)	
CRi (without CRh*) - n (%)	6 (5.5)	4 (1.5)	
(95% CI)	(2.0, 11.6)	(0.4, 3.8)	
Blast free hypoplastic or aplastic bone marrow (without CRi) - n (%)	4 (3.7)	9 (3.4)	
(95% CI)	(1.0, 9.1)	(1.6, 6.3)	
Partial remission - n (%)	9 (8.3)	6 (2.2)	

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
Three blinatumomab subjects (31126002003, 31158006014, and 31165006001) were wrongly assigned as having a hematological relapse in the CRFs. These 3 subjects are included in the denominator for calculating response rates but are not represented with reasons for non-response

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-002-br-w12-saf.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.2. Best Response Within 12 Weeks of Treatment Initiation (Subjects in Full Analysis Set Who Were Dosed)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
(95% CI)	(3.8, 15.1)	(0.8, 4.8)	
Non-response - n (%)	15 (13.8)	41 (15.4)	
(95% CI)	(7.9, 21.7)	(11.3, 20.2)	
Progressive disease - n (%)	8 (7.3)	25 (9.4)	
(95% CI)	(3.2, 14.0)	(6.2, 13.5)	
Inevaluable/Missing post-baseline assessment within 12 weeks	40 (36.7)	64 (24.0)	
Reason for ending IP			
Adverse event	2 (1.8)	21 (7.9)	
Death	14 (12.8)	13 (4.9)	
Protocol specified criteria	21 (19.3)	27 (10.1)	
Failure to achieve CR/CRh*/CRi within 2 treatment cycles	0 (0.0)	1 (0.4)	
Intention to receive additional therapy other than allogeneic HSCT	6 (5.5)	5 (1.9)	

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
Three blinatumomab subjects (31126002003, 31158006014, and 31165006001) were wrongly assigned as having a hematological relapse in the CRFs. These 3 subjects are included in the denominator for calculating response rates but are not represented with reasons for non-response

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-002-br-w12-saf.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.2. Best Response Within 12 Weeks of Treatment Initiation (Subjects in Full Analysis Set Who Were Dosed)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Intention to receive allogeneic HSCT	5 (4.6)	3 (1.1)	
Premature end to induction phase due to disease/clinical progression without prior CR/CRh*/CRi	10 (9.2)	18 (6.7)	
Subject request	3 (2.8)	3 (1.1)	
Never received IP	0 (0.0)	0 (0.0)	
CR/CRh*/CRi - n (%)	33 (30.3)	119 (44.6)	14.3
(95% CI)	(21.8, 39.8)	(38.5, 50.8)	(3.8, 24.8)
p-value [a]			0.007

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
Three blinatumomab subjects (31126002003, 31158006014, and 31165006001) were wrongly assigned as having a hematological relapse in the CRFs. These 3 subjects are included in the denominator for calculating response rates but are not represented with reasons for non-response

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-002-br-w12-saf.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.3. Best Response Within 12 Weeks of Treatment Initiation
(Subjects in Full Analysis Set With an Evaluable Post-baseline Response Assessment Within 12 Weeks)

	SOC Chemotherapy (N=69)	Blinatumomab (N=203)	Treatment Difference
Subject Status			
CR - n (%)	21 (30.4)	91 (44.8)	14.4
(95% CI)	(19.9, 42.7)	(37.9, 51.9)	(1.6, 27.2)
p-value [a]			0.013
CRh* - n (%)	6 (8.7)	24 (11.8)	
(95% CI)	(3.3, 18.0)	(7.7, 17.1)	
CRi (without CRh*) - n (%)	6 (8.7)	4 (2.0)	
(95% CI)	(3.3, 18.0)	(0.5, 5.0)	
Blast free hypoplastic or aplastic bone marrow (without CRi) - n (%)	4 (5.8)	9 (4.4)	
(95% CI)	(1.6, 14.2)	(2.0, 8.2)	
Partial remission - n (%)	9 (13.0)	6 (3.0)	
(95% CI)	(6.1, 23.3)	(1.1, 6.3)	

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-003-br-w12-eff.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.3. Best Response Within 12 Weeks of Treatment Initiation
(Subjects in Full Analysis Set With an Evaluable Post-baseline Response Assessment Within 12 Weeks)

	SOC Chemotherapy (N=69)	Blinatumomab (N=203)	Treatment Difference
Non-response - n (%)	15 (21.7)	41 (20.2)	
(95% CI)	(12.7, 33.3)	(14.9, 26.4)	
Progressive disease - n (%)	8 (11.6)	25 (12.3)	
(95% CI)	(5.1, 21.6)	(8.1, 17.6)	
Inevaluable/Missing post-baseline assessment within 12 weeks	0 (0.0)	0 (0.0)	
Never received IP	0 (0.0)	0 (0.0)	
CR/CRh*/CRi - n (%)	33 (47.8)	119 (58.6)	10.8
(95% CI)	(35.6, 60.2)	(51.5, 65.5)	(-2.8, 24.4)
p-value [a]			0.063

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-003-br-w12-eff.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.4. Best Response Within 12 Weeks of Treatment Initiation: Using CRF Values for the Stratification Factors (Subjects in Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Subject Status			
CR - n (%)	21 (15.7)	91 (33.6)	17.9
(95% CI)	(10.0, 23.0)	(28.0, 39.5)	(9.6, 26.2)
p-value [a]			< 0.001
CRh* - n (%)	6 (4.5)	24 (8.9)	
(95% CI)	(1.7, 9.5)	(5.8, 12.9)	
CRi (without CRh*) - n (%)	6 (4.5)	4 (1.5)	
(95% CI)	(1.7, 9.5)	(0.4, 3.7)	
Blast free hypoplastic or aplastic bone marrow (without CRi) - n (%)	4 (3.0)	9 (3.3)	
(95% CI)	(0.8, 7.5)	(1.5, 6.2)	
Partial remission - n (%)	9 (6.7)	6 (2.2)	

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
Three blinatumomab subjects (31126002003, 31158006014, and 31165006001) were wrongly assigned as having a hematological relapse in the CRFs. These 3 subjects are included in the denominator for calculating response rates but are not represented with reasons for non-response

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-004-br-w12-crfstrat-fas.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.4. Best Response Within 12 Weeks of Treatment Initiation: Using CRF Values for the Stratification Factors (Subjects in Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
(95% CI)	(3.1, 12.4)	(0.8, 4.8)	
Non-response - n (%)	15 (11.2)	41 (15.1)	
(95% CI)	(6.4, 17.8)	(11.1, 20.0)	
Progressive disease - n (%)	8 (6.0)	25 (9.2)	
(95% CI)	(2.6, 11.4)	(6.1, 13.3)	
Inevaluable/Missing post-baseline assessment within 12 weeks	65 (48.5)	68 (25.1)	
Reason for ending IP			
Adverse event	4 (3.0)	21 (7.7)	
Death	15 (11.2)	15 (5.5)	
Protocol specified criteria	21 (15.7)	28 (10.3)	
Failure to achieve CR/CRh*/CRi within 2 treatment cycles	0 (0.0)	1 (0.4)	
Intention to receive additional therapy other than allogeneic HSCT	6 (4.5)	5 (1.8)	

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
Three blinatumomab subjects (31126002003, 31158006014, and 31165006001) were wrongly assigned as having a hematological relapse in the CRFs. These 3 subjects are included in the denominator for calculating response rates but are not represented with reasons for non-response

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-004-br-w12-crfstrat-fas.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Table 14-4.1.4. Best Response Within 12 Weeks of Treatment Initiation: Using CRF Values for the Stratification Factors (Subjects in Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Intention to receive allogeneic HSCT	5 (3.7)	3 (1.1)	
Premature end to induction phase due to disease/clinical progression without prior CR/CRh*/CRi	10 (7.5)	19 (7.0)	
Subject request	25 (18.7)	4 (1.5)	
Never received IP	25 (18.7)	4 (1.5)	
CR/CRh*/CRi - n (%)	33 (24.6)	119 (43.9)	19.3
(95% CI)	(17.6, 32.8)	(37.9, 50.0)	(9.9, 28.7)
p-value [a]			< 0.001

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CI = Confidence Interval.
IP = Investigational Product.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
Three blinatumomab subjects (31126002003, 31158006014, and 31165006001) were wrongly assigned as having a hematological relapse in the CRFs. These 3 subjects are included in the denominator for calculating response rates but are not represented with reasons for non-response

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-br-w12.sas
Output: t14-04-001-004-br-w12-crfstrat-fas.rtf (Date generated: 28JUN2016:06:42) Source data: adam.adsl, adam.adrs

Anhang 4-G2.5: MRD-Remission

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Minimal Residual Disease (MRD)			
Number of subjects assessed[c]	69	166	
Events - n (%)	19 (27.5)	81 (48.8)	21.3
Unstratified odds ratio[b]			2.51
(95% CI)			(1.36, 4.61)
p-value			0.0031
Stratified odds ratio[a, b]			2.54
(95% CI)			(1.38, 4.68)
p-value			0.0028
Unstratified risk ratio[b]			1.77
(95% CI)			(1.17, 2.68)
p-value			0.0067
Stratified risk ratio[a, b]			1.78
(95% CI)			(1.18, 2.69)
p-value			0.0060
Absolute risk reduction			0.21
(95% CI)			(0.08, 0.34)
p-value			0.0013

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 29MAY2025:03:07) Source data: adam_pa.adsl, adam_pa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete MRD remission			
Number of subjects assessed[c]	69	166	
Events - n (%)	12 (17.4)	64 (38.6)	21.2
Unstratified odds ratio[b]			2.98
(95% CI)			(1.49, 5.98)
p-value			0.0021
Stratified odds ratio[a, b]			3.13
(95% CI)			(1.54, 6.34)
p-value			0.0015
Unstratified risk ratio[b]			2.22
(95% CI)			(1.28, 3.84)
p-value			0.0045
Stratified risk ratio[a, b]			2.21
(95% CI)			(1.29, 3.81)
p-value			0.0041
Absolute risk reduction			0.21
(95% CI)			(0.10, 0.33)
p-value			0.0004

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 29MAY2025:03:07) Source data: adam_pa.adsl, adam_pa.adrs

Anhang 4-G2.6: MRD-Remission - Sensitivitätsanalyse

Table 14-4.2.2. MRD Remission Within 12 Weeks of Treatment Initiation (Subjects in Full Analysis Set Who Were Dosed)

	SOC Chemotherapy (N = 109)	Blinatumomab (N = 267)	Treatment Difference
Number of subjects	109	267	
MRD remission - n (%)	19 (17.4)	81 (30.3)	12.9
(95% CI)	(10.8, 25.9)	(24.9, 36.2)	(3.9, 21.9)
p-value [a]			0.009
MRD complete remission - n (%)	12 (11.0)	64 (24.0)	13.0
(95% CI)	(5.8, 18.4)	(19.0, 29.6)	(5.2, 20.8)
p-value [a]			0.004
No MRD remission - n (%)	50 (45.9)	85 (31.8)	
No post-baseline MRD assessment - n (%)	40 (36.7)	101 (37.8)	
Number of subjects with a CR	21	91	
MRD remission - n (%)	11 (52.4)	57 (62.6)	10.3
(95% CI)	(29.8, 74.3)	(51.9, 72.6)	(-13.3, 33.8)
p-value [a]			0.32
MRD complete remission - n (%)	7 (33.3)	43 (47.3)	13.9
(95% CI)	(14.6, 57.0)	(36.7, 58.0)	(-8.7, 36.5)
p-value [a]			0.20
No MRD remission - n (%)	10 (47.6)	17 (18.7)	
No post-baseline MRD assessment - n (%)	0 (0.0)	17 (18.7)	
Number of subjects with a CR/CRh*/CRi	33	119	
MRD remission - n (%)	16 (48.5)	74 (62.2)	13.7
(95% CI)	(30.8, 66.5)	(52.8, 70.9)	(-5.4, 32.8)
p-value [a]			0.17
MRD complete remission - n (%)	10 (30.3)	58 (48.7)	18.4
(95% CI)	(15.6, 48.7)	(39.5, 58.1)	(0.4, 36.5)
p-value [a]			0.050
No MRD remission - n (%)	17 (51.5)	23 (19.3)	
No post-baseline MRD assessment - n (%)	0 (0.0)	22 (18.5)	

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CI = Confidence Interval.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-mrd-w12.sas Output: t14-04-002-002-mrd-w12-saf.rtf (Date Generated: 11MAY2016: 3:58:14) Source Data: adam.adsl, adam.adrs

Table 14-4.2.3. MRD Remission Within 12 Weeks of Treatment Initiation (Subjects in Full Analysis Set With an Evaluable Post-baseline MRD Assessment)

	SOC Chemotherapy (N = 69)	Blinatumomab (N = 166)	Treatment Difference
Number of subjects	69	166	
MRD remission - n (%)	19 (27.5)	81 (48.8)	21.3
(95% CI)	(17.5, 39.6)	(41.0, 56.7)	(8.3, 34.3)
p-value [a]			0.002
MRD complete remission - n (%)	12 (17.4)	64 (38.6)	21.2
(95% CI)	(9.3, 28.4)	(31.1, 46.4)	(9.6, 32.8)
p-value [a]			0.001
No MRD remission - n (%)	50 (72.5)	85 (51.2)	
No post-baseline MRD assessment - n (%)	0 (0.0)	0 (0.0)	
Number of subjects with a CR	21	74	
MRD remission - n (%)	11 (52.4)	57 (77.0)	24.6
(95% CI)	(29.8, 74.3)	(65.8, 86.0)	(1.2, 48.1)
p-value [a]			0.027
MRD complete remission - n (%)	7 (33.3)	43 (58.1)	24.8
(95% CI)	(14.6, 57.0)	(46.1, 69.5)	(1.7, 47.9)
p-value [a]			0.042
No MRD remission - n (%)	10 (47.6)	17 (23.0)	
No post-baseline MRD assessment - n (%)	0 (0.0)	0 (0.0)	
Number of subjects with a CR/CRh*/CRi	33	97	
MRD remission - n (%)	16 (48.5)	74 (76.3)	27.8
(95% CI)	(30.8, 66.5)	(66.6, 84.3)	(8.8, 46.8)
p-value [a]			0.007
MRD complete remission - n (%)	10 (30.3)	58 (59.8)	29.5
(95% CI)	(15.6, 48.7)	(49.3, 69.6)	(11.0, 48.0)
p-value [a]			0.004
No MRD remission - n (%)	17 (51.5)	23 (23.7)	
No post-baseline MRD assessment - n (%)	0 (0.0)	0 (0.0)	

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CI = Confidence Interval.
[a]Cochran-Mantel-Haenszel test adjusting for the stratification factors: age (<35 vs.≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-mrd-w12.sas Output: t14-04-002-003-mrd-w12-eff.rtf (Date Generated: 11MAY2016: 3:58:14) Source Data: adam.adsl, adam.adrs

Anhang 4-G2.7: Symptomatik

Anhang 4-G2.7.1: Dauer bis zur Verschlechterung des EORTC-QLQ-C30 (Symptomatik)

Table 14-4.2.707. Time to Deterioration - Fatigue from Symptom Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	69 (73.4)	139 (57.4)	
Censored - n (%)	25 (26.6)	103 (42.6)	
Stratified log-rank test[a]			
Normal score[b]			-23.72
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-24.36
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.3	1.0	
95% CI (median)	(0.3, 0.5)	(0.5, 1.5)	
Q1, Q3	0.3, 1.2	0.3, NE	
Min, Max	0.2, 1.6	0.3, 6.5	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-707-qs-tte-de-eortc-fs-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.707. Time to Deterioration - Fatigue from Symptom Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.6	
Q1, Q3	1.0, 2.0	1.0, 5.4	
Min, Max	0.3, 3.4	0.3, 17.7	
KM estimate - %			
At time 3 months[c]	18.8	37.8	
(95% CI)	(10.2, 29.3)	(30.9, 44.7)	
At time 6 months[c]	NE	32.8	
(95% CI)	(NE, NE)	(25.4, 40.4)	
At time 12 months[c]	NE	30.6	
(95% CI)	(NE, NE)	(22.7, 38.9)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.53
(95% CI)			(0.40, 0.71)

The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-707-qs-tte-de-eortc-fs-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.708. Time to Deterioration - Pain from Symptom Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	245	
Events - n (%)	67 (71.3)	135 (55.1)	
Censored - n (%)	27 (28.7)	110 (44.9)	
Stratified log-rank test[a]			
Normal score[b]			-22.95
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-23.37
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.5	1.5	
95% CI (median)	(0.5, 1.0)	(1.1, 2.0)	
Q1, Q3	0.3, 1.7	0.5, NE	
Min, Max	0.2, 2.0	0.3, 6.5	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-708-qs-tte-de-eortc-pas-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.708. Time to Deterioration - Pain from Symptom Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.9	2.6	
Q1, Q3	1.2, 2.8	1.0, 5.5	
Min, Max	0.3, 3.5	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	20.1	39.4	
(95% CI)	(11.3, 30.6)	(32.2, 46.5)	
At time 6 months[c]	NE	28.9	
(95% CI)	(NE, NE)	(20.9, 37.4)	
At time 12 months[c]	NE	27.0	
(95% CI)	(NE, NE)	(18.8, 35.8)	
At time 18 months[c]	NE	27.0	
(95% CI)	(NE, NE)	(18.8, 35.8)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.54
(95% CI)			(0.40, 0.73)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-708-qs-tte-de-eortc-pas-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.709. Time to Deterioration - Nausea and Vomitting from Symptom Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	54 (57.4)	92 (38.0)	
Censored - n (%)	40 (42.6)	150 (62.0)	
Stratified log-rank test[a]			
Normal score[b]			-25.28
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-25.55
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.5	4.2	
95% CI (median)	(0.3, 1.9)	(3.1, 6.5)	
Q1, Q3	0.3, NE	1.0, NE	
Min, Max	0.2, 2.8	0.3, 6.5	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-709-qs-tte-de-eortc-nvs-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.709. Time to Deterioration - Nausea and Vomitting from Symptom Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.4	
Q1, Q3	1.0, 2.3	1.0, 4.6	
Min, Max	0.2, 3.4	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	27.4	59.7	
(95% CI)	(11.8, 45.8)	(51.9, 66.8)	
At time 6 months[c]	NE	44.0	
(95% CI)	(NE, NE)	(34.0, 53.4)	
At time 12 months[c]	NE	35.9	
(95% CI)	(NE, NE)	(24.6, 47.2)	
At time 18 months[c]	NE	35.9	
(95% CI)	(NE, NE)	(24.6, 47.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.36
(95% CI)			(0.25, 0.51)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-709-qs-tte-de-eortc-nvs-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.710. Time to Deterioration - Dyspnea from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	93	241	
Events - n (%)	39 (41.9)	75 (31.1)	
Censored - n (%)	54 (58.1)	166 (68.9)	
Stratified log-rank test[a]			
Normal score[b]			-11.92
p-value			0.006
Unstratified log-rank test			
Normal score[b]			-11.61
p-value			0.008
Time to event (KM) (months)[c]			
Median	2.3	NE	
95% CI (median)	(1.2, NE)	(NE, NE)	
Q1, Q3	0.5, NE	1.0, NE	
Min, Max	0.2, 2.6	0.3, 5.3	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-710-qs-tte-de-eortc-dys-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.710. Time to Deterioration - Dyspnea from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.0, 2.0	1.0, 5.1	
Min, Max	0.3, 4.1	0.3, 17.7	
KM estimate - %			
At time 3 months[c]	35.0	62.6	
(95% CI)	(16.4, 54.3)	(55.0, 69.3)	
At time 6 months[c]	NE	59.3	
(95% CI)	(NE, NE)	(50.6, 66.9)	
At time 12 months[c]	NE	59.3	
(95% CI)	(NE, NE)	(50.6, 66.9)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.59
(95% CI)			(0.39, 0.87)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-710-qs-tte-de-eortc-dys-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.711. Time to Deterioration - Loss of Appetite from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	93	241	
Events - n (%)	59 (63.4)	110 (45.6)	
Censored - n (%)	34 (36.6)	131 (54.4)	
Stratified log-rank test[a]			
Normal score[b]			-25.56
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-26.11
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.5	3.1	
95% CI (median)	(0.4, 1.0)	(2.3, 4.4)	
Q1, Q3	0.3, 2.6	0.5, 8.1	
Min, Max	0.2, 2.6	0.3, 8.1	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-711-qs-tte-de-eortc-aps-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.711. Time to Deterioration - Loss of Appetite from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.6	
Q1, Q3	1.0, 2.3	1.0, 5.3	
Min, Max	0.2, 3.4	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	22.8	52.6	
(95% CI)	(11.2, 36.9)	(45.0, 59.7)	
At time 6 months[c]	NE	37.7	
(95% CI)	(NE, NE)	(28.7, 46.7)	
At time 12 months[c]	NE	23.7	
(95% CI)	(NE, NE)	(7.5, 44.8)	
At time 18 months[c]	NE	23.7	
(95% CI)	(NE, NE)	(7.5, 44.8)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.40
(95% CI)			(0.28, 0.56)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-711-qs-tte-de-eortc-aps-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.712. Time to Deterioration - Insomnia from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	48 (51.1)	119 (49.2)	
Censored - n (%)	46 (48.9)	123 (50.8)	
Stratified log-rank test[a]			
Normal score[b]			-7.33
p-value			0.15
Unstratified log-rank test			
Normal score[b]			-8.74
p-value			0.086
Time to event (KM) (months)[c]			
Median	1.0	2.0	
95% CI (median)	(0.5, 2.5)	(1.1, 6.2)	
Q1, Q3	0.3, NE	0.5, 10.0	
Min, Max	0.2, 2.5	0.3, 10.0	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-712-qs-tte-de-eortc-sls-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.712. Time to Deterioration - Insomnia from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.4	2.5	
Q1, Q3	1.0, 2.3	1.0, 5.1	
Min, Max	0.2, 3.4	0.3, 13.0	
KM estimate - %			
At time 3 months[c]	31.8	48.6	
(95% CI)	(17.0, 47.7)	(41.3, 55.4)	
At time 6 months[c]	NE	42.0	
(95% CI)	(NE, NE)	(33.6, 50.1)	
At time 12 months[c]	NE	22.7	
(95% CI)	(NE, NE)	(7.1, 43.7)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.79
(95% CI)			(0.55, 1.11)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-712-qs-tte-de-eortc-sls-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.713. Time to Deterioration - Constipation from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	240	
Events - n (%)	43 (45.7)	73 (30.4)	
Censored - n (%)	51 (54.3)	167 (69.6)	
Stratified log-rank test[a]			
Normal score[b]			-16.04
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-15.80
p-value			<0.001
Time to event (KM) (months)[c]			
Median	1.7	NE	
95% CI (median)	(1.0, NE)	(5.0, NE)	
Q1, Q3	0.5, NE	1.2, NE	
Min, Max	0.2, 2.0	0.3, 5.0	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-713-qs-tte-de-eortc-cos-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.713. Time to Deterioration - Constipation from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.4	2.3	
Q1, Q3	1.0, 2.3	1.0, 4.6	
Min, Max	0.2, 4.1	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	42.3	67.7	
(95% CI)	(29.2, 54.8)	(60.3, 74.0)	
At time 6 months[c]	NE	57.8	
(95% CI)	(NE, NE)	(48.2, 66.2)	
At time 12 months[c]	NE	57.8	
(95% CI)	(NE, NE)	(48.2, 66.2)	
At time 18 months[c]	NE	57.8	
(95% CI)	(NE, NE)	(48.2, 66.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.48
(95% CI)			(0.33, 0.71)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-713-qs-tte-de-eortc-cos-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.714. Time to Deterioration - Diarrhea from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	240	
Events - n (%)	52 (55.3)	78 (32.5)	
Censored - n (%)	42 (44.7)	162 (67.5)	
Stratified log-rank test[a]			
Normal score[b]			-25.54
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-25.54
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.8	6.0	
95% CI (median)	(0.5, 2.5)	(3.4, NE)	
Q1, Q3	0.3, 4.1	1.4, NE	
Min, Max	0.2, 4.1	0.3, 6.0	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-714-qs-tte-de-eortc-dis-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.714. Time to Deterioration - Diarrhea from Individual Item Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.4	2.4	
Q1, Q3	1.0, 2.3	1.0, 5.4	
Min, Max	0.2, 3.5	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	35.4	64.0	
(95% CI)	(21.7, 49.4)	(56.0, 70.9)	
At time 6 months[c]	0.0	48.4	
(95% CI)	(NE, NE)	(38.0, 58.1)	
At time 12 months[c]	0.0	48.4	
(95% CI)	(NE, NE)	(38.0, 58.1)	
At time 18 months[c]	0.0	48.4	
(95% CI)	(NE, NE)	(38.0, 58.1)	
At time 24 months[c]	0.0	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.34
(95% CI)			(0.23, 0.49)

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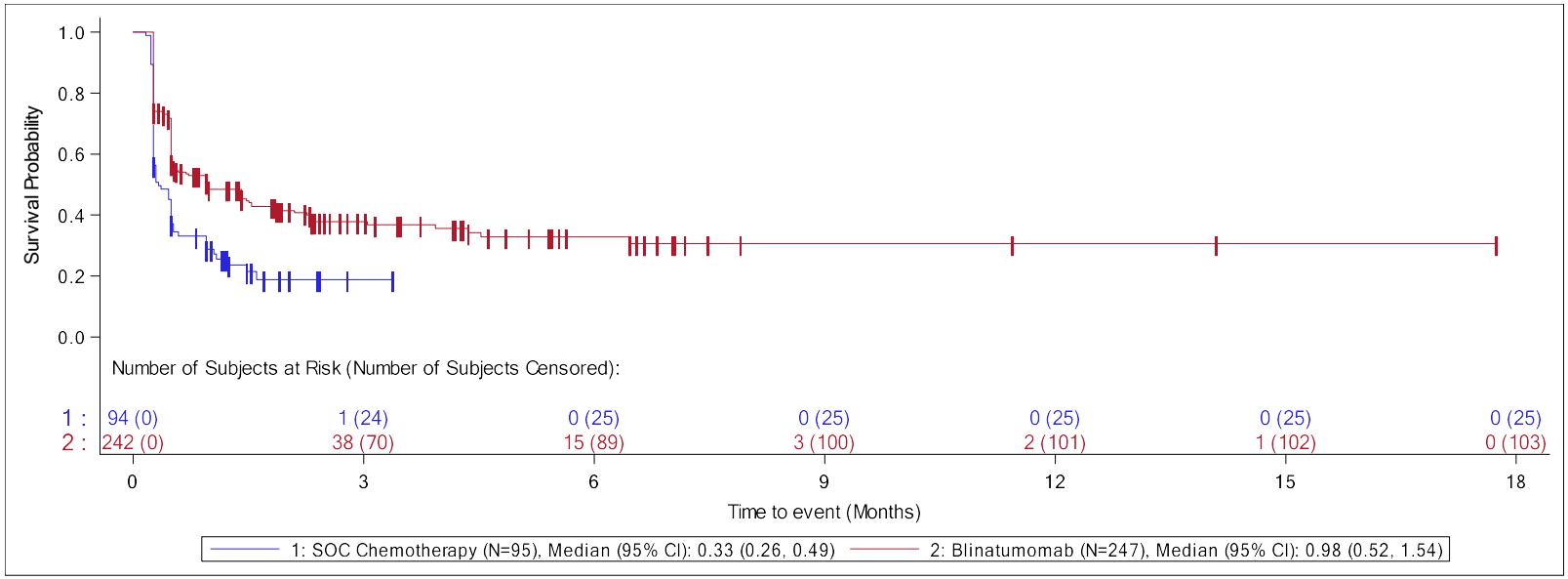
The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-714-qs-tte-de-eortc-dis-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

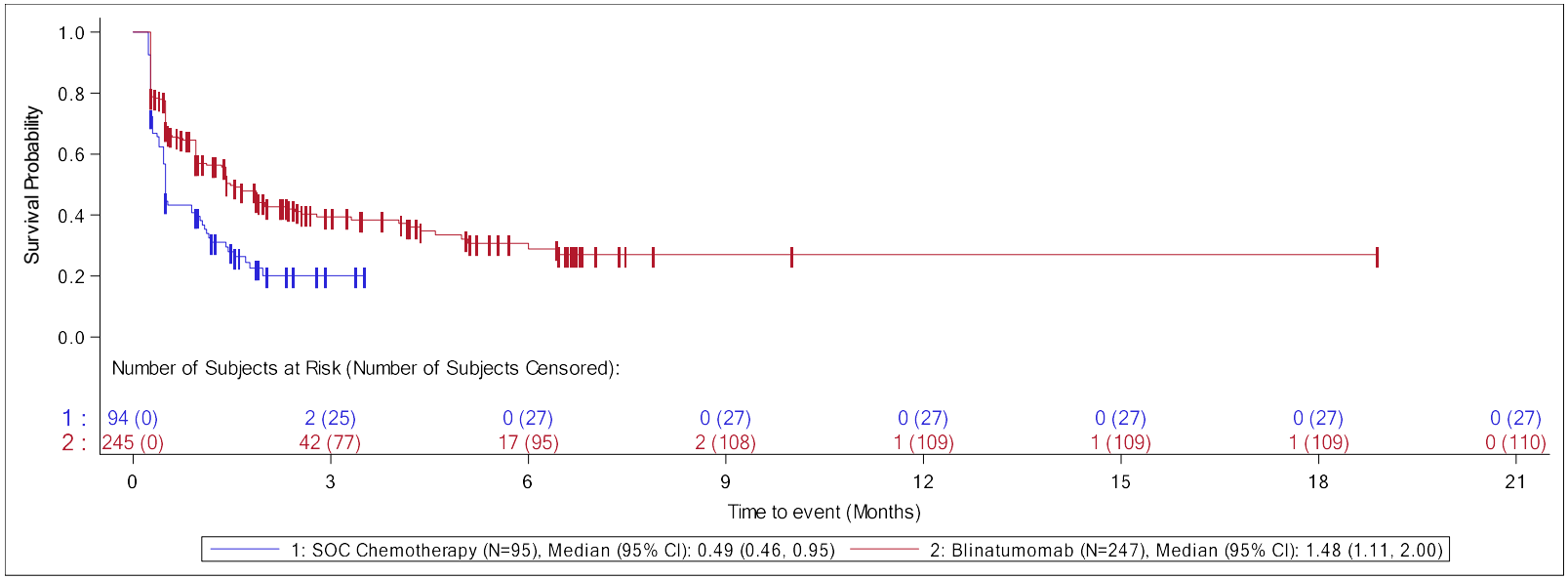
Figure 14-4.3.20. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-fs-eqcas.sas
Output: f14-04-003-020-km-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

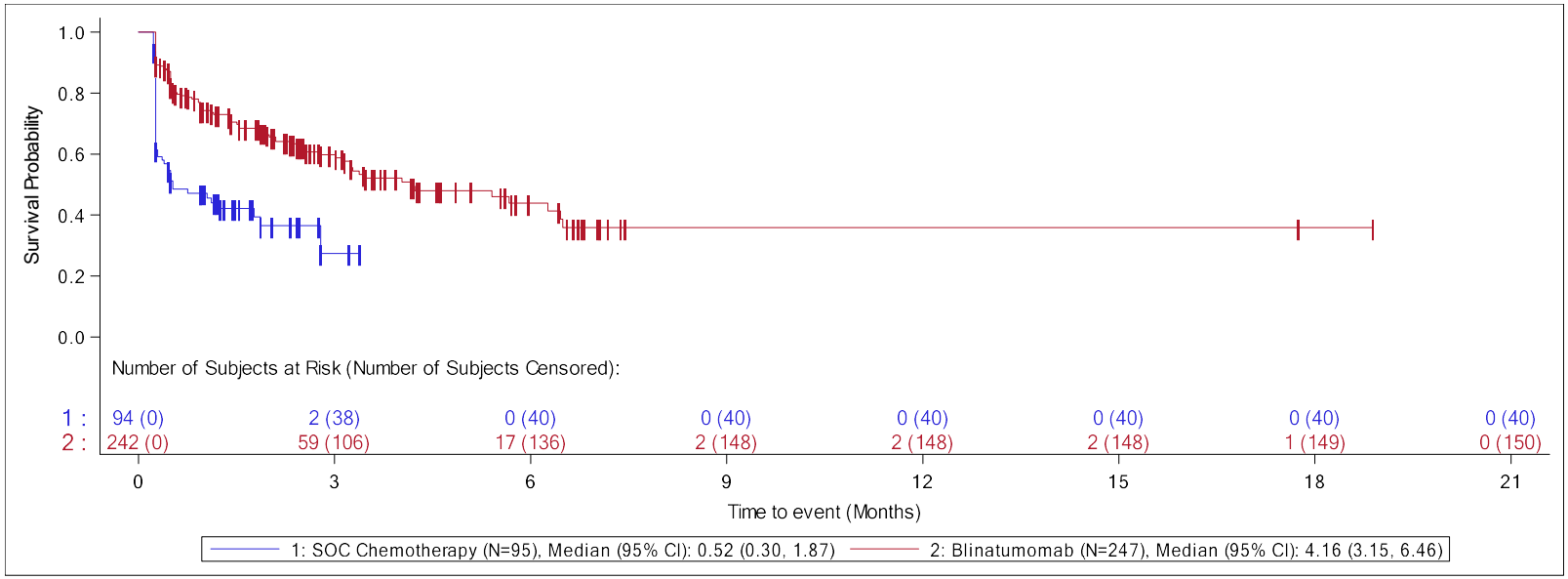
Figure 14-4.3.21. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-pas-eqcas.sas
Output: f14-04-003-021-km-de-eortc-pas-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

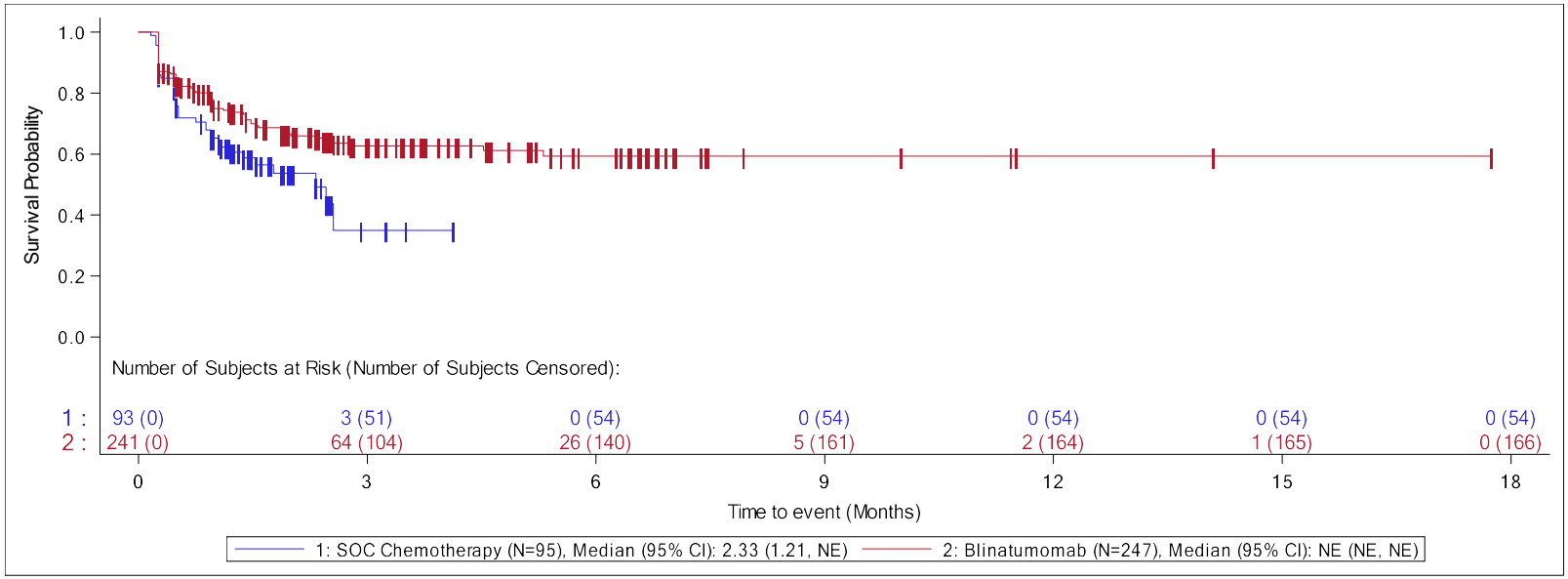
Figure 14-4.3.22. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-nvs-eqcas.sas
Output: f14-04-003-022-km-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

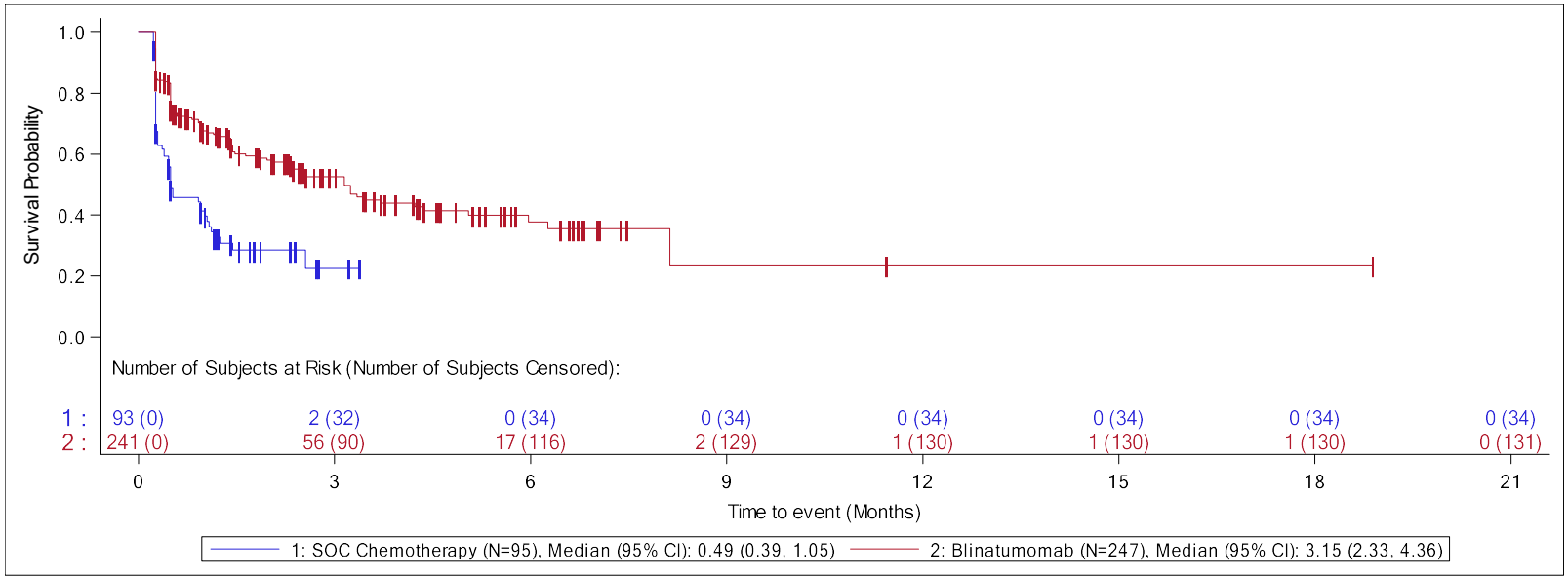
Figure 14-4.3.23. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-dys-eqcas.sas
Output: f14-04-003-023-km-de-eortc-dys-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

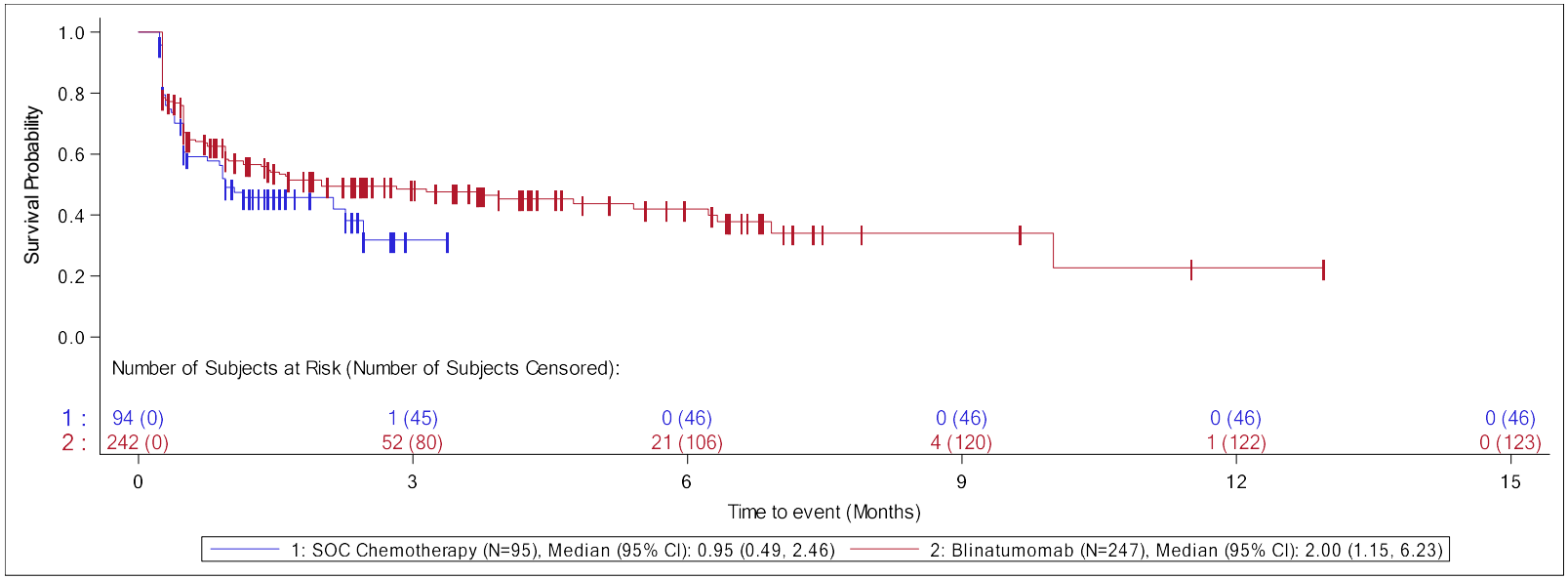
Figure 14-4.3.24. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-aps-eqcas.sas
Output: f14-04-003-024-km-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

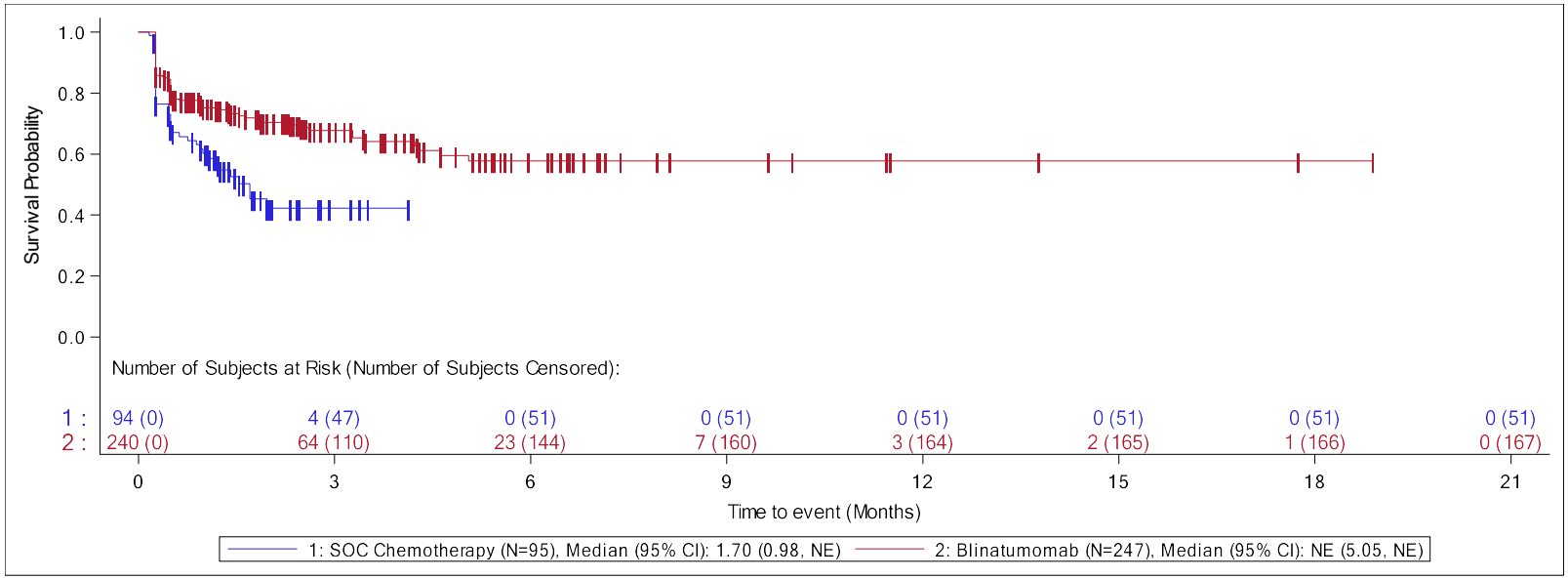
Figure 14-4.3.25. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-sls-eqcas.sas
Output: f14-04-003-025-km-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

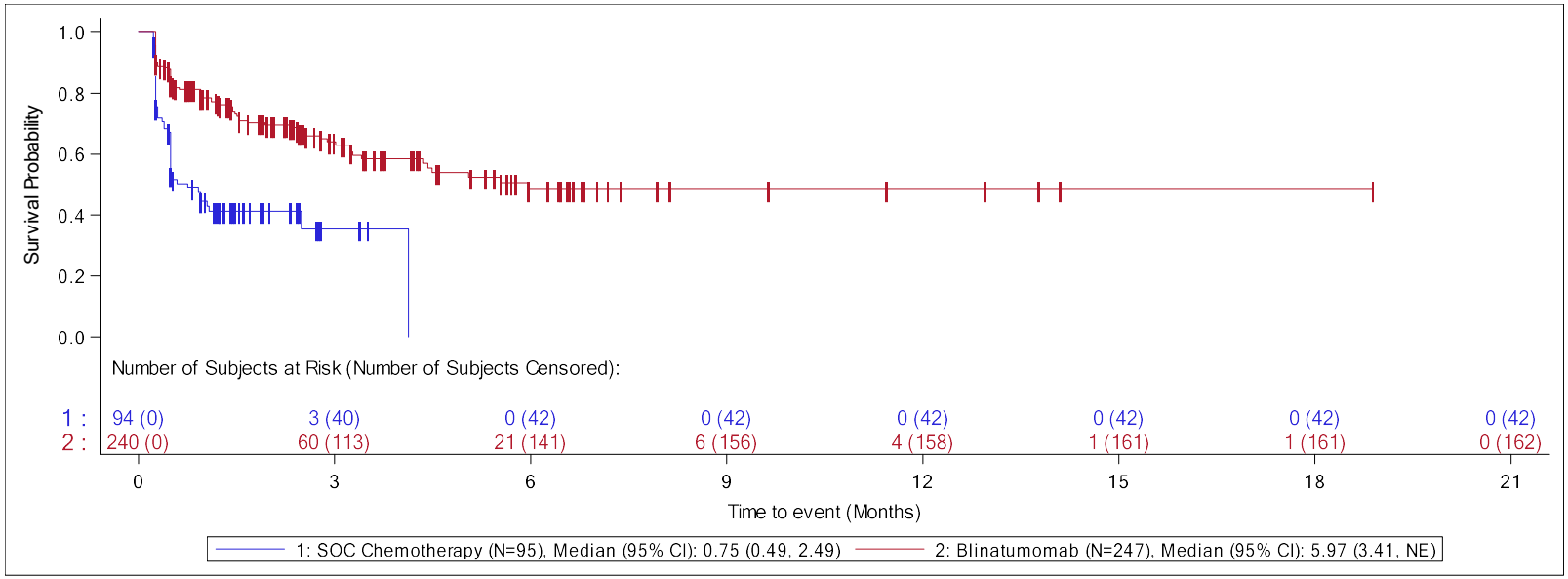
Figure 14-4.3.26. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-cos-eqcas.sas
Output: f14-04-003-026-km-de-eortc-cos-eqcas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

Figure 14-4.3.27. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-dis-eqcas.sas
Output: f14-04-003-027-km-de-eortc-dis-eqcas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

Anhang 4-G2.7.2: Dauer bis zur Verschlechterung des ALLSS-Fragebogens

Table 14-4.3.1. Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	51 (59.3)	93 (41.9)	
Censored - n (%)	35 (40.7)	129 (58.1)	
Unstratified log-rank test			
Normal score[a]			-19.60
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-18.46
p-value			<0.0001

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-de-allss-ts-allas.sas
Output: t14-04-003-001-tte-de-allss-ts-allas.rtf (Date generated: 16JUN2025:03:58) Source data: adam_pa.adsl, adam_pa.adqs, adam.adtteqs

Table 14-4.3.1. Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.15	2.79	
95% CI (median)	(0.89, 1.48)	(1.64, 13.77)	
Q1, Q3	0.49, 2.39	0.95, 13.77	
Min, Max	0.2, 2.5	0.3, 13.8	
Time to censoring (months)[c,d]			
Median	1.54	2.69	
Q1, Q3	0.95, 2.72	0.85, 5.41	
Min, Max	0.2, 3.5	0.3, 17.7	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-de-allss-ts-allas.sas
Output: t14-04-003-001-tte-de-allss-ts-allas.rtf (Date generated: 16JUN2025:03:58) Source data: adam_pa.adsl, adam_pa.adqs, adam.adtteqs

Table 14-4.3.1. Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	17.89 (7.29, 32.27)	48.11 (39.77, 55.96)	
At time 6 months[c]	NE (NE, NE)	42.96 (34.12, 51.48)	
At time 12 months[c]	NE (NE, NE)	34.37 (18.65, 50.69)	
At time 18 months[c]	NE (NE, NE)	NE (NE, NE)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.51
(95% CI)			(0.35, 0.72)
p-value			0.0002

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-de-allss-ts-allas.sas
Output: t14-04-003-001-tte-de-allss-ts-allas.rtf (Date generated: 16JUN2025:03:58) Source data: adam_pa.adsl, adam_pa.adqs, adam.adtteqs

Table 14-4.5.715. Time to Deterioration - Tiredness of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	53 (61.6)	102 (45.9)	
Censored - n (%)	33 (38.4)	120 (54.1)	
Stratified log-rank test[a]			
Normal score[b]			-17.29
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-17.49
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.5	3.2	
95% CI (median)	(0.5, 1.1)	(1.4, 11.5)	
Q1, Q3	0.3, NE	0.5, NE	
Min, Max	0.2, 1.8	0.3, 11.5	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-715-qs-tte-de-allss-ttdda1t-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.715. Time to Deterioration - Tiredness of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.8	
Q1, Q3	1.0, 2.3	1.0, 5.5	
Min, Max	0.2, 3.4	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	31.4	50.3	
(95% CI)	(20.4, 43.0)	(42.6, 57.5)	
At time 6 months[c]	NE	48.1	
(95% CI)	(NE, NE)	(40.1, 55.5)	
At time 12 months[c]	NE	32.9	
(95% CI)	(NE, NE)	(18.0, 48.6)	
At time 18 months[c]	NE	32.9	
(95% CI)	(NE, NE)	(18.0, 48.6)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.54
(95% CI)			(0.39, 0.77)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-715-qs-tte-de-allss-ttdda1t-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.716. Time to Deterioration - Weakness of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	59 (68.6)	104 (46.8)	
Censored - n (%)	27 (31.4)	118 (53.2)	
Stratified log-rank test[a]			
Normal score[b]			-21.68
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-22.68
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.5	2.5	
95% CI (median)	(0.5, 1.0)	(1.0, 11.5)	
Q1, Q3	0.3, 1.5	0.5, NE	
Min, Max	0.2, 1.8	0.3, 11.5	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-716-qs-tte-de-allss-ttdda2pw-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.716. Time to Deterioration - Weakness of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.0, 2.3	1.0, 5.6	
Min, Max	0.3, 3.4	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	21.3	46.9	
(95% CI)	(11.3, 33.3)	(39.0, 54.4)	
At time 6 months[c]	NE	44.7	
(95% CI)	(NE, NE)	(36.6, 52.4)	
At time 12 months[c]	NE	33.1	
(95% CI)	(NE, NE)	(18.7, 48.3)	
At time 18 months[c]	NE	33.1	
(95% CI)	(NE, NE)	(18.7, 48.3)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.49
(95% CI)			(0.35, 0.68)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-716-qs-tte-de-allss-ttdda2pw-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.717. Time to Deterioration - Bruise of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	38 (44.2)	58 (26.1)	
Censored - n (%)	48 (55.8)	164 (73.9)	
Stratified log-rank test[a]			
Normal score[b]			-13.68
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-14.54
p-value			<0.001
Time to event (KM) (months)[c]			
Median	2.3	NE	
95% CI (median)	(0.9, NE)	(8.1, NE)	
Q1, Q3	0.5, NE	1.2, NE	
Min, Max	0.3, 2.3	0.3, 8.1	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-717-qs-tte-de-allss-ttdda3br-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.717. Time to Deterioration - Bruise of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.6	2.5	
Q1, Q3	1.0, 2.4	1.0, 4.9	
Min, Max	0.2, 5.2	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	48.7	72.2	
(95% CI)	(35.8, 60.5)	(65.1, 78.2)	
At time 6 months[c]	NE	67.2	
(95% CI)	(NE, NE)	(58.3, 74.7)	
At time 12 months[c]	NE	58.8	
(95% CI)	(NE, NE)	(40.1, 73.5)	
At time 18 months[c]	NE	58.8	
(95% CI)	(NE, NE)	(40.1, 73.5)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.50
(95% CI)			(0.33, 0.76)

The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-717-qs-tte-de-allss-ttdda3br-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.718. Time to Deterioration - Bleeding of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	27 (31.4)	60 (27.0)	
Censored - n (%)	59 (68.6)	162 (73.0)	
Stratified log-rank test[a]			
Normal score[b]			-4.38
p-value			0.26
Unstratified log-rank test			
Normal score[b]			-4.73
p-value			0.23
Time to event (KM) (months)[c]			
Median	NE	NE	
95% CI (median)	(2.4, NE)	(8.1, NE)	
Q1, Q3	0.8, NE	1.4, NE	
Min, Max	0.2, 2.5	0.3, 8.1	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-718-qs-tte-de-allss-ttdda4bl-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.718. Time to Deterioration - Bleeding of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.0, 2.4	1.0, 4.6	
Min, Max	0.2, 5.2	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	57.5	71.2	
(95% CI)	(40.3, 71.4)	(63.9, 77.2)	
At time 6 months[c]	NE	68.4	
(95% CI)	(NE, NE)	(60.4, 75.2)	
At time 12 months[c]	NE	57.0	
(95% CI)	(NE, NE)	(39.4, 71.3)	
At time 18 months[c]	NE	57.0	
(95% CI)	(NE, NE)	(39.4, 71.3)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.78
(95% CI)			(0.49, 1.24)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-718-qs-tte-de-allss-ttdda4bl-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.719. Time to Deterioration - Fever of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	59 (68.6)	149 (67.1)	
Censored - n (%)	27 (31.4)	73 (32.9)	
Stratified log-rank test[a]			
Normal score[b]			0.29
p-value			0.96
Unstratified log-rank test			
Normal score[b]			-0.16
p-value			0.98
Time to event (KM) (months)[c]			
Median	0.5	0.5	
95% CI (median)	(0.5, 0.9)	(0.3, 0.5)	
Q1, Q3	0.3, 2.1	0.3, NE	
Min, Max	0.2, 2.3	0.2, 5.1	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-719-qs-tte-de-allss-ttdda5f-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.719. Time to Deterioration - Fever of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.0, 2.4	1.0, 5.3	
Min, Max	0.3, 2.9	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	NE	30.6	
(95% CI)	(NE, NE)	(24.1, 37.3)	
At time 6 months[c]	NE	25.9	
(95% CI)	(NE, NE)	(18.7, 33.5)	
At time 12 months[c]	NE	25.9	
(95% CI)	(NE, NE)	(18.7, 33.5)	
At time 18 months[c]	NE	25.9	
(95% CI)	(NE, NE)	(18.7, 33.5)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			1.09
(95% CI)			(0.80, 1.49)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-719-qs-tte-de-allss-ttdda5f-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.720. Time to Deterioration - Joint or bone pain of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	40 (46.5)	108 (48.6)	
Censored - n (%)	46 (53.5)	114 (51.4)	
Stratified log-rank test[a]			
Normal score[b]			-4.00
p-value			0.41
Unstratified log-rank test			
Normal score[b]			-3.43
p-value			0.49
Time to event (KM) (months)[c]			
Median	1.4	2.4	
95% CI (median)	(1.0, NE)	(1.4, 3.9)	
Q1, Q3	0.5, NE	0.5, 11.5	
Min, Max	0.2, 1.8	0.3, 11.5	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-720-qs-tte-de-allss-ttdda6p-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.720. Time to Deterioration - Joint or bone pain of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.6	
Q1, Q3	1.0, 2.4	1.0, 6.3	
Min, Max	0.3, 5.2	0.3, 17.7	
KM estimate - %			
At time 3 months[c]	44.4	44.6	
(95% CI)	(31.6, 56.4)	(36.7, 52.3)	
At time 6 months[c]	NE	36.9	
(95% CI)	(NE, NE)	(28.3, 45.5)	
At time 12 months[c]	NE	24.6	
(95% CI)	(NE, NE)	(7.9, 46.1)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.87
(95% CI)			(0.60, 1.27)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-720-qs-tte-de-allss-ttdda6p-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.721. Time to Deterioration - Itch of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	38 (44.2)	90 (40.5)	
Censored - n (%)	48 (55.8)	132 (59.5)	
Stratified log-rank test[a]			
Normal score[b]			-10.46
p-value			0.017
Unstratified log-rank test			
Normal score[b]			-9.67
p-value			0.030
Time to event (KM) (months)[c]			
Median	2.3	4.9	
95% CI (median)	(0.9, NE)	(2.5, 6.0)	
Q1, Q3	0.4, NE	1.0, 11.4	
Min, Max	0.2, 2.3	0.2, 11.4	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-721-qs-tte-de-allss-ttdda7i-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.721. Time to Deterioration - Itch of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.0, 2.3	1.0, 4.6	
Min, Max	0.2, 5.2	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	48.3	55.5	
(95% CI)	(34.4, 60.8)	(47.2, 63.1)	
At time 6 months[c]	NE	37.1	
(95% CI)	(NE, NE)	(26.0, 48.2)	
At time 12 months[c]	NE	20.1	
(95% CI)	(NE, NE)	(5.9, 40.2)	
At time 18 months[c]	NE	20.1	
(95% CI)	(NE, NE)	(5.9, 40.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.62
(95% CI)			(0.42, 0.92)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-721-qs-tte-de-allss-ttdda7i-allas.rtf (Date generated: 13FEB2017:02:38) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.722. Time to Deterioration - Swollen lymph nodes of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	17 (19.8)	38 (17.1)	
Censored - n (%)	69 (80.2)	184 (82.9)	
Stratified log-rank test[a]			
Normal score[b]			-3.46
p-value			0.26
Unstratified log-rank test			
Normal score[b]			-3.70
p-value			0.23
Time to event (KM) (months)[c]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	4.5, NE	
Min, Max	0.3, 1.2	0.3, 4.5	

The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-722-qs-tte-de-allss-ttdda8sl-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.722. Time to Deterioration - Swollen lymph nodes of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.0, 2.3	0.8, 5.1	
Min, Max	0.2, 5.2	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	77.9	79.9	
(95% CI)	(66.7, 85.8)	(72.6, 85.4)	
At time 6 months[c]	NE	74.1	
(95% CI)	(NE, NE)	(65.0, 81.2)	
At time 12 months[c]	NE	74.1	
(95% CI)	(NE, NE)	(65.0, 81.2)	
At time 18 months[c]	NE	74.1	
(95% CI)	(NE, NE)	(65.0, 81.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.72
(95% CI)			(0.40, 1.29)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-722-qs-tte-de-allss-ttdda8sl-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.723. Time to Deterioration - Fighting infection of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	58 (67.4)	120 (54.1)	
Censored - n (%)	28 (32.6)	102 (45.9)	
Stratified log-rank test[a]			
Normal score[b]			-14.46
p-value			0.006
Unstratified log-rank test			
Normal score[b]			-17.19
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.6	1.5	
95% CI (median)	(0.5, 1.1)	(1.0, 3.0)	
Q1, Q3	0.5, 2.3	0.5, NE	
Min, Max	0.2, 3.0	0.3, 6.9	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-723-qs-tte-de-allss-ttdda9fi-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.723. Time to Deterioration - Fighting infection of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.7	
Q1, Q3	1.0, 2.7	1.0, 5.4	
Min, Max	0.3, 3.4	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	9.7	42.7	
(95% CI)	(1.2, 29.4)	(35.1, 50.0)	
At time 6 months[c]	NE	30.1	
(95% CI)	(NE, NE)	(21.5, 39.1)	
At time 12 months[c]	NE	25.1	
(95% CI)	(NE, NE)	(14.5, 37.2)	
At time 18 months[c]	NE	25.1	
(95% CI)	(NE, NE)	(14.5, 37.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.65
(95% CI)			(0.47, 0.90)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-723-qs-tte-de-allss-ttdda9fi-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.724. Time to Deterioration - Short of breath of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	41 (47.7)	74 (33.3)	
Censored - n (%)	45 (52.3)	148 (66.7)	
Stratified log-rank test[a]			
Normal score[b]			-12.51
p-value			0.004
Unstratified log-rank test			
Normal score[b]			-14.17
p-value			0.001
Time to event (KM) (months)[c]			
Median	1.9	NE	
95% CI (median)	(1.0, 2.6)	(5.0, NE)	
Q1, Q3	0.5, 2.8	1.0, NE	
Min, Max	0.2, 2.8	0.3, 5.3	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-724-qs-tte-de-allss-ttdda10b-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.724. Time to Deterioration - Short of breath of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.6	
Q1, Q3	1.1, 2.0	1.0, 4.6	
Min, Max	0.2, 3.5	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	19.3	63.2	
(95% CI)	(4.3, 42.2)	(55.4, 69.9)	
At time 6 months[c]	NE	53.9	
(95% CI)	(NE, NE)	(43.6, 63.2)	
At time 12 months[c]	NE	53.9	
(95% CI)	(NE, NE)	(43.6, 63.2)	
At time 18 months[c]	NE	53.9	
(95% CI)	(NE, NE)	(43.6, 63.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.57
(95% CI)			(0.38, 0.85)

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-724-qs-tte-de-allss-ttdda10b-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.725. Time to Deterioration - Unable to eat of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	53 (61.6)	124 (55.9)	
Censored - n (%)	33 (38.4)	98 (44.1)	
Stratified log-rank test[a]			
Normal score[b]			-12.15
p-value			0.019
Unstratified log-rank test			
Normal score[b]			-13.36
p-value			0.010
Time to event (KM) (months)[c]			
Median	0.5	1.4	
95% CI (median)	(0.4, 1.4)	(1.0, 2.0)	
Q1, Q3	0.3, NE	0.5, 5.0	
Min, Max	0.2, 2.5	0.3, 6.3	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-725-qs-tte-de-allss-ttdda11e-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.725. Time to Deterioration - Unable to eat of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.7	2.6	
Q1, Q3	1.1, 2.7	1.0, 4.6	
Min, Max	0.2, 4.1	0.3, 13.0	
KM estimate - %			
At time 3 months[c]	29.9	37.6	
(95% CI)	(18.4, 42.2)	(30.0, 45.3)	
At time 6 months[c]	NE	25.0	
(95% CI)	(NE, NE)	(16.5, 34.4)	
At time 12 months[c]	NE	18.7	
(95% CI)	(NE, NE)	(9.9, 29.7)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.68
(95% CI)			(0.49, 0.95)

The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-725-qs-tte-de-allss-ttdda11e-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

Table 14-4.5.726. Time to Deterioration - Night sweats of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	43 (50.0)	109 (49.1)	
Censored - n (%)	43 (50.0)	113 (50.9)	
Stratified log-rank test[a]			
Normal score[b]			-1.51
p-value			0.77
Unstratified log-rank test			
Normal score[b]			-2.67
p-value			0.60
Time to event (KM) (months)[c]			
Median	1.4	1.9	
95% CI (median)	(0.9, NE)	(1.0, 6.5)	
Q1, Q3	0.5, NE	0.4, NE	
Min, Max	0.2, 2.5	0.3, 6.5	

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The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-726-qs-tte-de-allss-ttdda12s-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

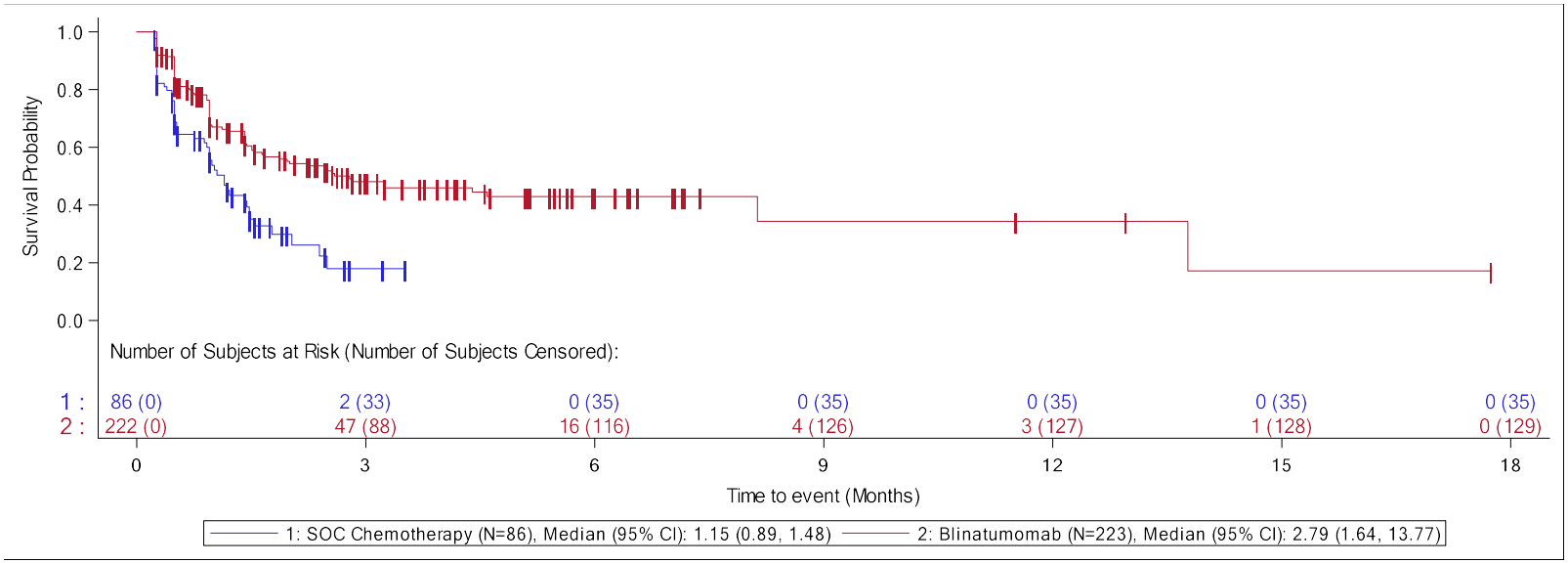
Table 14-4.5.726. Time to Deterioration - Night sweats of ALLSS (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.5	
Q1, Q3	1.1, 2.4	1.0, 5.4	
Min, Max	0.3, 4.1	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	37.5	45.5	
(95% CI)	(23.2, 51.8)	(37.9, 52.8)	
At time 6 months[c]	NE	42.6	
(95% CI)	(NE, NE)	(34.4, 50.5)	
At time 12 months[c]	NE	40.1	
(95% CI)	(NE, NE)	(31.1, 48.9)	
At time 18 months[c]	NE	40.1	
(95% CI)	(NE, NE)	(31.1, 48.9)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.97
(95% CI)			(0.68, 1.40)

The ALLSS Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte-de-allss.sas
Output: t14-04-005-726-qs-tte-de-allss-ttdda12s-allas.rtf (Date generated: 13FEB2017:02:39) Source data: adam.adqs, adam.adtteqs

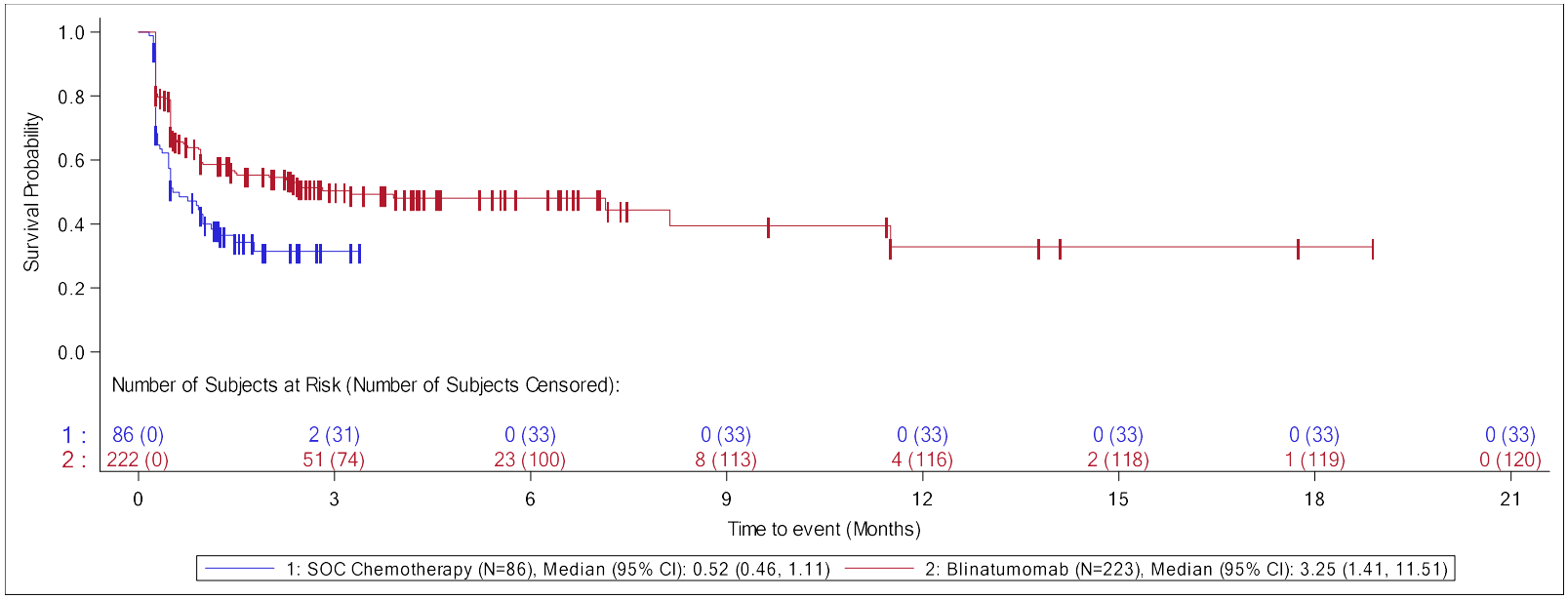
Figure 14-4.3.1. Kaplan-Meier plot for Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ts-allas.sas
Output: f14-04-003-001-km-de-allss-ts-allas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam.adtteqs

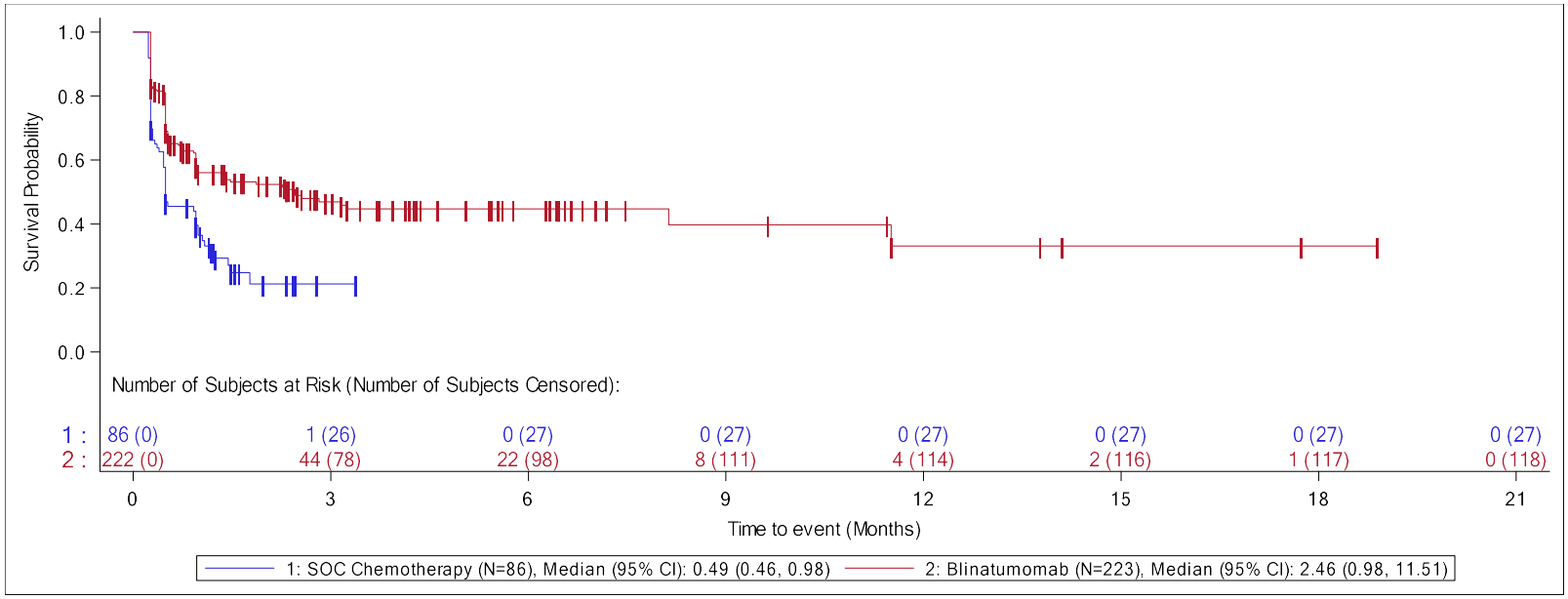
Figure 14-4.3.2. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Tiredness (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda1t-allas.sas
Output: f14-04-003-002-km-de-allss-ttda1t-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

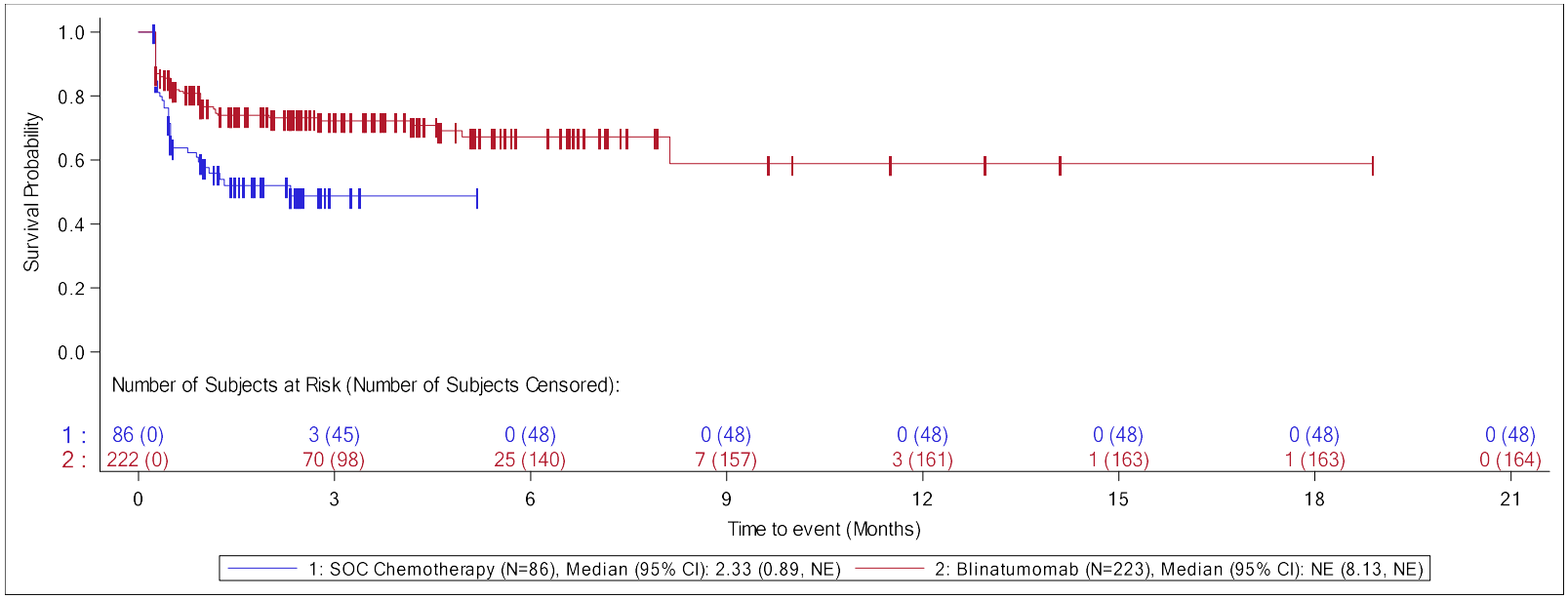
Figure 14-4.3.3. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Weakness (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda2pw-allas.sas
Output: f14-04-003-003-km-de-allss-ttda2pw-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

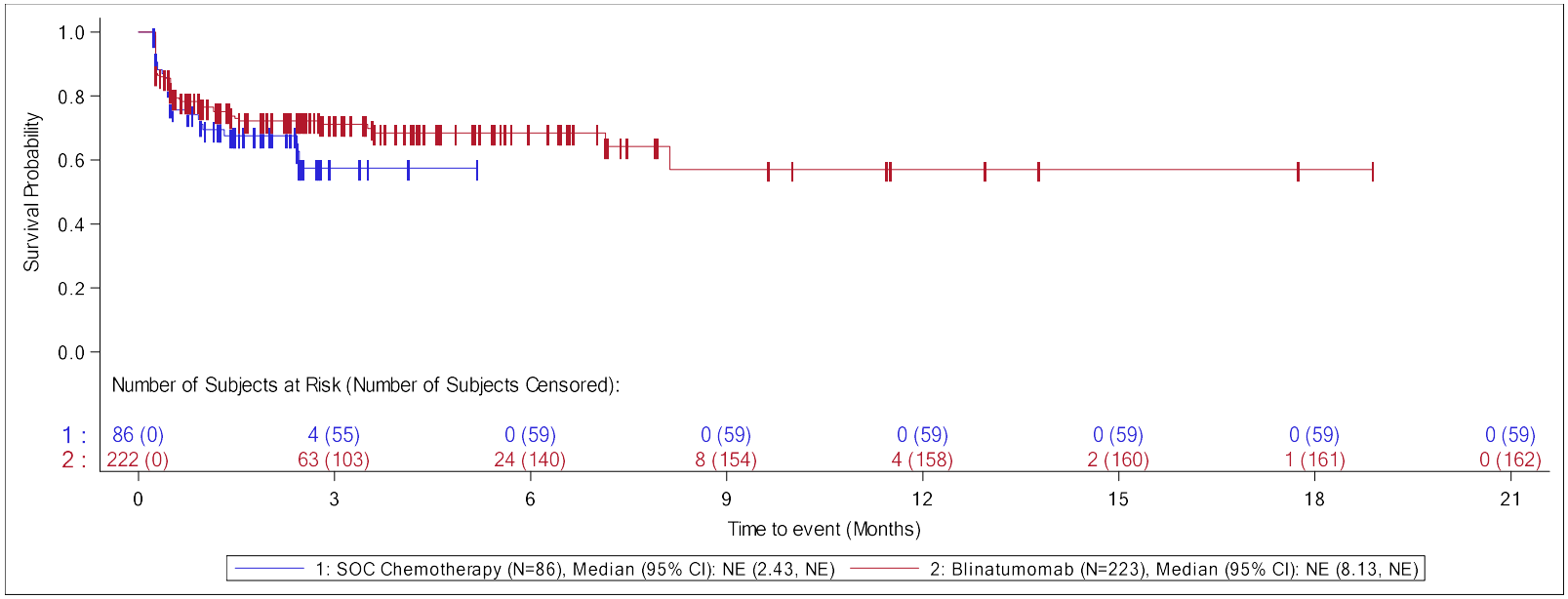
Figure 14-4.3.4. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bruise (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda3br-allas.sas
Output: f14-04-003-004-km-de-allss-ttda3br-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

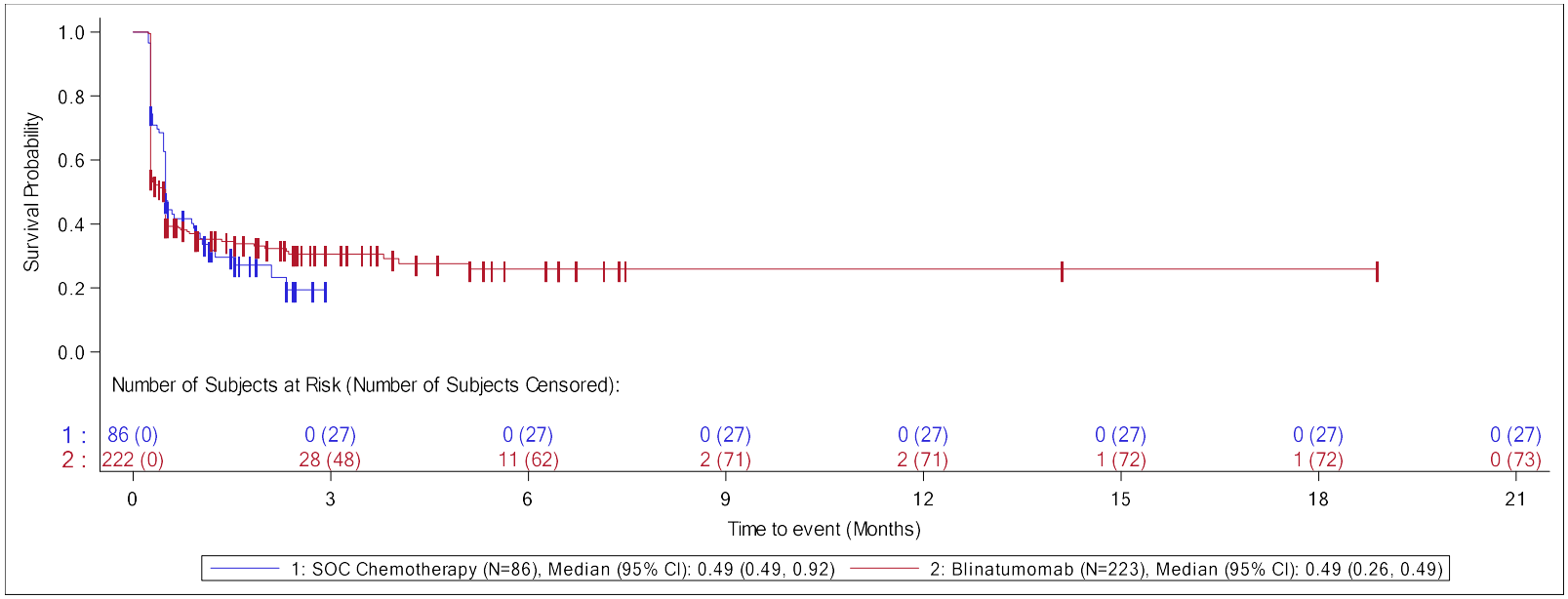
Figure 14-4.3.5. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bleeding (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda4bl-allas.sas
Output: f14-04-003-005-km-de-allss-ttda4bl-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

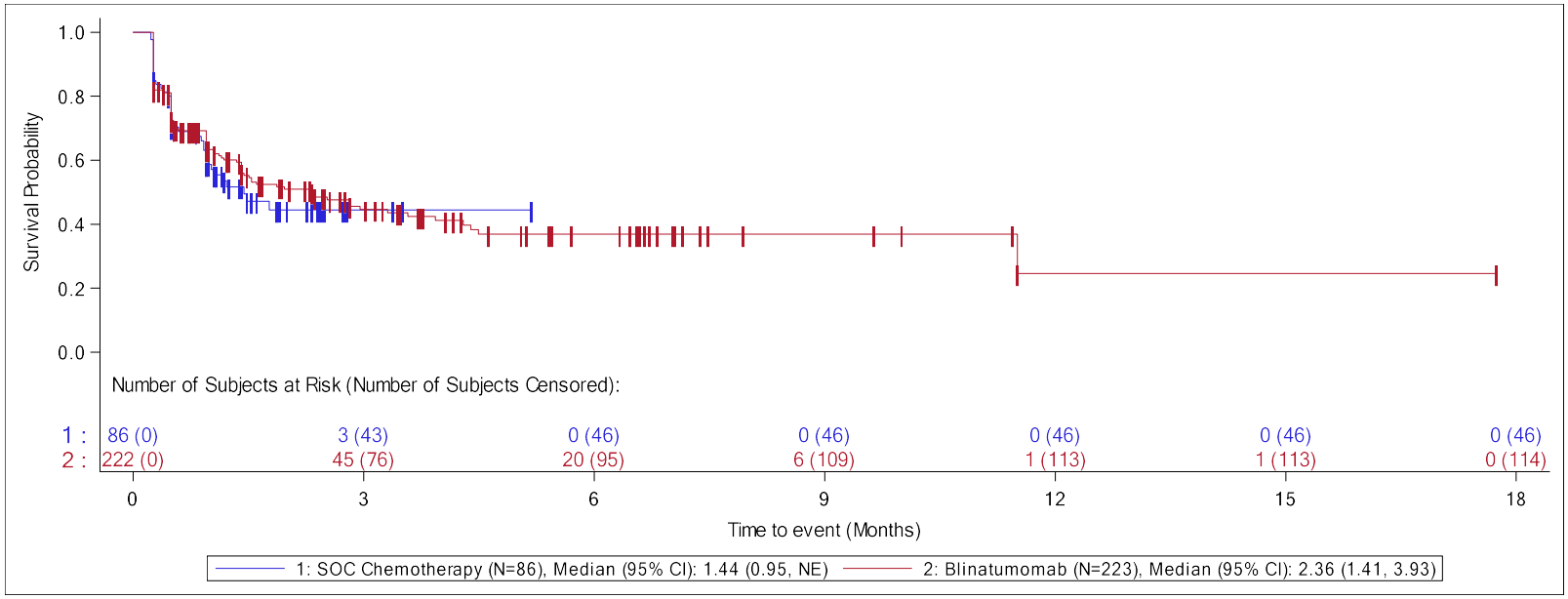
Figure 14-4.3.6. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fever (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda5f-allas.sas
Output: f14-04-003-006-km-de-allss-ttda5f-allas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

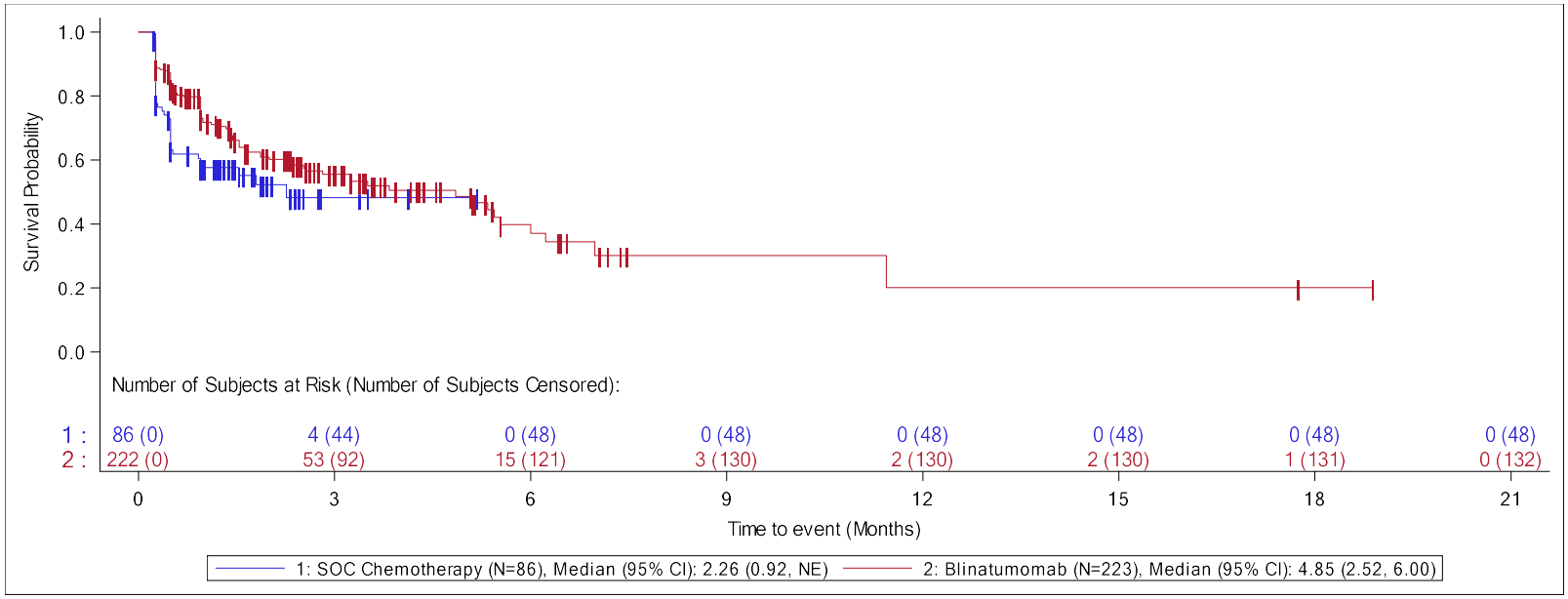
Figure 14-4.3.7. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Joint or bone pain
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda6p-allas.sas
Output: f14-04-003-007-km-de-allss-ttda6p-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

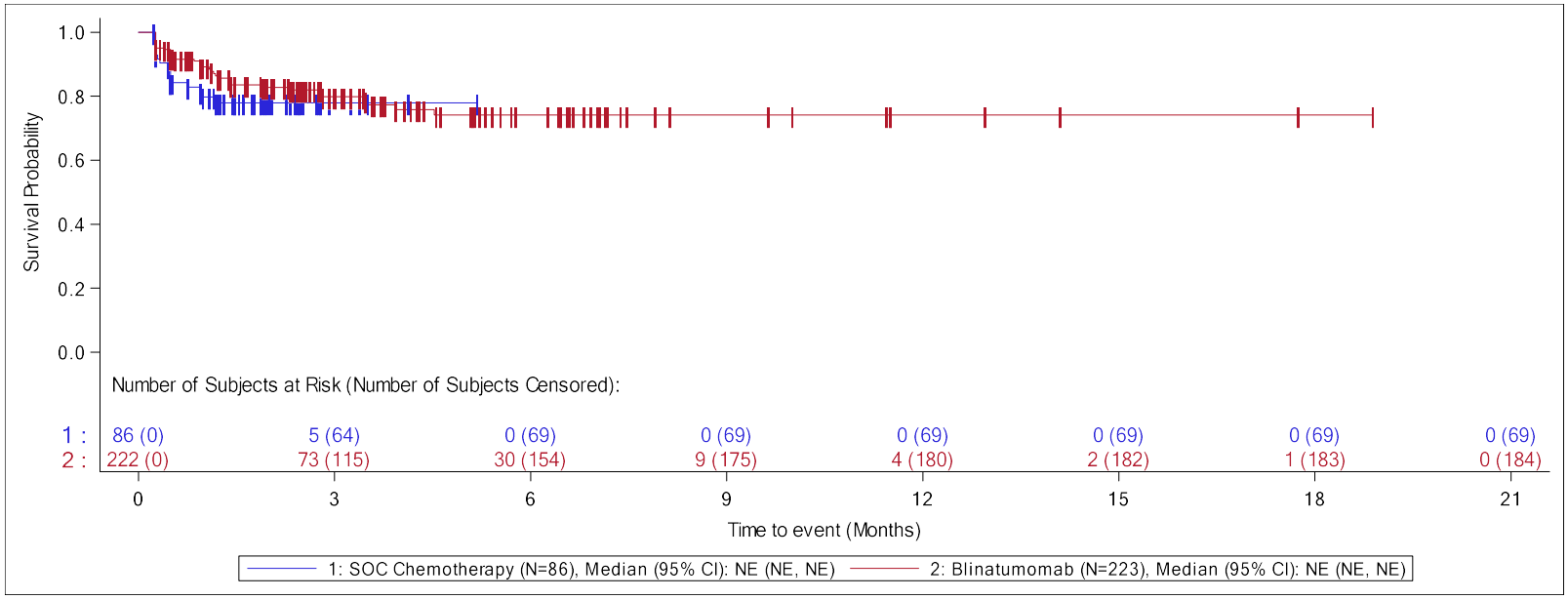
Figure 14-4.3.8. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Itch (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda7i-allas.sas
Output: f14-04-003-008-km-de-allss-ttda7i-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

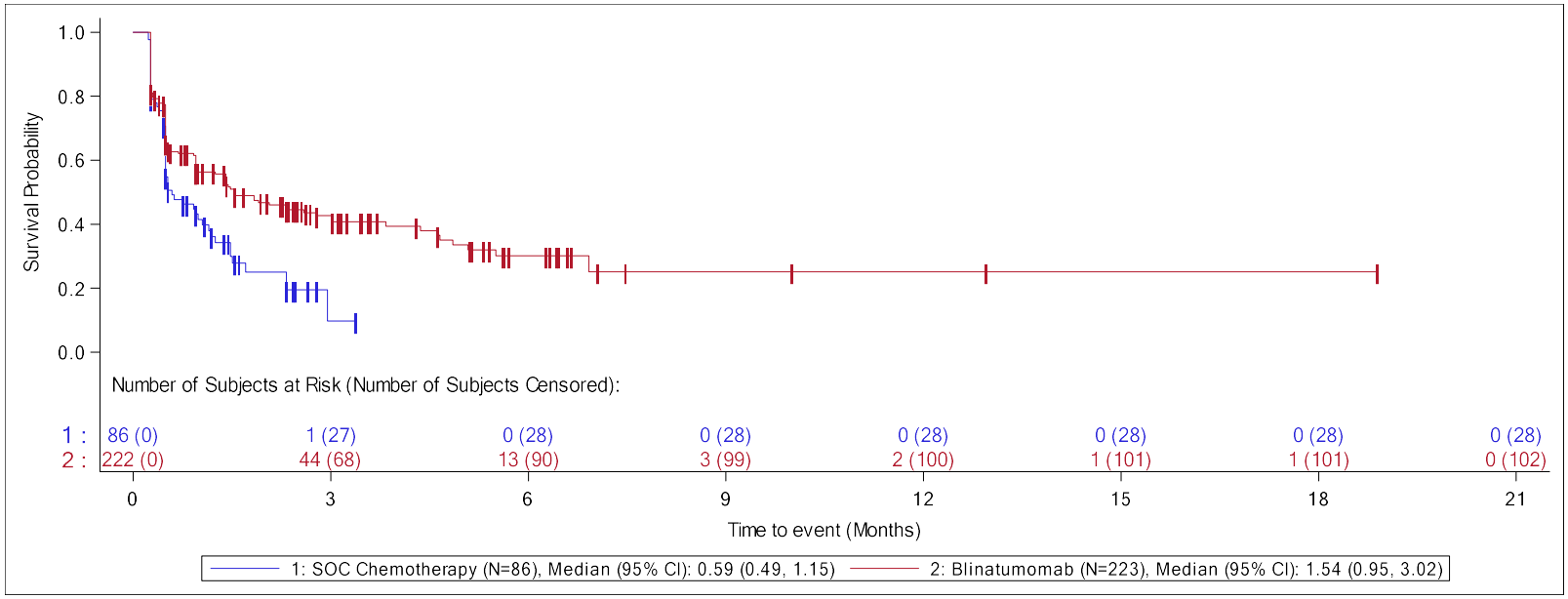
Figure 14-4.3.9. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Swollen lymph nodes (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda8sl-allas.sas
Output: f14-04-003-009-km-de-allss-ttda8sl-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

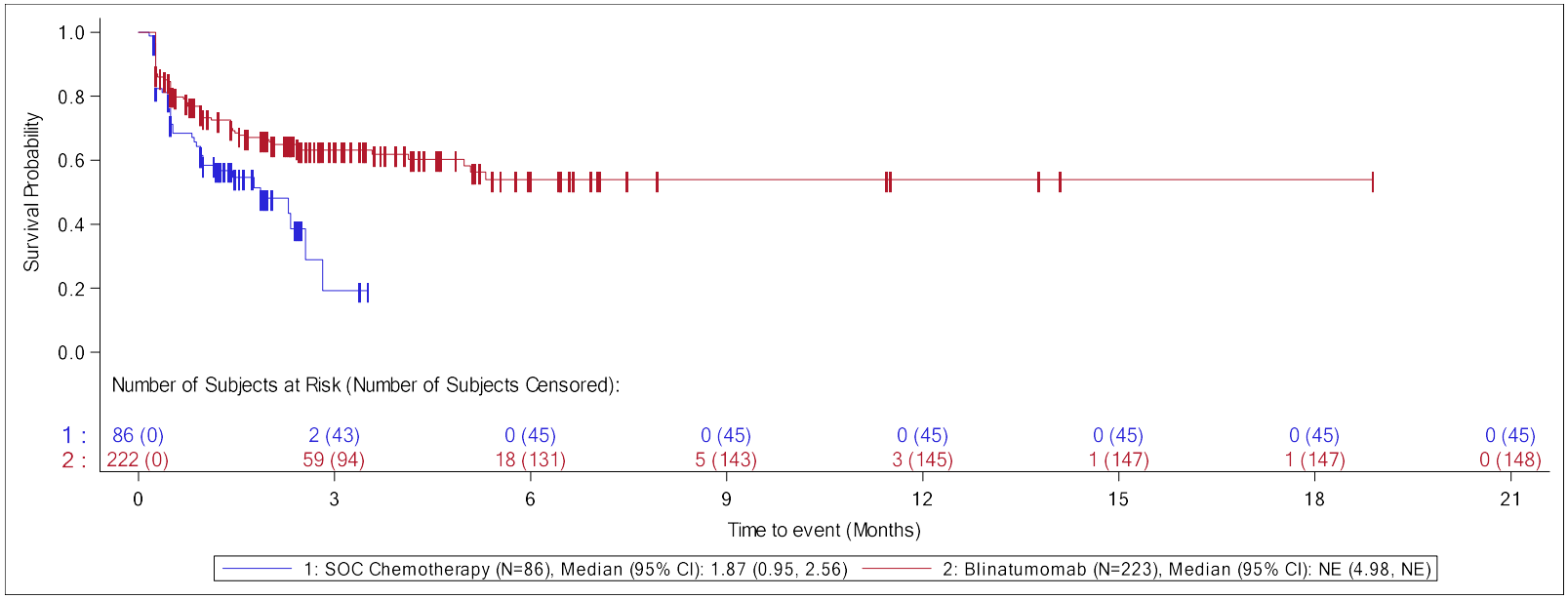
Figure 14-4.3.10. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fighting infection
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda9fi-allas.sas
Output: f14-04-003-010-km-de-allss-ttda9fi-allas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

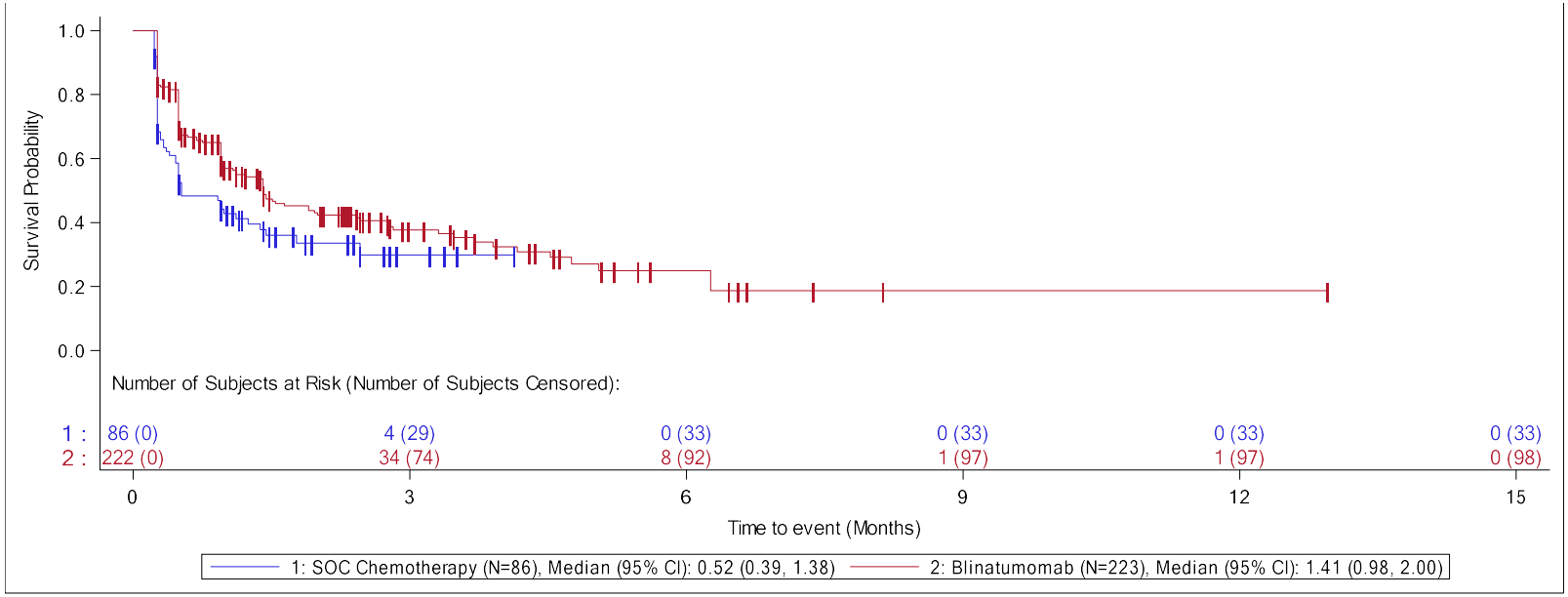
Figure 14-4.3.11. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Short of breath
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda10b-allas.sas
Output: f14-04-003-011-km-de-allss-ttda10b-allas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

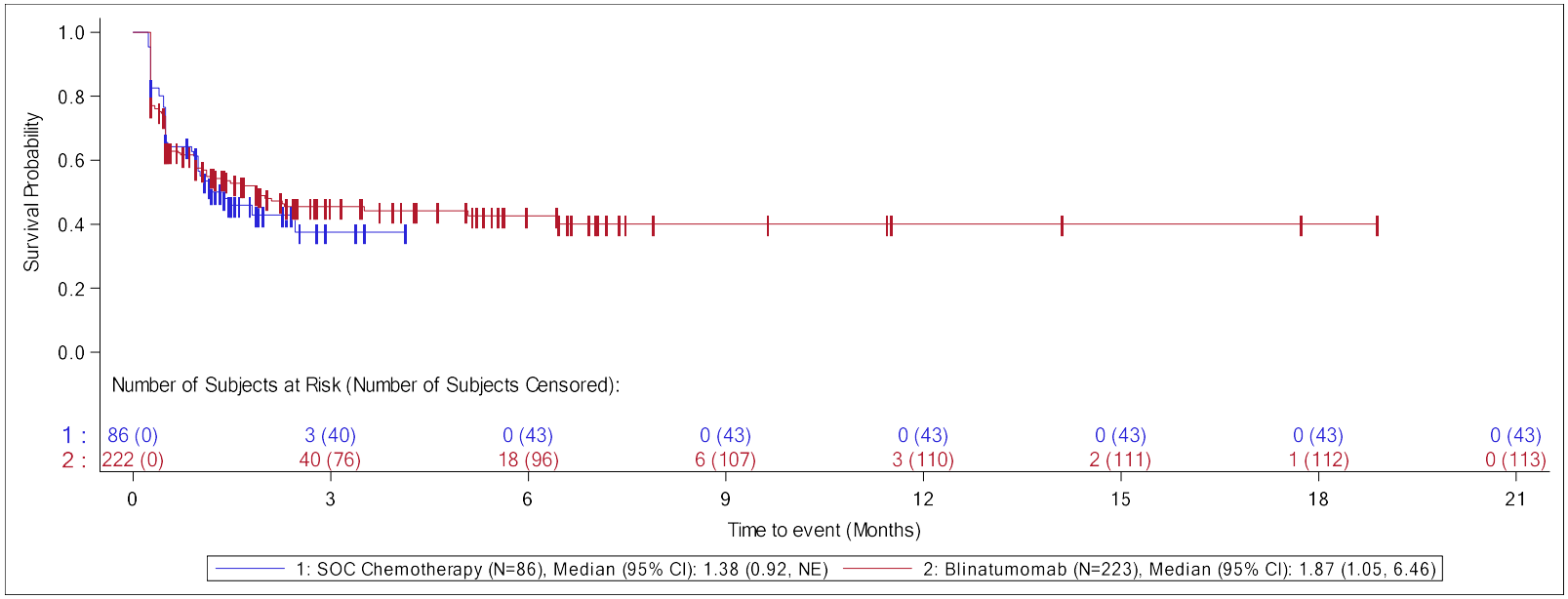
Figure 14-4.3.12. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Unable to eat (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda11e-allas.sas
Output: f14-04-003-012-km-de-allss-ttda11e-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

Figure 14-4.3.13. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Night sweats
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-allss-ttda12s-allas.sas
Output: f14-04-003-013-km-de-allss-ttda12s-allas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

Anhang 4-G2.8: Dauer bis zur Verschlechterung des EORTC-QLQ-C30 (gesundheitsbezogene Lebensqualität)

Table 14-4.2.701. Time to Deterioration - Global Health Status or QoL of EORTC QLQ-C30
(EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	95	240	
Events - n (%)	50 (52.6)	99 (41.3)	
Censored - n (%)	45 (47.4)	141 (58.8)	
Stratified log-rank test[a]			
Normal score[b]			-14.53
p-value			0.003
Unstratified log-rank test			
Normal score[b]			-15.49
p-value			0.001
Time to event (KM) (months)[c]			
Median	1.0	8.1	
95% CI (median)	(0.5, 1.8)	(2.8, NE)	
Q1, Q3	0.3, NE	0.5, NE	
Min, Max	0.2, 2.5	0.3, 8.1	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-701-qs-tte-de-eortc-ghs-eqcas.rtf (Date generated: 01FEB2017:08:30) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.701. Time to Deterioration - Global Health Status or QoL of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.6	
Q1, Q3	0.5, 2.4	1.0, 5.4	
Min, Max	0.2, 3.4	0.3, 14.1	
KM estimate - %			
At time 3 months[c]	32.8	55.8	
(95% CI)	(19.8, 46.4)	(48.4, 62.5)	
At time 6 months[c]	NE	52.2	
(95% CI)	(NE, NE)	(44.2, 59.5)	
At time 12 months[c]	NE	43.0	
(95% CI)	(NE, NE)	(28.1, 57.1)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.60
(95% CI)			(0.42, 0.85)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-701-qs-tte-de-eortc-ghs-eqcas.rtf (Date generated: 01FEB2017:08:30) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.702. Time to Deterioration - Physical Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	241	
Events - n (%)	59 (62.8)	126 (52.3)	
Censored - n (%)	35 (37.2)	115 (47.7)	
Stratified log-rank test[a]			
Normal score[b]			-13.12
p-value			0.015
Unstratified log-rank test			
Normal score[b]			-15.17
p-value			0.005
Time to event (KM) (months)[c]			
Median	0.9	1.5	
95% CI (median)	(0.5, 1.0)	(1.0, 3.1)	
Q1, Q3	0.3, 2.5	0.5, NE	
Min, Max	0.2, 2.5	0.3, 11.5	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-702-qs-tte-de-eortc-pf-eqcas.rtf (Date generated: 01FEB2017:08:30) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.702. Time to Deterioration - Physical Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	3.1	
Q1, Q3	1.0, 2.4	1.0, 5.7	
Min, Max	0.2, 3.5	0.3, 17.7	
KM estimate - %			
At time 3 months[c]	24.4	45.3	
(95% CI)	(13.2, 37.5)	(38.3, 52.1)	
At time 6 months[c]	NE	39.9	
(95% CI)	(NE, NE)	(32.5, 47.1)	
At time 12 months[c]	NE	29.9	
(95% CI)	(NE, NE)	(13.9, 47.8)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.69
(95% CI)			(0.50, 0.95)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-702-qs-tte-de-eortc-pf-eqcas.rtf (Date generated: 01FEB2017:08:30) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.703. Time to Deterioration - Role Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	91	241	
Events - n (%)	66 (72.5)	139 (57.7)	
Censored - n (%)	25 (27.5)	102 (42.3)	
Stratified log-rank test[a]			
Normal score[b]			-18.34
p-value			<0.001
Unstratified log-rank test			
Normal score[b]			-19.63
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.5	1.0	
95% CI (median)	(0.3, 1.0)	(0.6, 1.8)	
Q1, Q3	0.3, 1.7	0.3, 11.5	
Min, Max	0.2, 2.0	0.3, 11.5	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-703-qs-tte-de-eortc-rf-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.703. Time to Deterioration - Role Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.6	2.6	
Q1, Q3	1.1, 2.3	1.0, 5.8	
Min, Max	0.2, 4.1	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	14.8	37.8	
(95% CI)	(6.6, 26.1)	(30.7, 44.7)	
At time 6 months[c]	NE	30.8	
(95% CI)	(NE, NE)	(23.3, 38.5)	
At time 12 months[c]	NE	23.1	
(95% CI)	(NE, NE)	(10.7, 38.2)	
At time 18 months[c]	NE	23.1	
(95% CI)	(NE, NE)	(10.7, 38.2)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.60
(95% CI)			(0.44, 0.81)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-703-qs-tte-de-eortc-rf-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.704. Time to Deterioration - Cognitive Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	95	242	
Events - n (%)	58 (61.1)	126 (52.1)	
Censored - n (%)	37 (38.9)	116 (47.9)	
Stratified log-rank test[a]			
Normal score[b]			-14.18
p-value			0.006
Unstratified log-rank test			
Normal score[b]			-16.66
p-value			0.001
Time to event (KM) (months)[c]			
Median	0.9	2.0	
95% CI (median)	(0.5, 1.4)	(1.4, 3.2)	
Q1, Q3	0.3, 2.1	0.5, NE	
Min, Max	0.2, 2.5	0.3, 7.4	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-704-qs-tte-de-eortc-cf-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.704. Time to Deterioration - Cognitive Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.6	2.8	
Q1, Q3	1.0, 2.4	1.0, 5.6	
Min, Max	0.2, 3.5	0.3, 17.7	
KM estimate - %			
At time 3 months[c]	19.9	44.6	
(95% CI)	(9.1, 33.7)	(37.1, 51.7)	
At time 6 months[c]	NE	32.8	
(95% CI)	(NE, NE)	(24.6, 41.2)	
At time 12 months[c]	NE	26.2	
(95% CI)	(NE, NE)	(14.1, 40.0)	
At time 18 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.67
(95% CI)			(0.48, 0.92)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-704-qs-tte-de-eortc-cf-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.705. Time to Deterioration - Emotional Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	241	
Events - n (%)	35 (37.2)	73 (30.3)	
Censored - n (%)	59 (62.8)	168 (69.7)	
Stratified log-rank test[a]			
Normal score[b]			-9.75
p-value			0.020
Unstratified log-rank test			
Normal score[b]			-11.10
p-value			0.007
Time to event (KM) (months)[c]			
Median	2.8	11.5	
95% CI (median)	(1.5, NE)	(6.7, NE)	
Q1, Q3	0.5, NE	1.5, NE	
Min, Max	0.2, 2.8	0.3, 11.5	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-705-qs-tte-de-eortc-ef-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.705. Time to Deterioration - Emotional Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.5	2.6	
Q1, Q3	0.8, 2.3	1.0, 5.6	
Min, Max	0.2, 5.2	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	43.8	66.6	
(95% CI)	(24.4, 61.7)	(59.1, 73.0)	
At time 6 months[c]	NE	60.7	
(95% CI)	(NE, NE)	(52.2, 68.2)	
At time 12 months[c]	NE	44.8	
(95% CI)	(NE, NE)	(26.7, 61.4)	
At time 18 months[c]	NE	44.8	
(95% CI)	(NE, NE)	(26.7, 61.4)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.61
(95% CI)			(0.40, 0.93)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-705-qs-tte-de-eortc-ef-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.706. Time to Deterioration - Social Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	53 (56.4)	134 (55.4)	
Censored - n (%)	41 (43.6)	108 (44.6)	
Stratified log-rank test[a]			
Normal score[b]			-6.80
p-value			0.21
Unstratified log-rank test			
Normal score[b]			-8.42
p-value			0.12
Time to event (KM) (months)[c]			
Median	1.0	1.1	
95% CI (median)	(0.5, 1.8)	(1.0, 2.0)	
Q1, Q3	0.3, NE	0.5, NE	
Min, Max	0.2, 2.5	0.2, 5.8	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-706-qs-tte-de-eortc-sf-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.706. Time to Deterioration - Social Functioning from Functional Subscales of EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.6	2.9	
Q1, Q3	0.8, 2.4	1.0, 6.3	
Min, Max	0.2, 4.1	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	25.9	39.3	
(95% CI)	(13.5, 40.3)	(32.2, 46.3)	
At time 6 months[c]	NE	30.9	
(95% CI)	(NE, NE)	(23.0, 39.0)	
At time 12 months[c]	NE	30.9	
(95% CI)	(NE, NE)	(23.0, 39.0)	
At time 18 months[c]	NE	30.9	
(95% CI)	(NE, NE)	(23.0, 39.0)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.83
(95% CI)			(0.60, 1.14)

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-706-qs-tte-de-eortc-sf-eqcas.rtf (Date generated: 01FEB2017:08:31) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.715. Time to Deterioration - Financial Impact from EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	238	
Events - n (%)	31 (33.0)	78 (32.8)	
Censored - n (%)	63 (67.0)	160 (67.2)	
Stratified log-rank test[a]			
Normal score[b]			-4.96
p-value			0.24
Unstratified log-rank test			
Normal score[b]			-4.68
p-value			0.27
Time to event (KM) (months)[c]			
Median	2.5	17.7	
95% CI (median)	(1.8, NE)	(4.4, NE)	
Q1, Q3	0.9, NE	1.0, NE	
Min, Max	0.2, 2.5	0.3, 17.7	

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The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-715-qs-tte-de-eortc-fis-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

Table 14-4.2.715. Time to Deterioration - Financial Impact from EORTC QLQ-C30 (EORTC QLQ-C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to censoring (months)[c,d]			
Median	1.4	2.5	
Q1, Q3	0.8, 2.3	1.0, 4.9	
Min, Max	0.2, 4.1	0.3, 18.9	
KM estimate - %			
At time 3 months[c]	46.7	61.4	
(95% CI)	(28.1, 63.4)	(53.5, 68.3)	
At time 6 months[c]	NE	57.7	
(95% CI)	(NE, NE)	(49.1, 65.3)	
At time 12 months[c]	NE	57.7	
(95% CI)	(NE, NE)	(49.1, 65.3)	
At time 18 months[c]	NE	28.8	
(95% CI)	(NE, NE)	(2.2, 66.7)	
At time 24 months[c]	NE	NE	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.79
(95% CI)			(0.51, 1.21)

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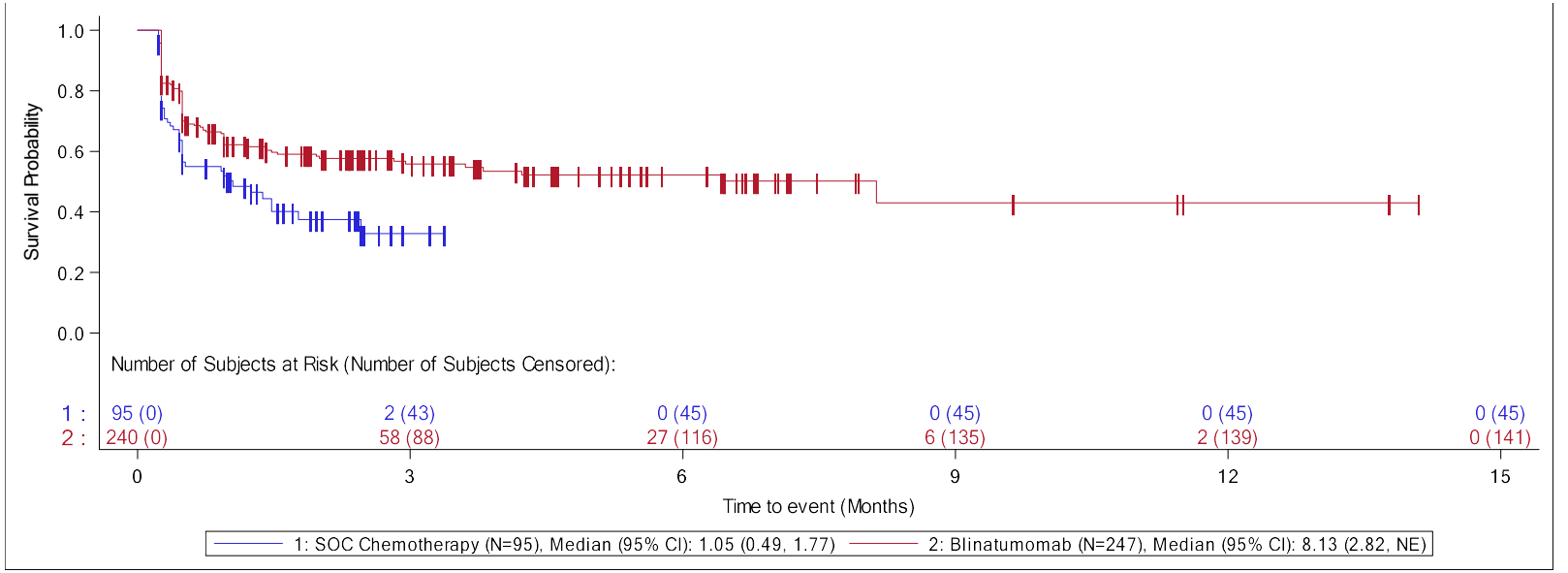
The EORTC QLQ-C30 Analysis Set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_ssap_pro/tables/program/t-qs-tte.sas
Output: t14-04-002-715-qs-tte-de-eortc-fis-eqcas.rtf (Date generated: 01FEB2017:08:32) Source data: adam.adqs, adam.adtteqs

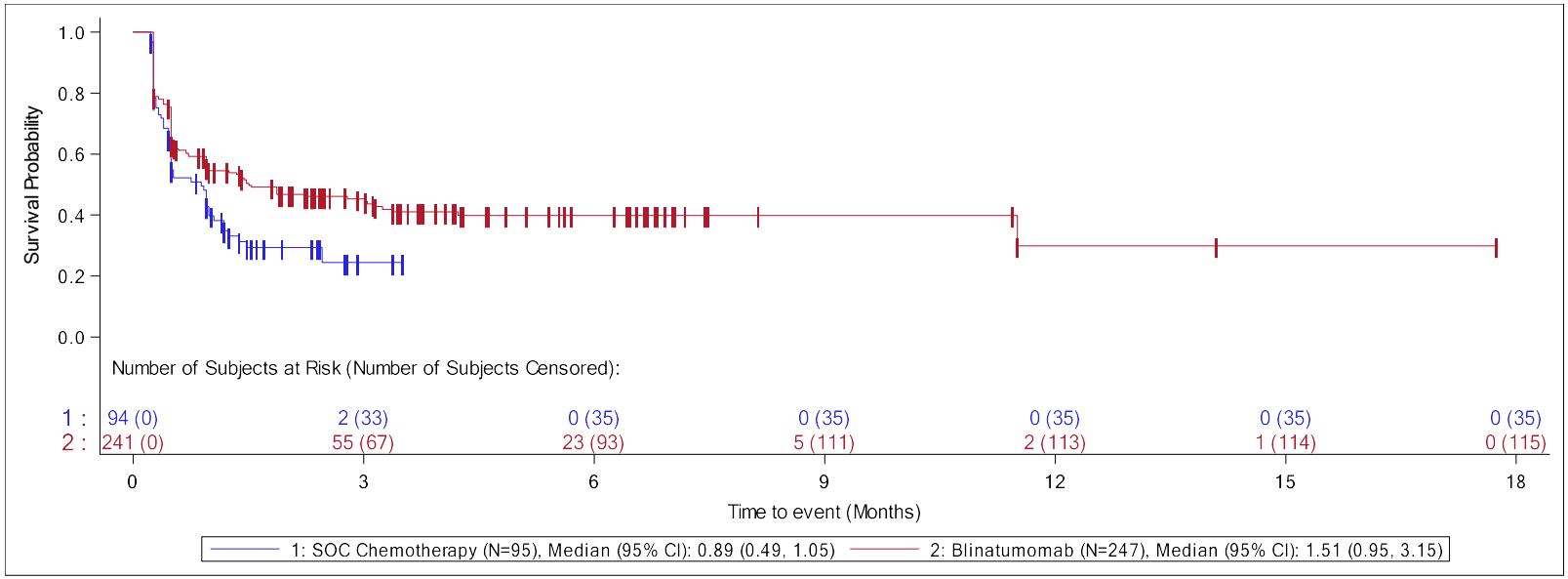
Figure 14-4.3.14. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-ghs-eqcas.sas
Output: f14-04-003-014-km-de-eortc-ghs-eqcas.rtf (Date Generated: 19OCT25 22:31) Source Data: adam_pa.adqs, adam_pa.adtteqs

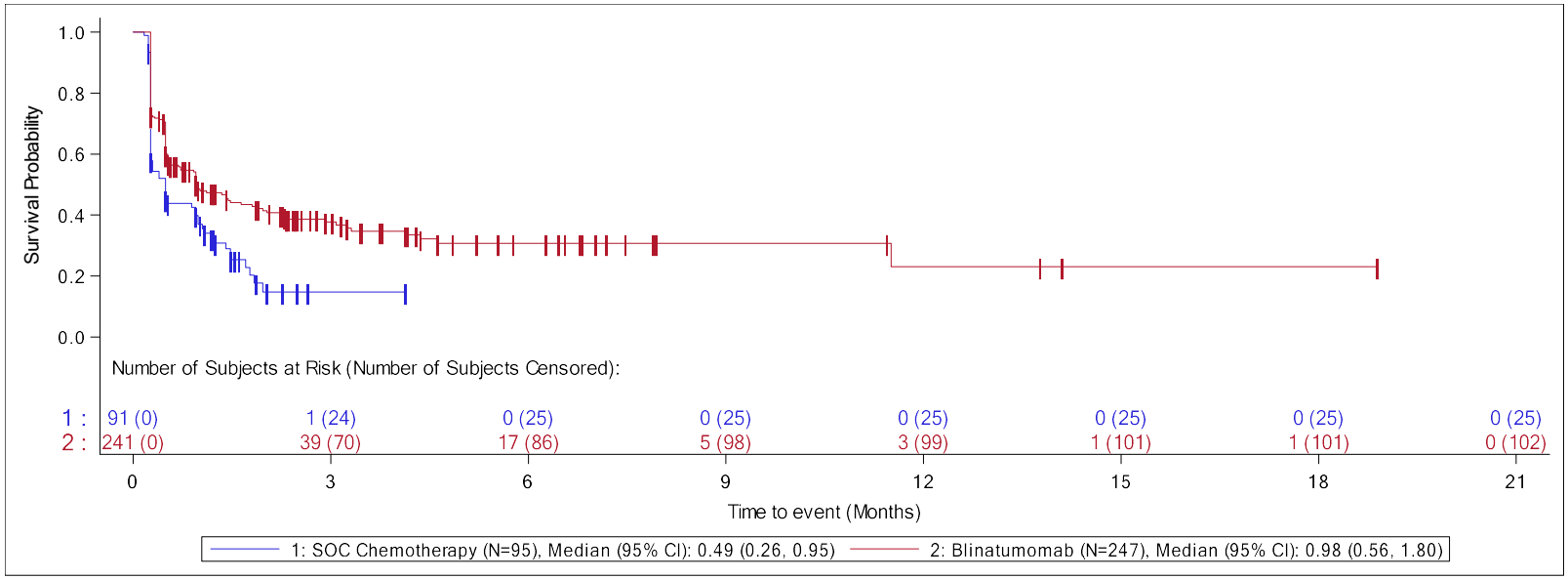
Figure 14-4.3.15. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-pf-eqcas.sas
Output: f14-04-003-015-km-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

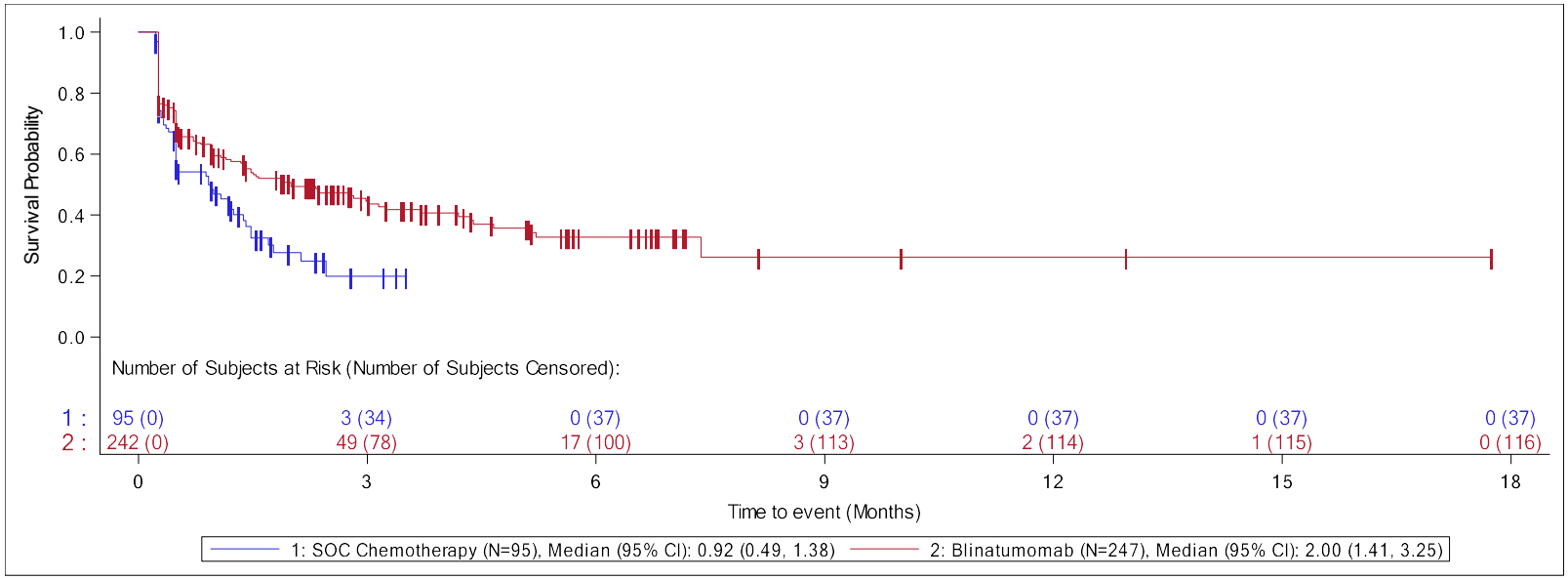
Figure 14-4.3.16. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-rf-eqcas.sas
Output: f14-04-003-016-km-de-eortc-rf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

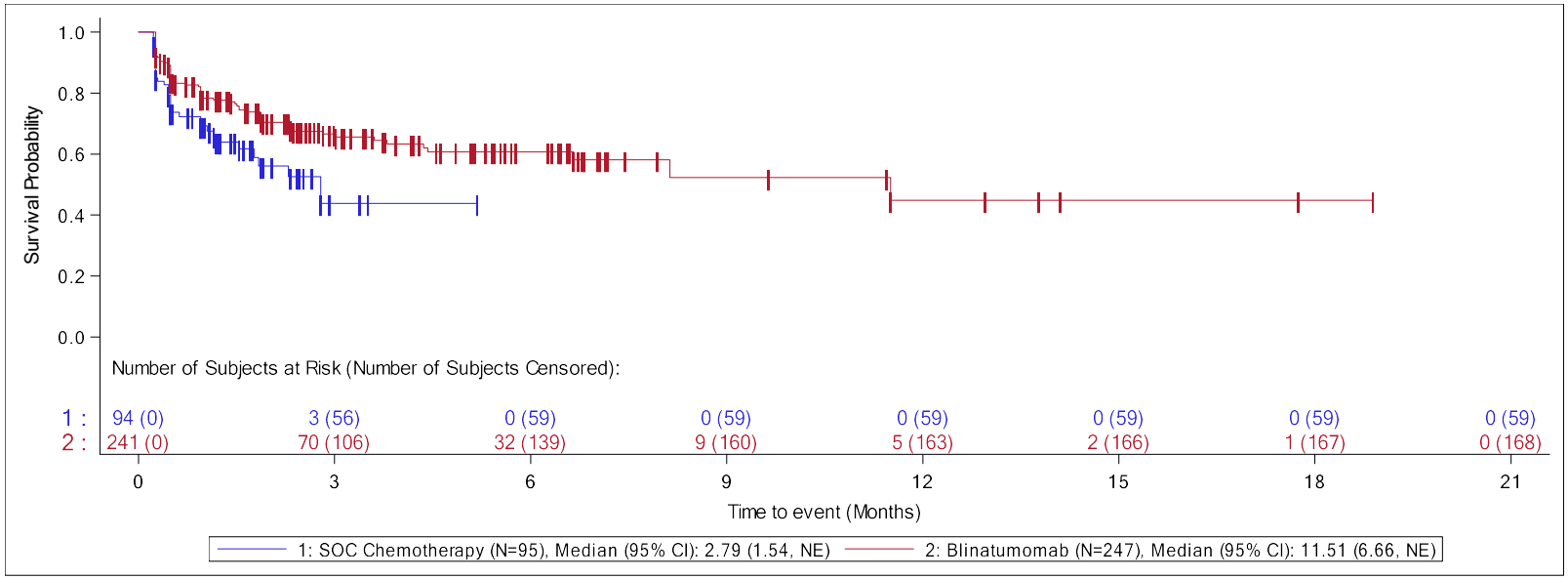
Figure 14-4.3.17. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-cf-eqcas.sas
Output: f14-04-003-017-km-de-eortc-cf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

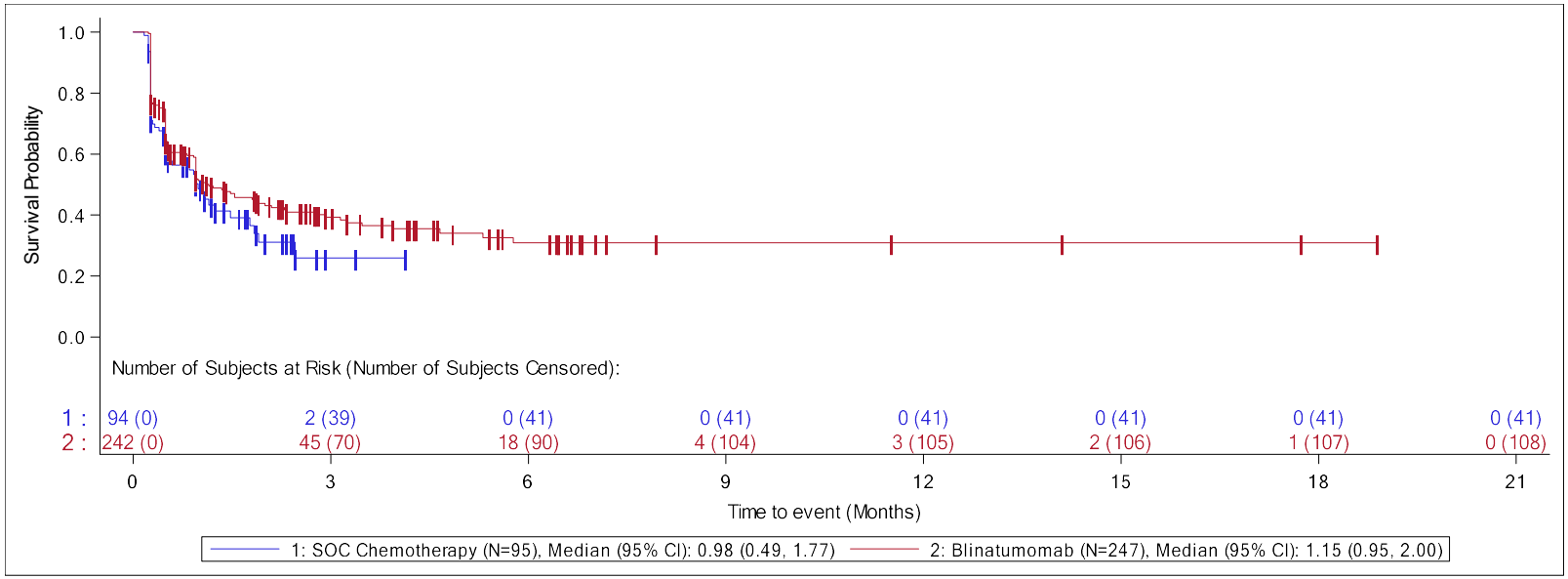
Figure 14-4.3.18. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-ef-eqcas.sas
Output: f14-04-003-018-km-de-eortc-ef-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

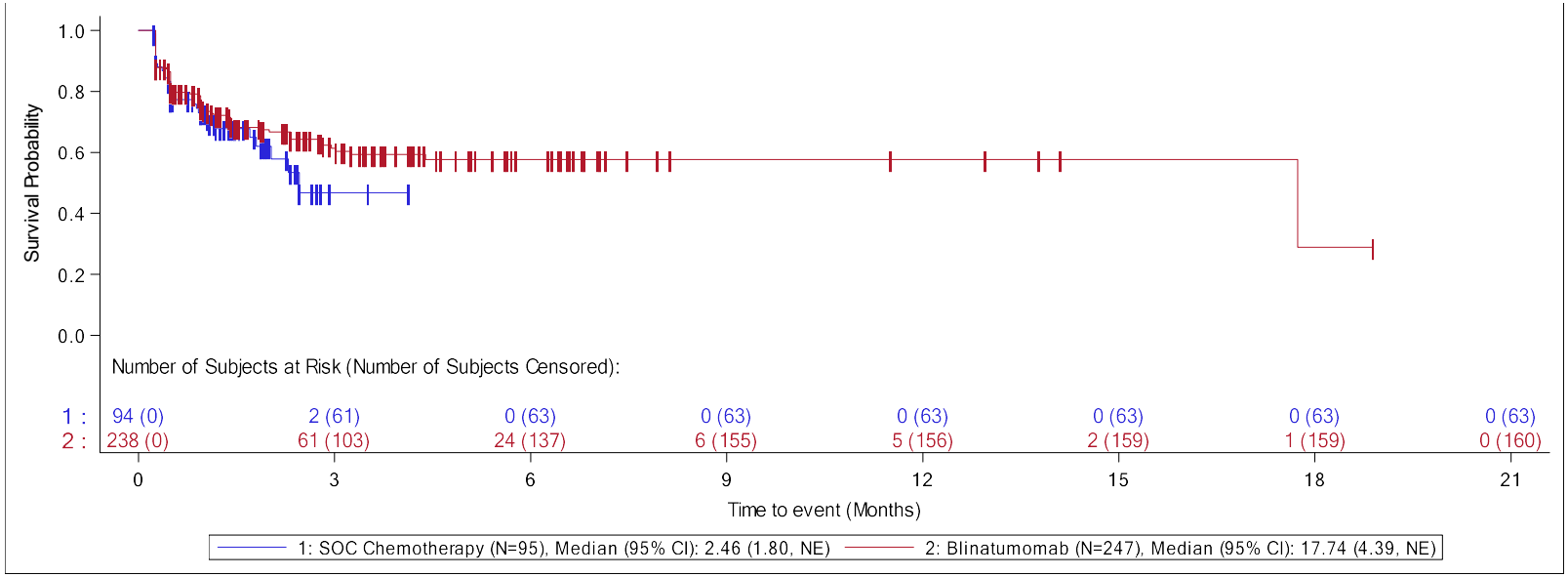
Figure 14-4.3.19. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-sf-eqcas.sas
Output: f14-04-003-019-km-de-eortc-sf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

Figure 14-4.3.28. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-de-eortc-fis-eqcas.sas
Output: f14-04-003-028-km-de-eortc-fis-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adqs, adam_pa.adtteqs

Anhang 4-G2.9: Sicherheitsrelevante Endpunkte

Anhang 4-G2.9.1: Sicherheit: Gesamtraten

Table 14-6.1.1. Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	108 (99.1)	263 (98.5)	
Unstratified log-rank test			
Normal score[b]			-0.22
p-value			0.9738
Stratified log-rank test[c]			
Normal score[b]			0.76
p-value			0.9098
Time to event (KM) (months)[d]			
Median	0.07	0.07	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.03, 0.10	0.03, 0.10	
Min, Max	0.0, 1.5	0.0, 3.6	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-saf.sas
Output: t14-06-001-001-tte-teae-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.1. Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.03
(95% CI)			(0.82, 1.28)
p-value			0.8280
Stratified hazard ratio[c,e]			1.03
(95% CI)			(0.82, 1.30)
p-value			0.7849

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-saf.sas
Output: t14-06-001-001-tte-teae-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.2. Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	48 (44.0)	165 (61.8)	
Unstratified log-rank test			
Normal score[b]			2.31
p-value			0.7008
Stratified log-rank test[c]			
Normal score[b]			1.91
p-value			0.7469
Time to event (KM) (months)[d]			
Median	1.87	1.54	
95% CI (median)	(1.11, NE)	(1.28, 2.46)	
Q1, Q3	0.43, NE	0.52, 5.80	
Min, Max	0.0, 2.8	0.0, 8.7	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-saf.sas
Output: t14-06-001-002-tte-ser-teae-saf.rtf (Date generated: 16JUN2025:03:53) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.2. Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.07
(95% CI)			(0.77, 1.48)
p-value			0.7041
Stratified hazard ratio[c,e]			1.06
(95% CI)			(0.76, 1.47)
p-value			0.7430

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-saf.sas
Output: t14-06-001-002-tte-ser-teae-saf.rtf (Date generated: 16JUN2025:03:53) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.3. Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	100 (91.7)	231 (86.5)	
Unstratified log-rank test			
Normal score[b]			-23.22
p-value			0.0011
Stratified log-rank test[c]			
Normal score[b]			-21.61
p-value			0.0023
Time to event (KM) (months)[d]			
Median	0.23	0.26	
95% CI (median)	(0.16, 0.26)	(0.16, 0.36)	
Q1, Q3	0.10, 0.33	0.07, 1.08	
Min, Max	0.0, 2.0	0.0, 8.3	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-saf.sas
Output: t14-06-001-003-tte-sev-teae-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.3. Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			0.68
(95% CI)			(0.53, 0.87)
p-value			0.0018
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.54, 0.88)
p-value			0.0031

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-saf.sas
Output: t14-06-001-003-tte-sev-teae-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.4. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	33 (12.4)	
Unstratified log-rank test			
Normal score[b]			1.05
p-value			0.6994
Stratified log-rank test[c]			
Normal score[b]			0.48
p-value			0.8573
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.15, NE)	
Q1, Q3	NE, NE	13.15, NE	
Min, Max	0.1, 0.8	0.0, 13.1	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-trt-disc-saf.sas
Output: t14-06-001-004-tte-teae-trt-disc-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.4. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.16
(95% CI)			(0.55, 2.45)
p-value			0.6994
Stratified hazard ratio[c,e]			1.07
(95% CI)			(0.51, 2.26)
p-value			0.8582

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-trt-disc-saf.sas
Output: t14-06-001-004-tte-teae-trt-disc-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.5. Time to First Onset of Treatment-emergent Adverse Event Leading to Death (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	19 (17.4)	51 (19.1)	
Unstratified log-rank test			
Normal score[b]			-2.86
p-value			0.4088
Stratified log-rank test[c]			
Normal score[b]			-3.33
p-value			0.3288
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(14.07, NE)	
Q1, Q3	NE, NE	14.07, NE	
Min, Max	0.0, 2.1	0.1, 14.1	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to death.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-fatal-saf.sas
Output: t14-06-001-005-tte-teae-fatal-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.5. Time to First Onset of Treatment-emergent Adverse Event Leading to Death (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.47, 1.37)
p-value			0.4112
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.45, 1.31)
p-value			0.3329

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to death.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-fatal-saf.sas
Output: t14-06-001-005-tte-teae-fatal-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.9. Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	108 (99.1)	263 (98.5)	
Unstratified log-rank test			
Normal score[b]			-0.22
p-value			0.9738
Stratified log-rank test[c]			
Normal score[b]			0.76
p-value			0.9098
Time to event (KM) (months)[d]			
Median	0.07	0.07	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.03, 0.10	0.03, 0.10	
Min, Max	0.0, 1.5	0.0, 3.6	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-edp-saf.sas
Output: t14-06-001-009-tte-teae-edp-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.9. Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.03
(95% CI)			(0.82, 1.28)
p-value			0.8280
Stratified hazard ratio[c,e]			1.03
(95% CI)			(0.82, 1.30)
p-value			0.7849

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-edp-saf.sas
Output: t14-06-001-009-tte-teae-edp-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.10. Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	48 (44.0)	164 (61.4)	
Unstratified log-rank test			
Normal score[b]			2.03
p-value			0.7350
Stratified log-rank test[c]			
Normal score[b]			1.79
p-value			0.7626
Time to event (KM) (months)[d]			
Median	1.87	1.54	
95% CI (median)	(1.11, NE)	(1.28, 2.46)	
Q1, Q3	0.43, NE	0.52, 5.80	
Min, Max	0.0, 2.8	0.0, 8.7	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-edp-saf.sas
Output: t14-06-001-010-tte-ser-teae-edp-saf.rtf (Date generated: 16JUN2025:03:53) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.10. Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.06
(95% CI)			(0.76, 1.47)
p-value			0.7382
Stratified hazard ratio[c,e]			1.05
(95% CI)			(0.76, 1.47)
p-value			0.7595

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-edp-saf.sas
Output: t14-06-001-010-tte-ser-teae-edp-saf.rtf (Date generated: 16JUN2025:03:53) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.11. Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	100 (91.7)	231 (86.5)	
Unstratified log-rank test			
Normal score[b]			-23.22
p-value			0.0011
Stratified log-rank test[c]			
Normal score[b]			-21.61
p-value			0.0023
Time to event (KM) (months)[d]			
Median	0.23	0.26	
95% CI (median)	(0.16, 0.26)	(0.16, 0.36)	
Q1, Q3	0.10, 0.33	0.07, 1.08	
Min, Max	0.0, 2.0	0.0, 8.3	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-edp-saf.sas
Output: t14-06-001-011-tte-sev-teae-edp-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.11. Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			0.68
(95% CI)			(0.53, 0.87)
p-value			0.0018
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.54, 0.88)
p-value			0.0031

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-edp-saf.sas
Output: t14-06-001-011-tte-sev-teae-edp-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.15. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	32 (12.0)	
Unstratified log-rank test			
Normal score[b]			0.75
p-value			0.7797
Stratified log-rank test[c]			
Normal score[b]			0.20
p-value			0.9399
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.15, NE)	
Q1, Q3	NE, NE	13.15, NE	
Min, Max	0.1, 0.8	0.0, 13.1	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment excluding disease-related events.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-trt-disc-edp-saf.sas
Output: t14-06-001-015-tte-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:02:14) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.15. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.11
(95% CI)			(0.53, 2.36)
p-value			0.7794
Stratified hazard ratio[c,e]			1.03
(95% CI)			(0.48, 2.18)
p-value			0.9411

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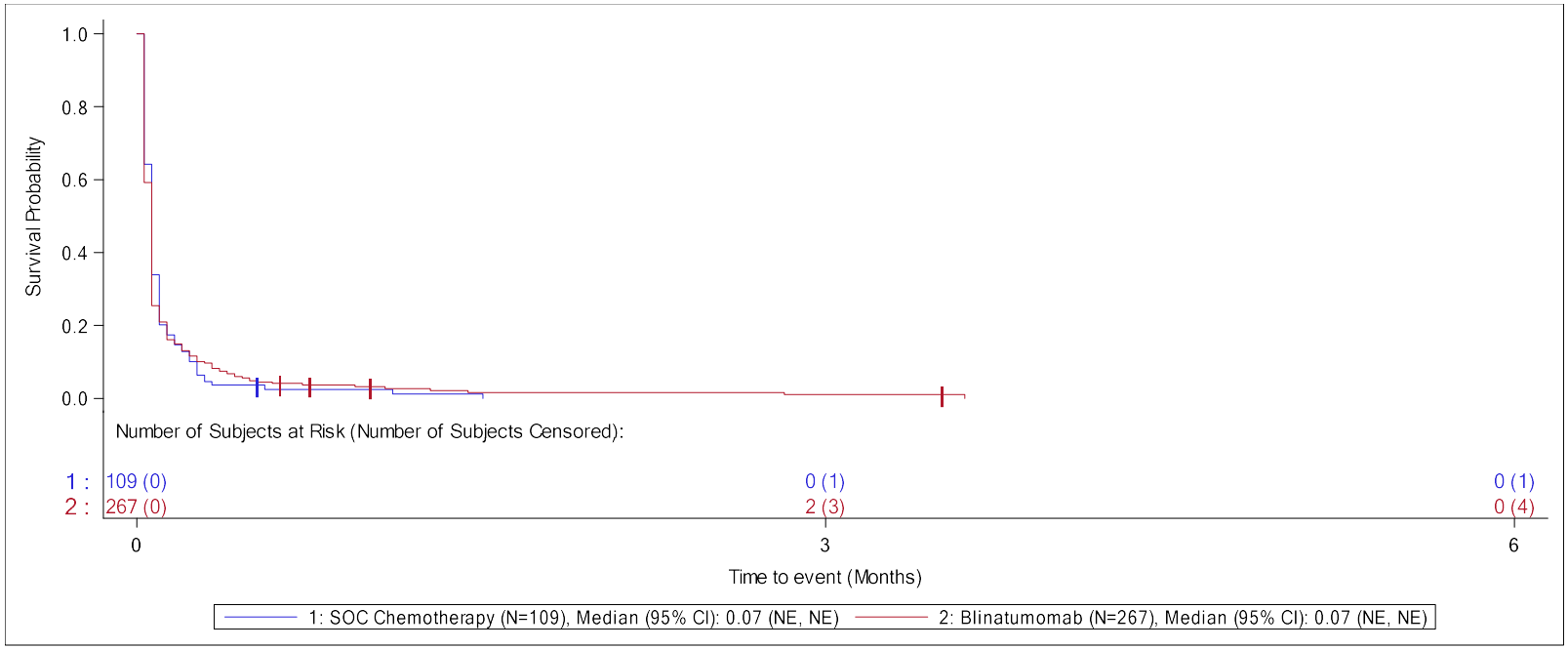
Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment excluding disease-related events.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-trt-disc-edp-saf.sas
Output: t14-06-001-015-tte-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:02:14) Source data: adam_pa.adsl, adam.adtteae

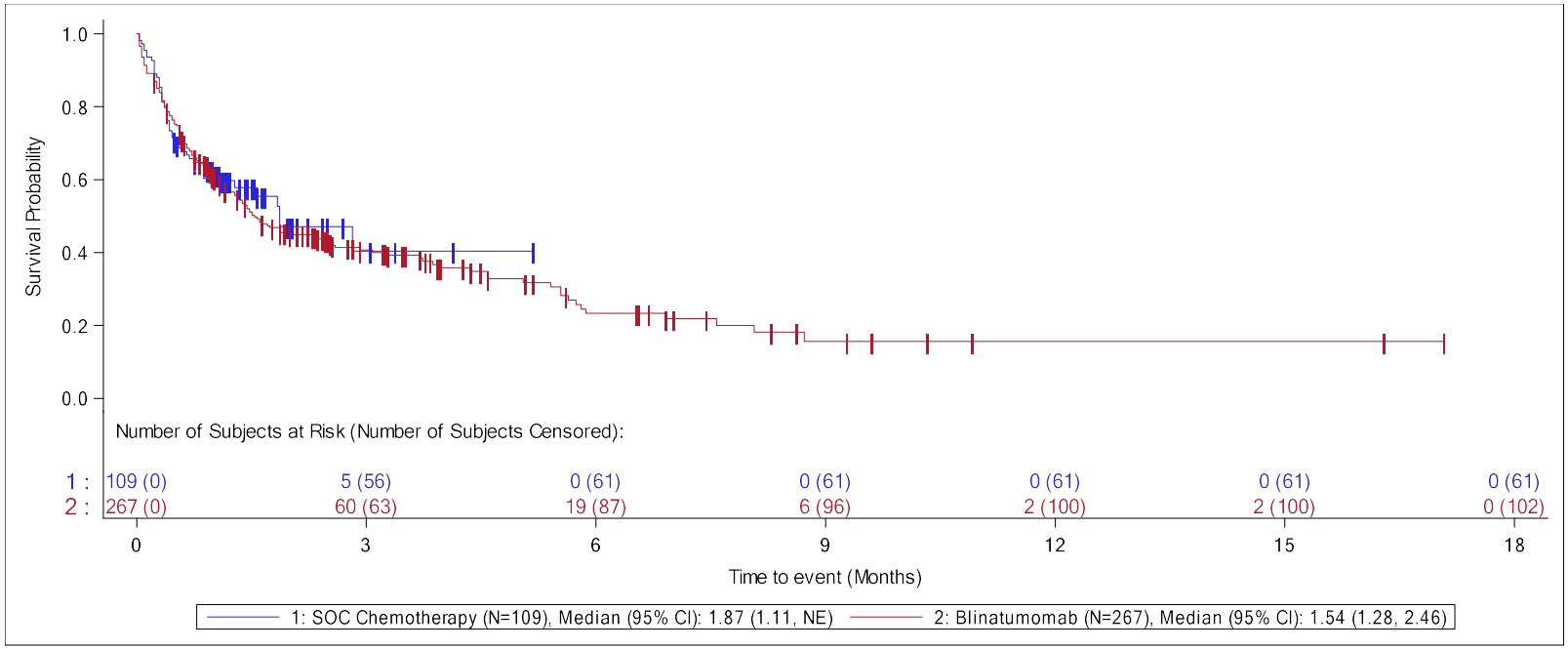
Figure 14-6.1.1. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-teae-saf.sas
Output: f14-06-001-001-km-teae-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

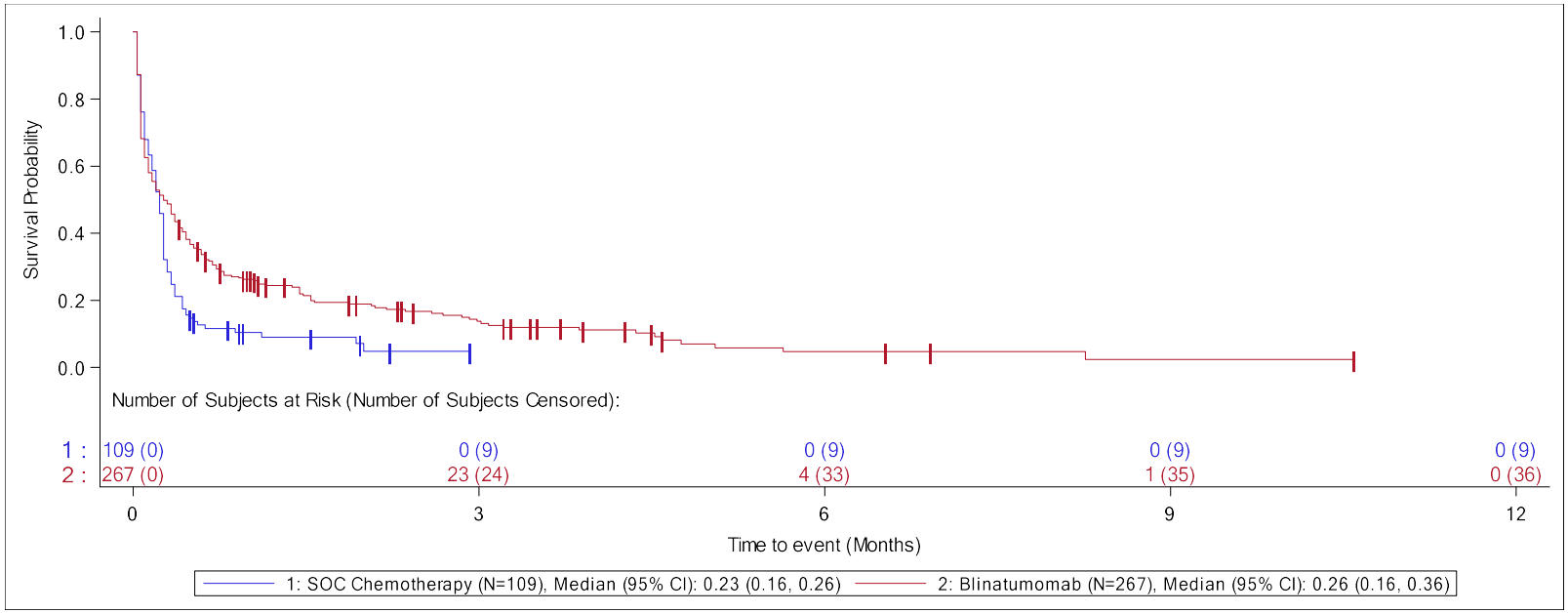
Figure 14-6.1.2. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-ser-teae-saf.sas
Output: f14-06-001-002-km-ser-teae-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

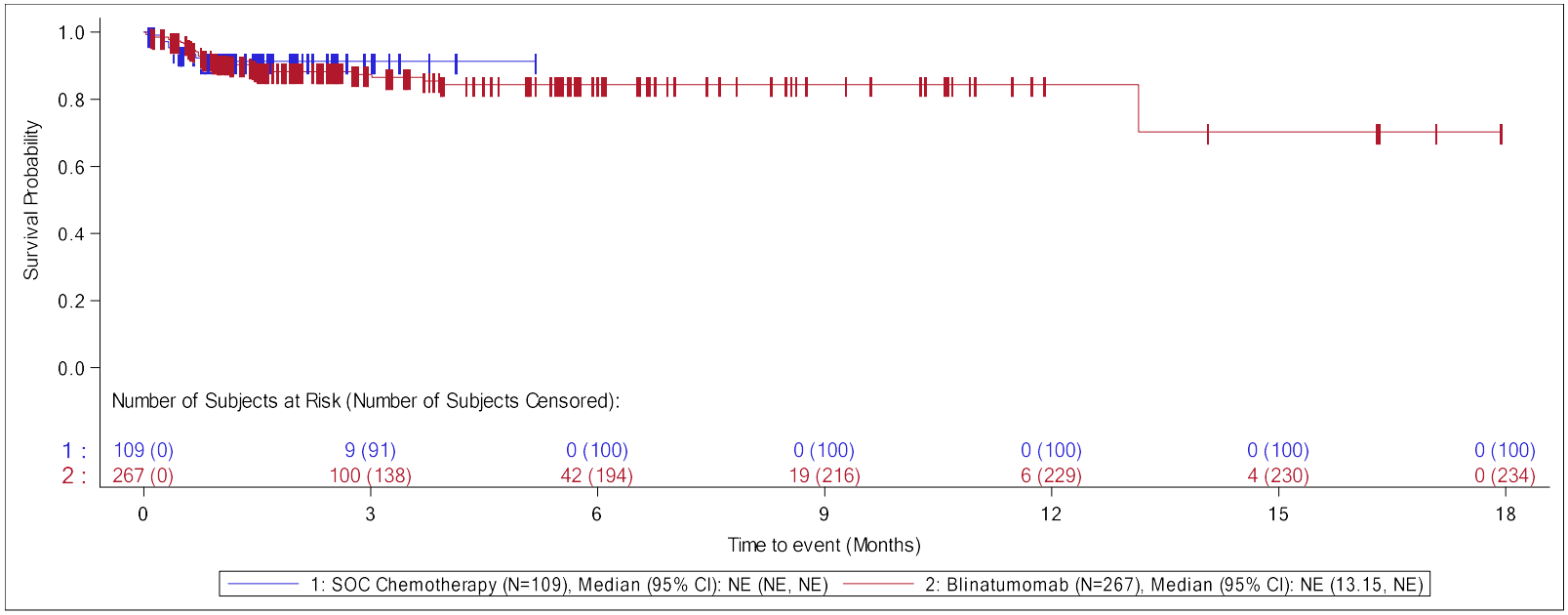
Figure 14-6.1.3. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-saf.sas
Output: f14-06-001-003-km-sev-teae-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

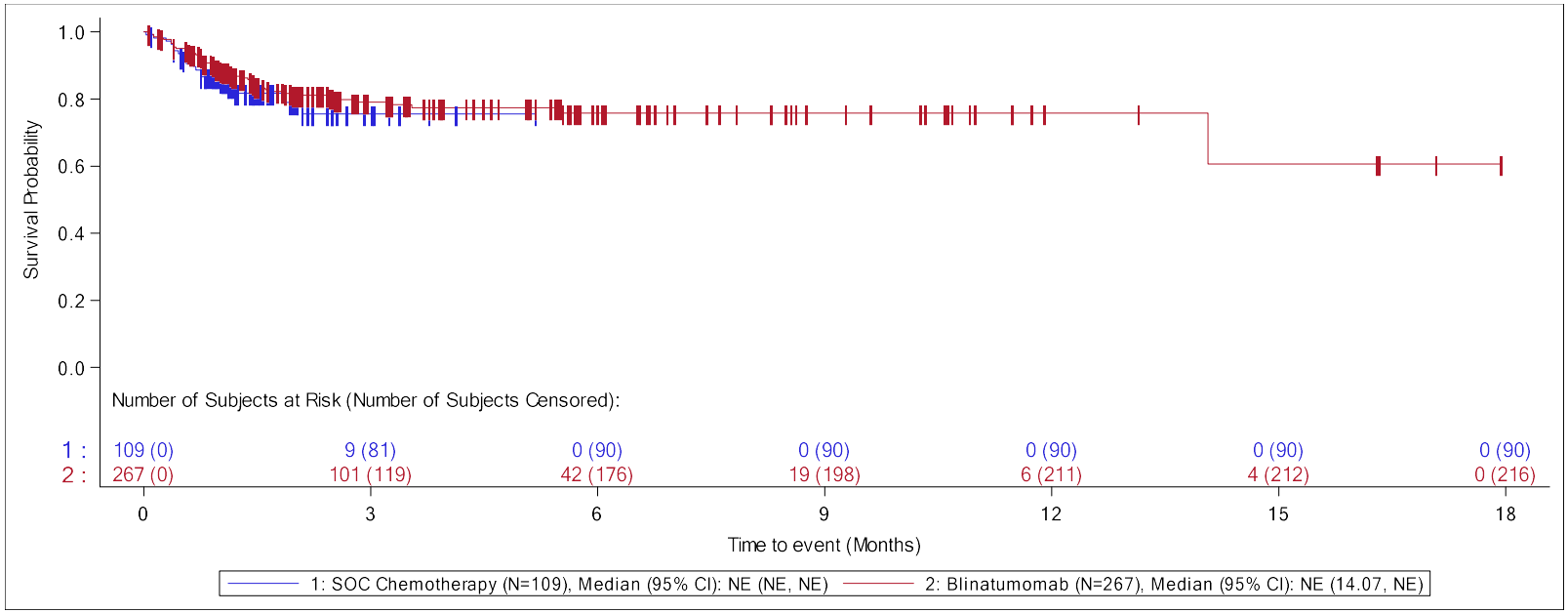
Figure 14-6.1.4. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-teae-trt-disc-saf.sas
Output: f14-06-001-004-km-teae-trt-disc-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

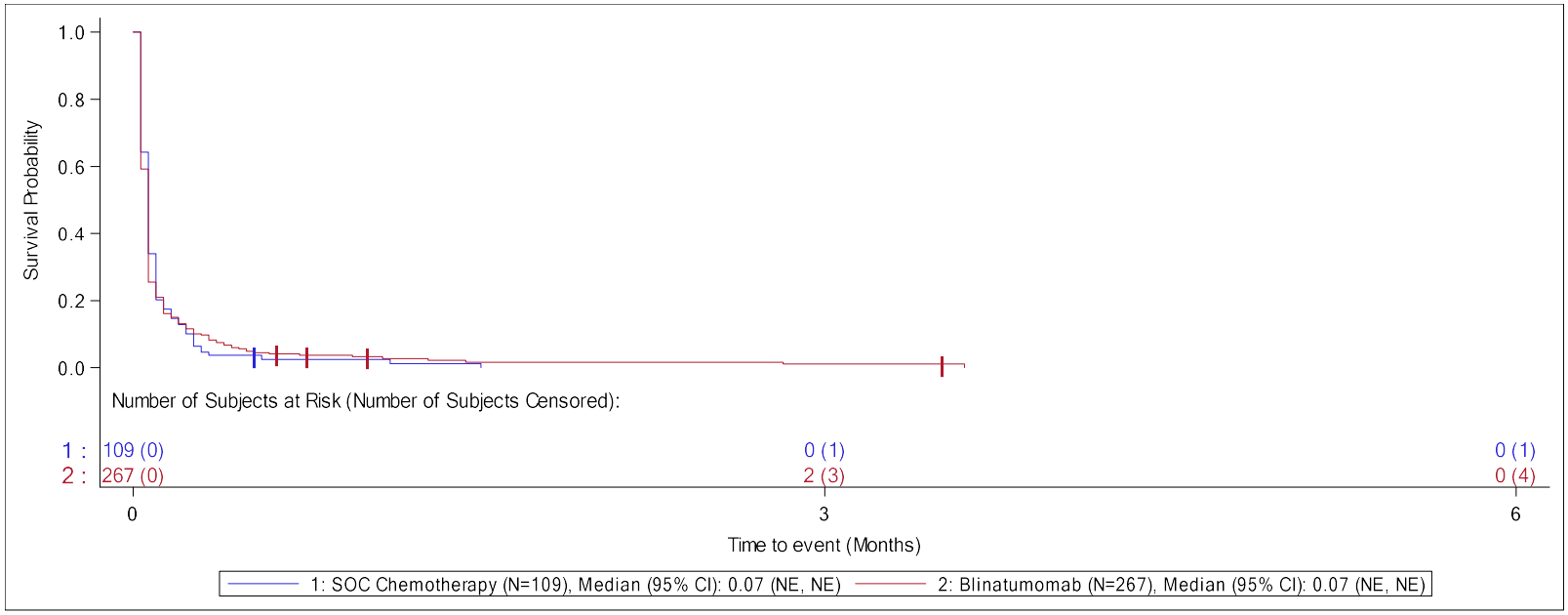
Figure 14-6.1.5. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event Leading to Death (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-teae-fatal-saf.sas
Output: f14-06-001-005-km-teae-fatal-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

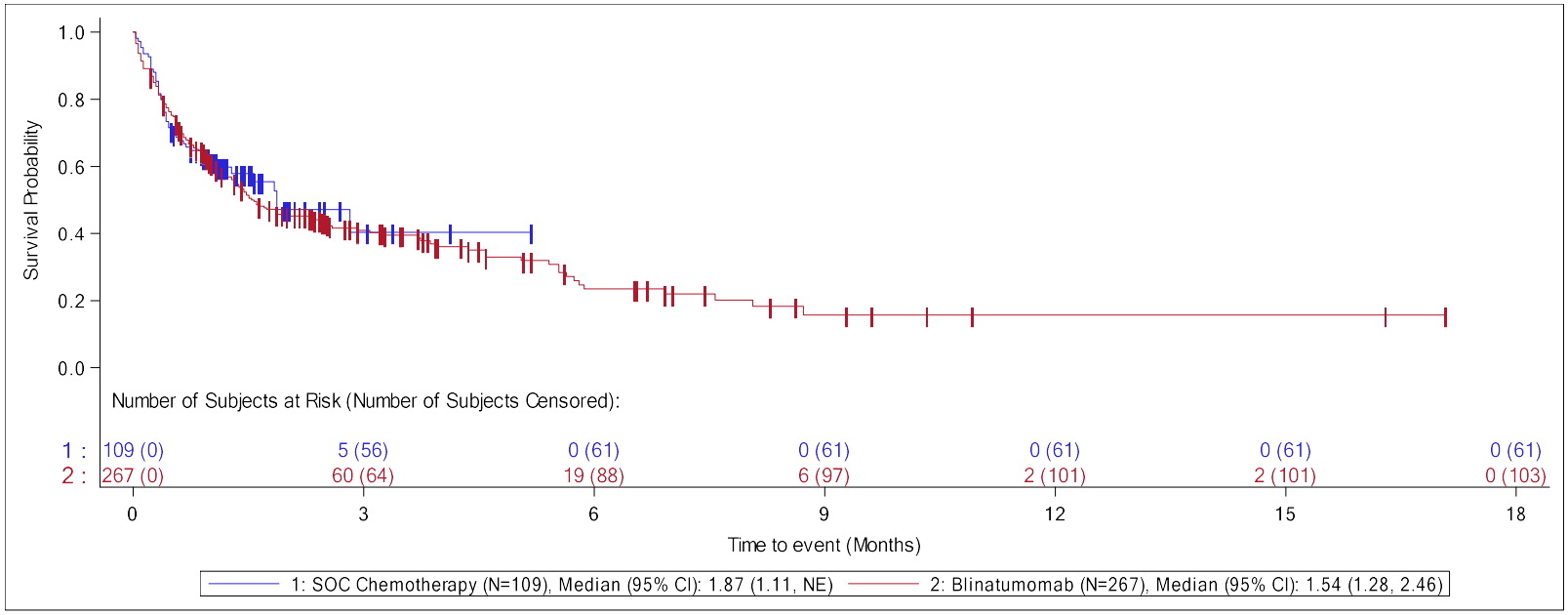
Figure 14-6.1.9. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-teae-edp-saf.sas
Output: f14-06-001-009-km-teae-edp-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

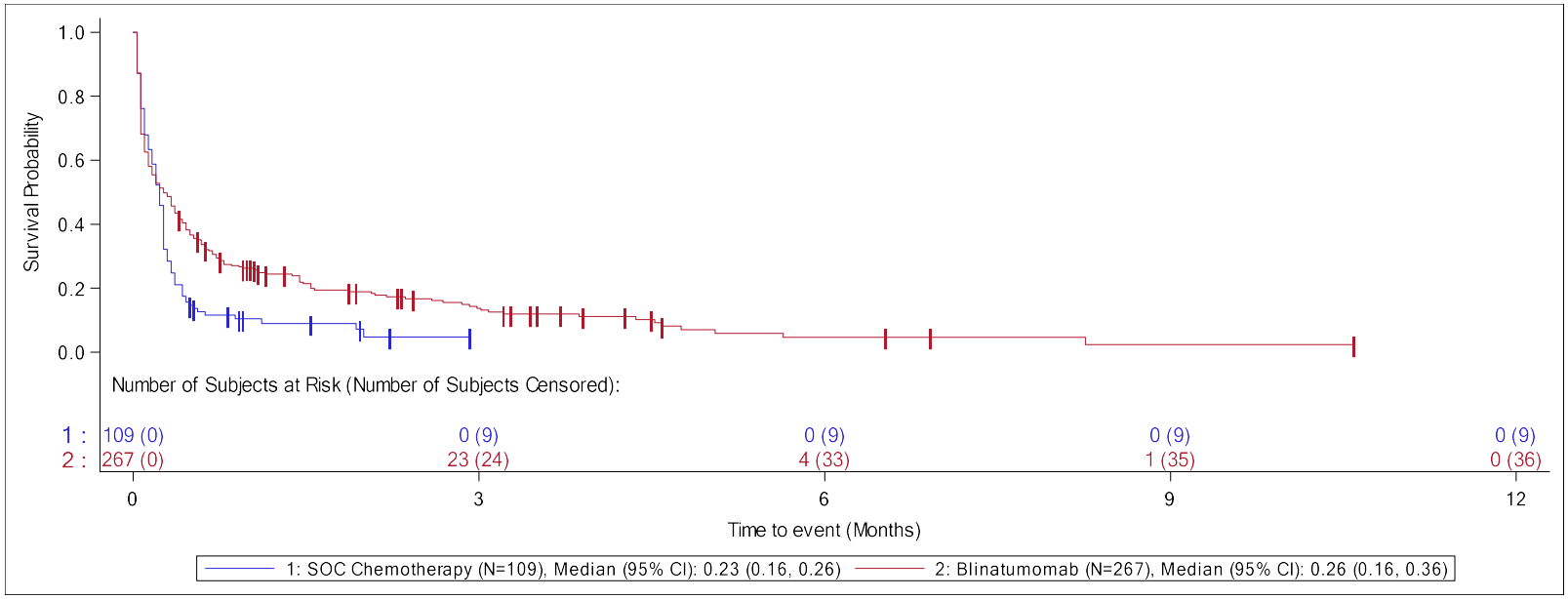
Figure 14-6.1.10. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-ser-teae-edp-saf.sas
Output: f14-06-001-010-km-ser-teae-edp-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

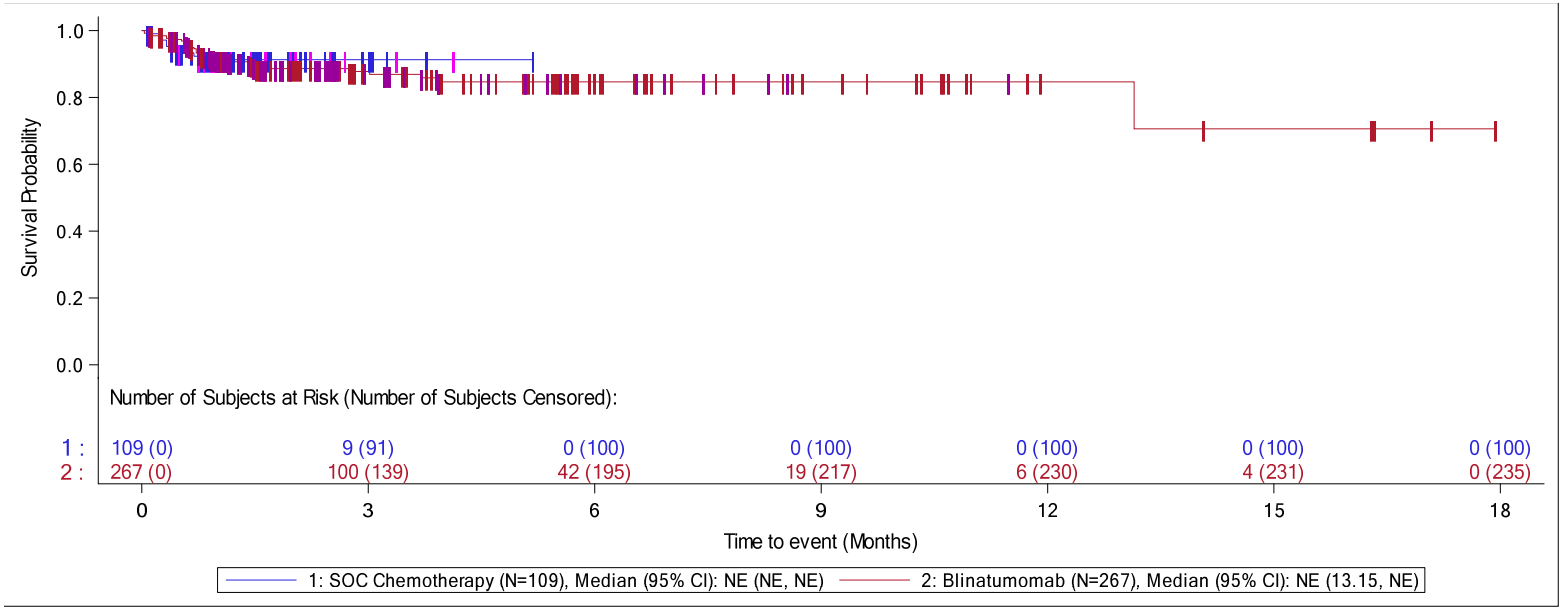
Figure 14-6.1.11. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-edp-saf.sas
Output: f14-06-001-011-km-sev-teae-edp-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.15. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-teae-trt-disc-edp-saf.sas
Output: f14-06-001-015-km-teae-trt-disc-edp-saf.rtf (Date Generated: 03DEC25 05:18) Source Data: adam_pa.adsl, adam.adtteae

Anhang 4-G2.9.2: Sicherheit: UE von besonderem Interesse

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Capillary leak syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	53 (48.6)	163 (61.0)	
Unstratified log-rank test			
Normal score[b]			8.67
p-value			0.1806
Stratified log-rank test[c]			
Normal score[b]			8.46
p-value			0.1872

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.31	0.92	
95% CI (median)	(0.69, NE)	(0.52, 1.44)	
Q1, Q3	0.23, NE	0.16, NE	
Min, Max	0.0, 1.4	0.0, 6.2	
Unstratified hazard ratio[e]			1.24
(95% CI)			(0.91, 1.69)
p-value			0.1795
Stratified hazard ratio[c,e]			1.23
(95% CI)			(0.90, 1.69)
p-value			0.1881

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Cytokine release syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	43 (16.1)	
Unstratified log-rank test			
Normal score[b]			12.34
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			12.09
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 8.3	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Decreased immunoglobulins (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	26 (9.7)	
Unstratified log-rank test			
Normal score[b]			1.87
p-value			0.2810
Stratified log-rank test[c]			
Normal score[b]			1.74
p-value			0.3027

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(8.30, NE)	
Q1, Q3	NE, NE	7.18, NE	
Min, Max	0.2, 0.5	0.6, 8.3	
Unstratified hazard ratio[e]			2.21
(95% CI)			(0.51, 9.66)
p-value			0.2922
Stratified hazard ratio[c,e]			2.15
(95% CI)			(0.49, 9.49)
p-value			0.3139

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Haematopoietic cytopenias (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	79 (72.5)	160 (59.9)	
Unstratified log-rank test			
Normal score[b]			-25.82
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-24.47
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	1.15	
95% CI (median)	(0.23, 0.30)	(0.62, 2.10)	
Q1, Q3	0.10, 2.49	0.13, 6.62	
Min, Max	0.0, 2.5	0.0, 8.3	
Unstratified hazard ratio[e]			0.56
(95% CI)			(0.42, 0.73)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.57
(95% CI)			(0.43, 0.76)
p-value			0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:56) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infections and infestations (SOC)			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	79 (72.5)	171 (64.0)	
Unstratified log-rank test			
Normal score[b]			-29.98
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-30.29
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.49	1.31	
95% CI (median)	(0.39, 0.62)	(1.05, 1.90)	
Q1, Q3	0.30, 1.51	0.39, 4.69	
Min, Max	0.0, 2.1	0.0, 8.1	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.38, 0.66)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.37, 0.65)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infusion reaction (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	129 (48.3)	
Unstratified log-rank test			
Normal score[b]			30.76
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			30.42
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	2.85	
95% CI (median)	(NE, NE)	(1.41, NE)	
Q1, Q3	NE, NE	0.07, NE	
Min, Max	0.0, 0.1	0.0, 6.2	
Unstratified hazard ratio[e]			5.25
(95% CI)			(2.90, 9.49)
p-value			<0.0001
Stratified hazard ratio[c,e]			5.23
(95% CI)			(2.89, 9.47)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Liver related investigations, signs and symptoms (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	27 (24.8)	58 (21.7)	
Unstratified log-rank test			
Normal score[b]			-3.85
p-value			0.3398
Stratified log-rank test[c]			
Normal score[b]			-3.61
p-value			0.3699

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(3.02, NE)	(NE, NE)	
Q1, Q3	3.02, NE	5.67, NE	
Min, Max	0.1, 3.0	0.0, 5.7	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.51, 1.27)
p-value			0.3469
Stratified hazard ratio[c,e]			0.82
(95% CI)			(0.51, 1.30)
p-value			0.3924

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Lymphopenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	5 (1.9)	
Unstratified log-rank test			
Normal score[b]			-1.89
p-value			0.1234
Stratified log-rank test[c]			
Normal score[b]			-1.77
p-value			0.1598

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.8	0.0, 7.1	
Unstratified hazard ratio[e]			0.34
(95% CI)			(0.08, 1.42)
p-value			0.1405
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.09, 1.54)
p-value			0.1756

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Medication errors and product use issues (AMQ) - Broad			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			3.19
p-value			0.0355
Stratified log-rank test[c]			
Normal score[b]			3.26
p-value			0.0330

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 2.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Neutropenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	70 (64.2)	111 (41.6)	
Unstratified log-rank test			
Normal score[b]			-32.43
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-32.18
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.36	4.79	
95% CI (median)	(0.26, 0.43)	(2.59, 6.69)	
Q1, Q3	0.20, NE	0.52, NE	
Min, Max	0.0, 2.5	0.0, 8.3	
Unstratified hazard ratio[e]			0.39
(95% CI)			(0.28, 0.53)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.28, 0.53)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Tumour lysis syndrome (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			1.75
p-value			0.2142
Stratified log-rank test[c]			
Normal score[b]			1.71
p-value			0.2200

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.87, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 13.9	
Unstratified hazard ratio[e]			3.42
(95% CI)			(0.43, 27.05)
p-value			0.2434
Stratified hazard ratio[c,e]			3.39
(95% CI)			(0.43, 26.90)
p-value			0.2484

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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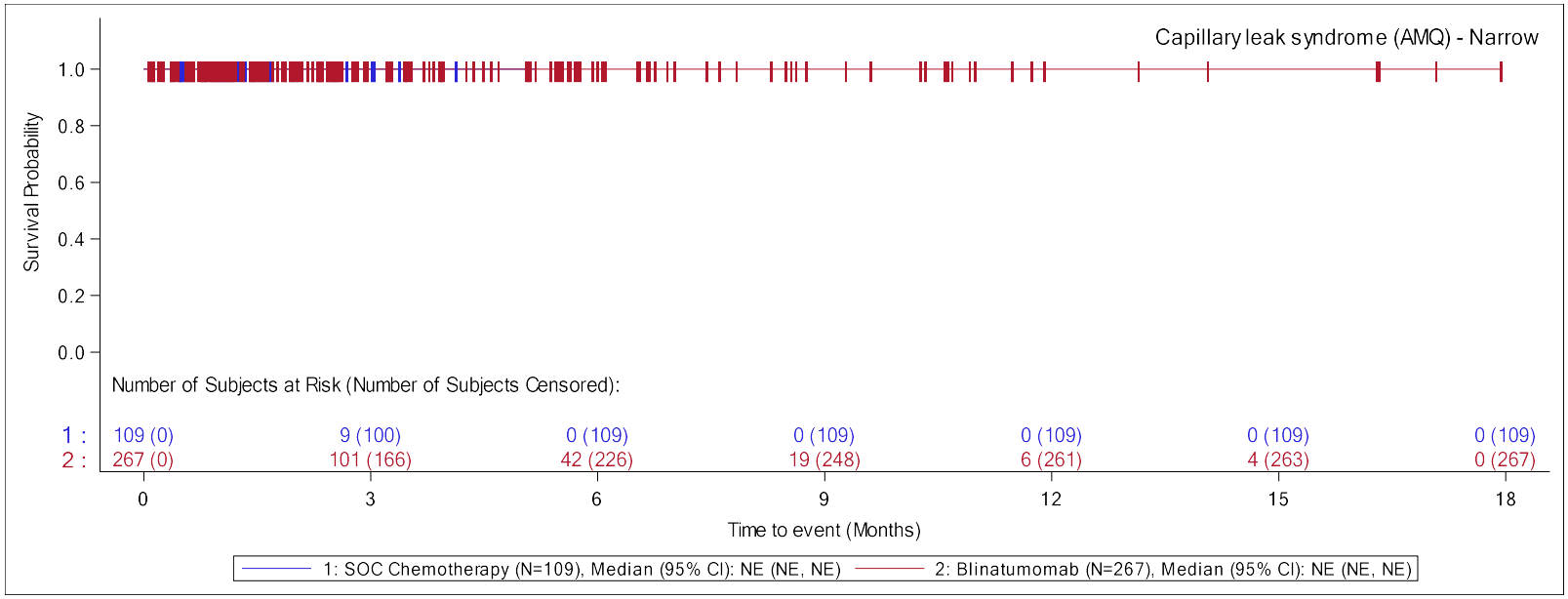
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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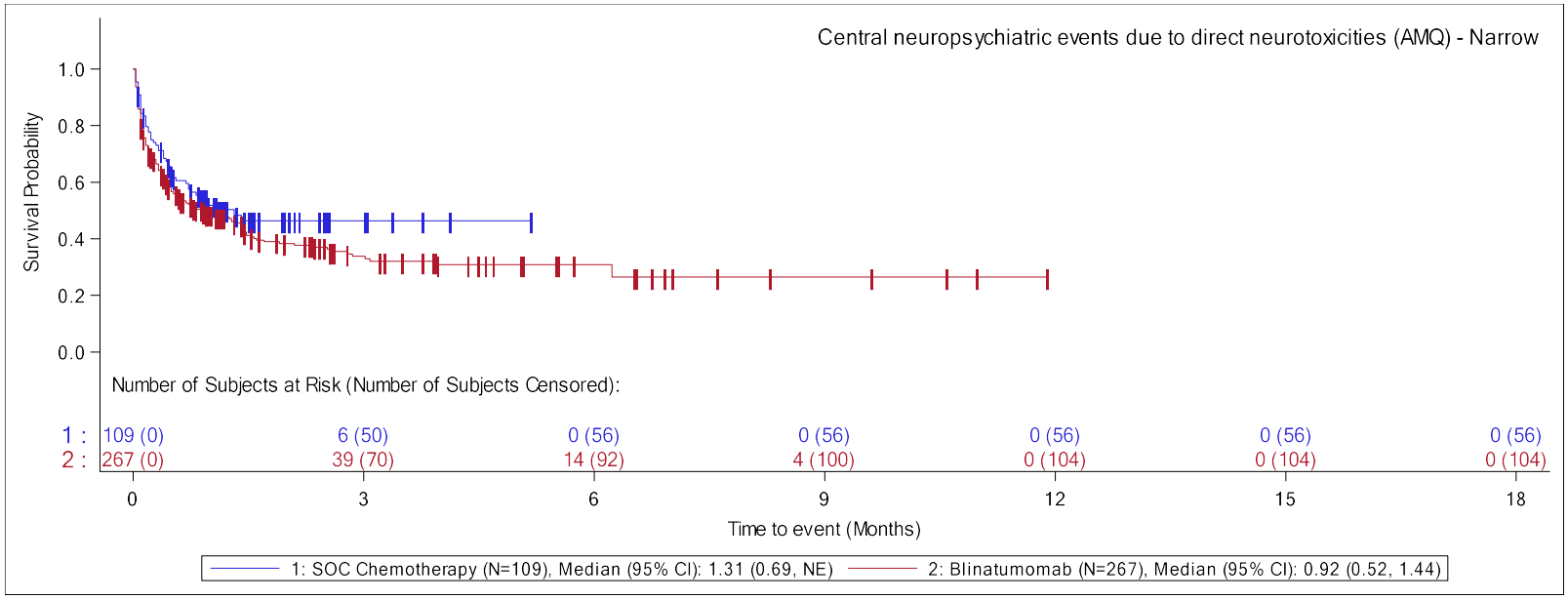
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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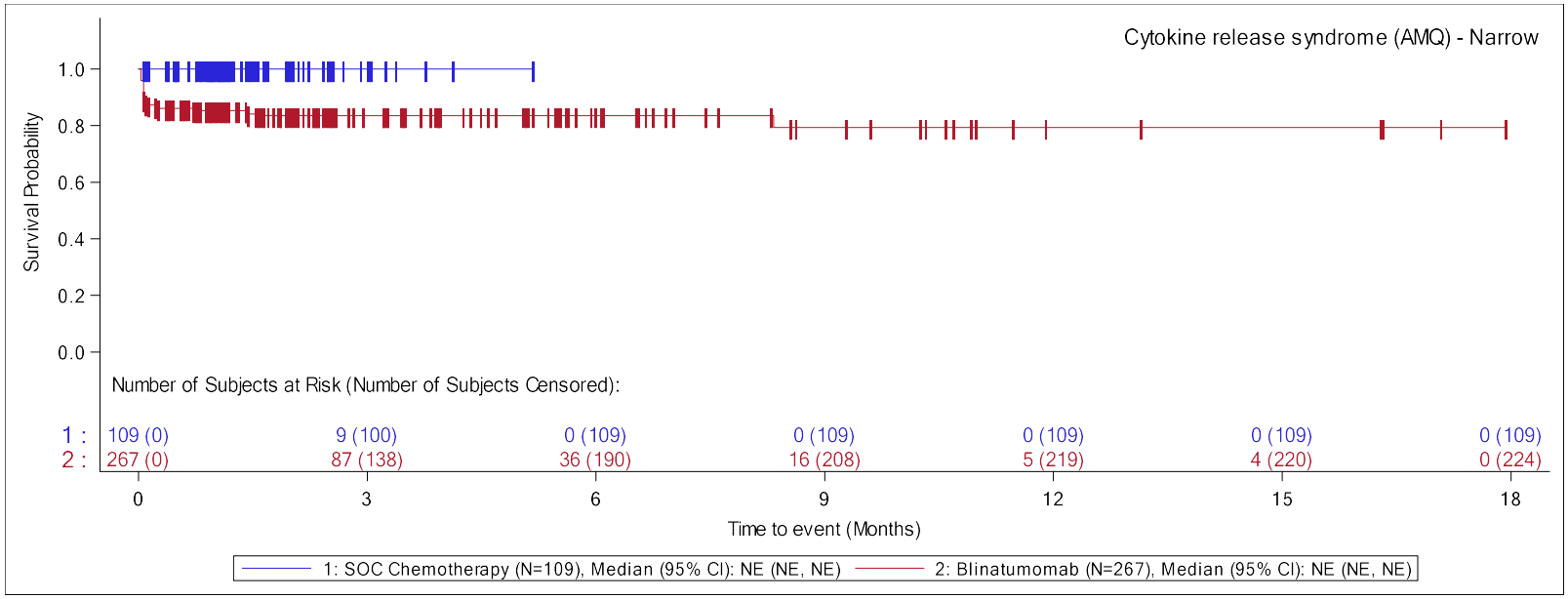
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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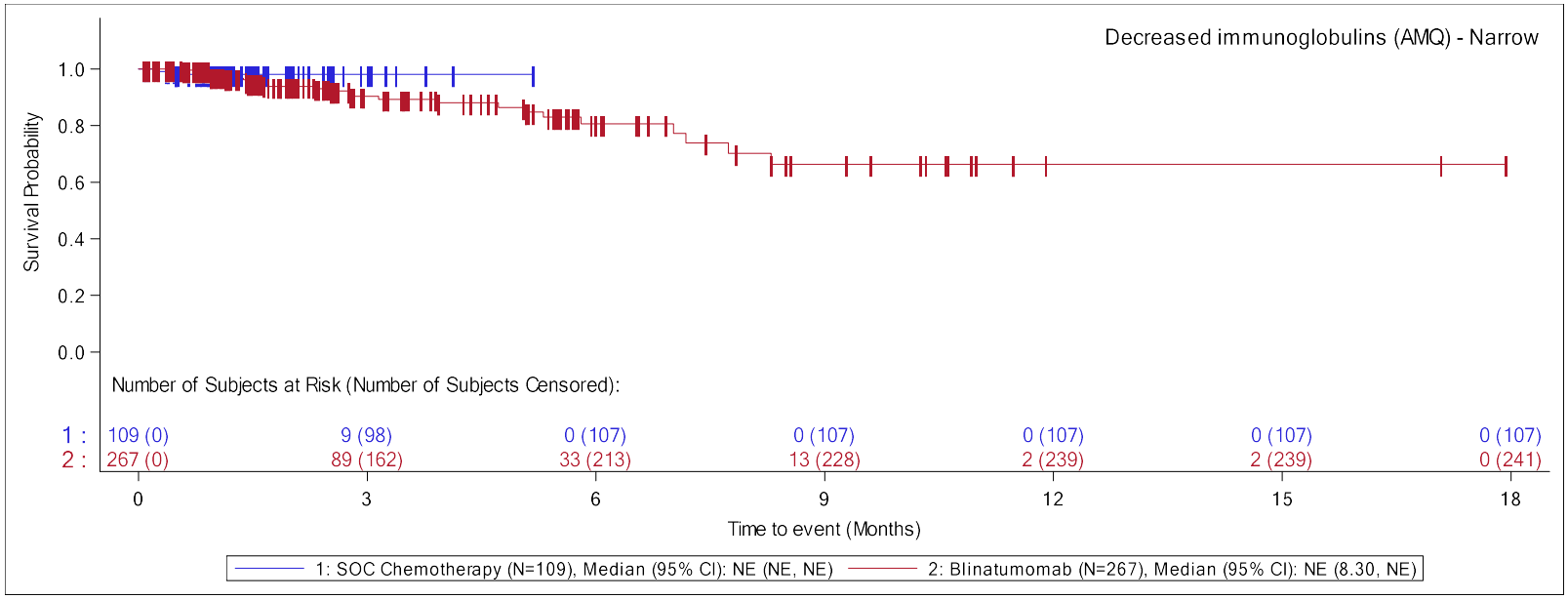
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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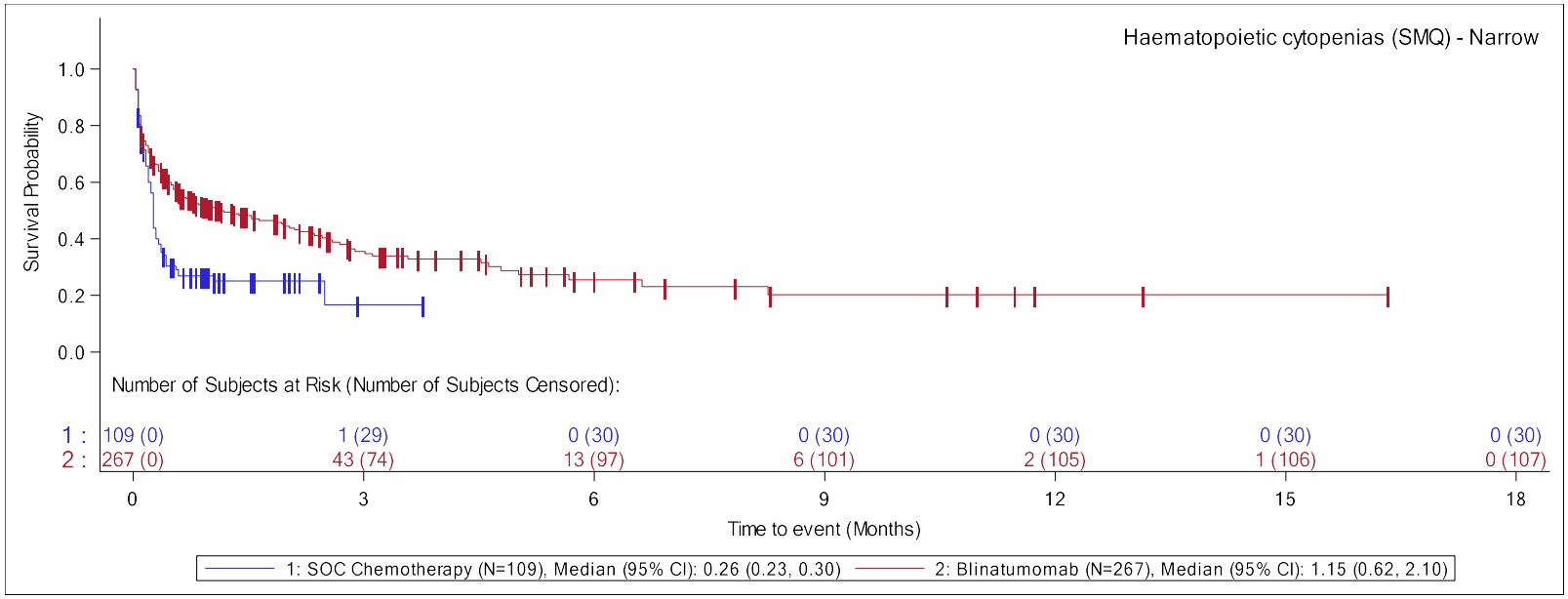
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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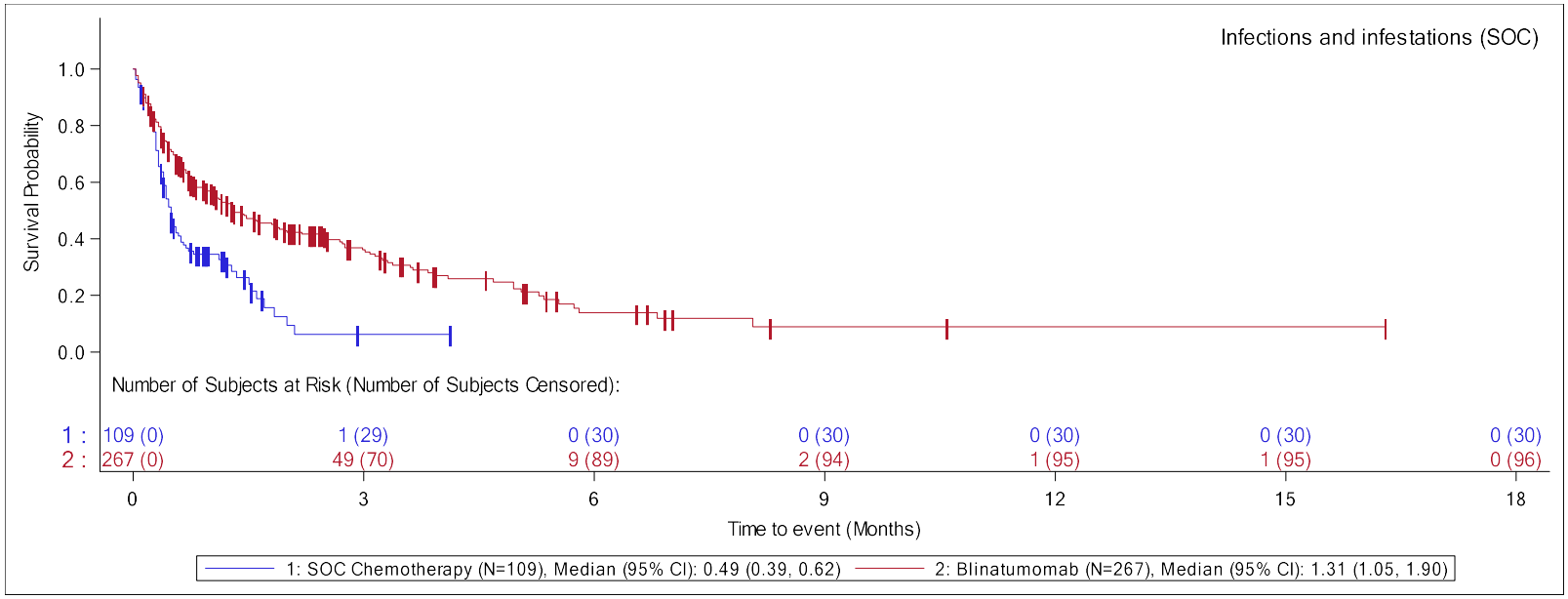
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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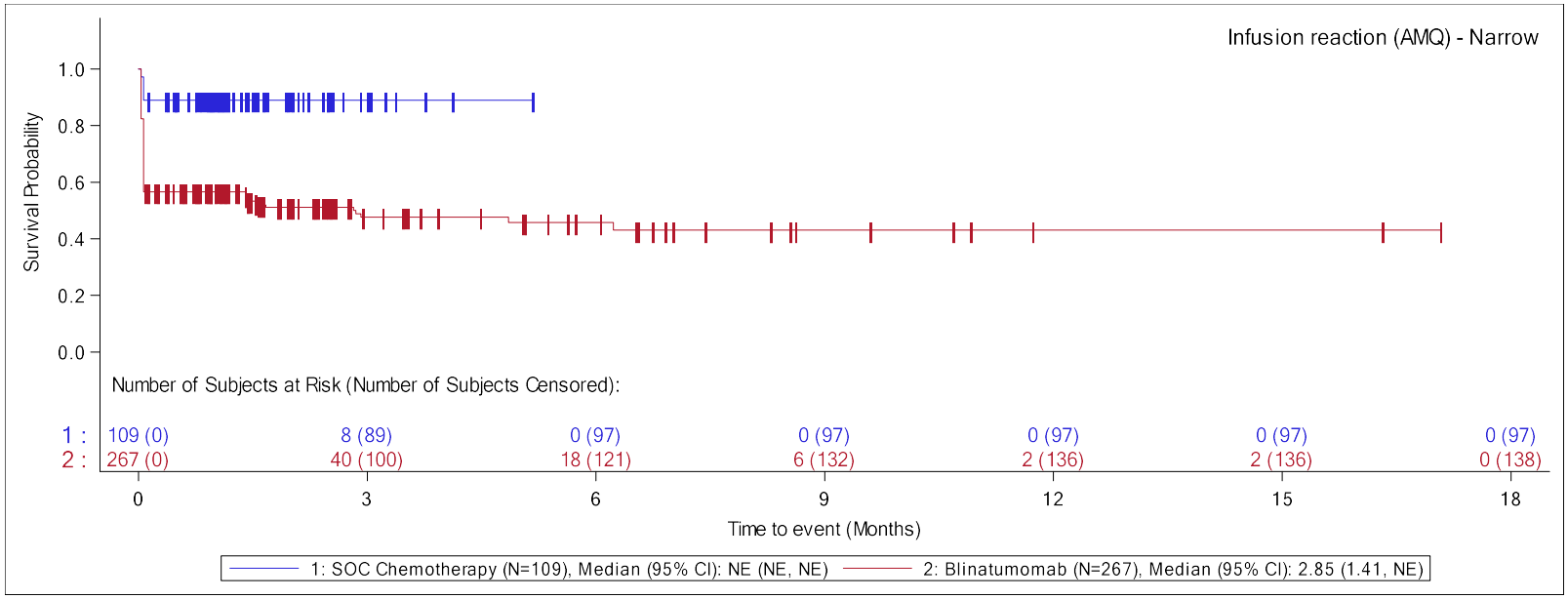
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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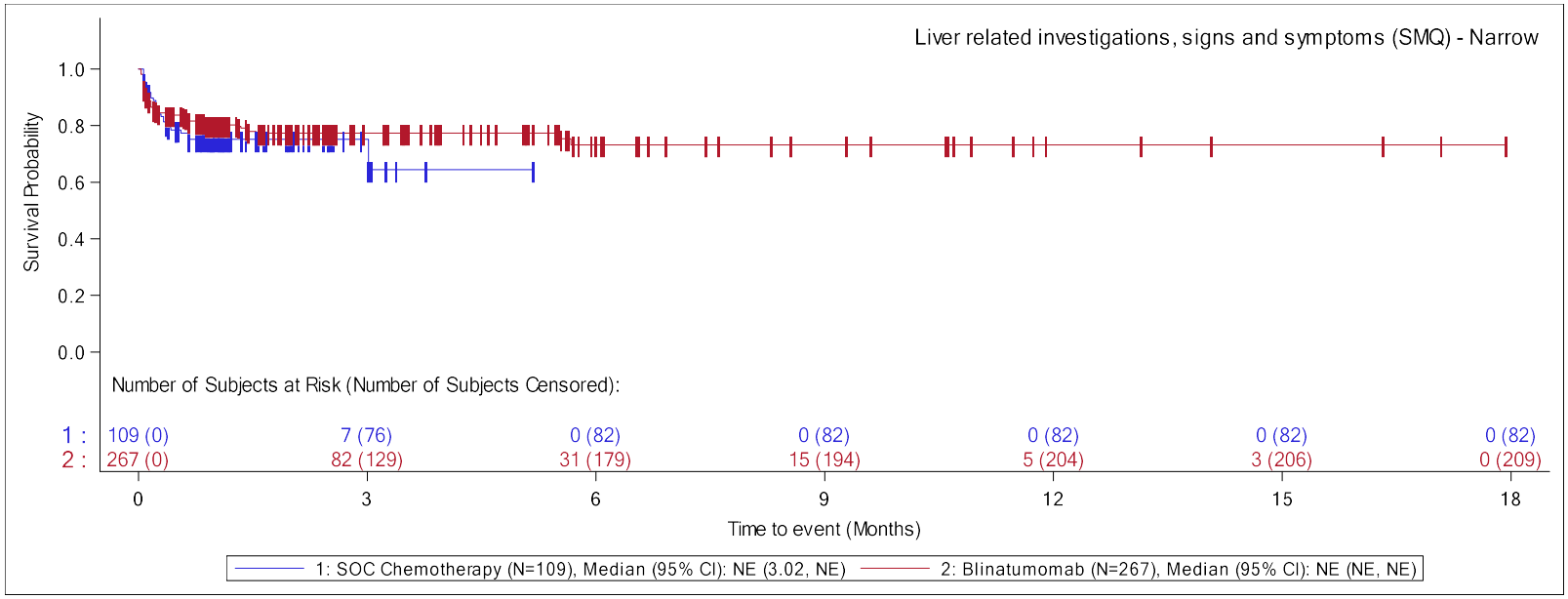
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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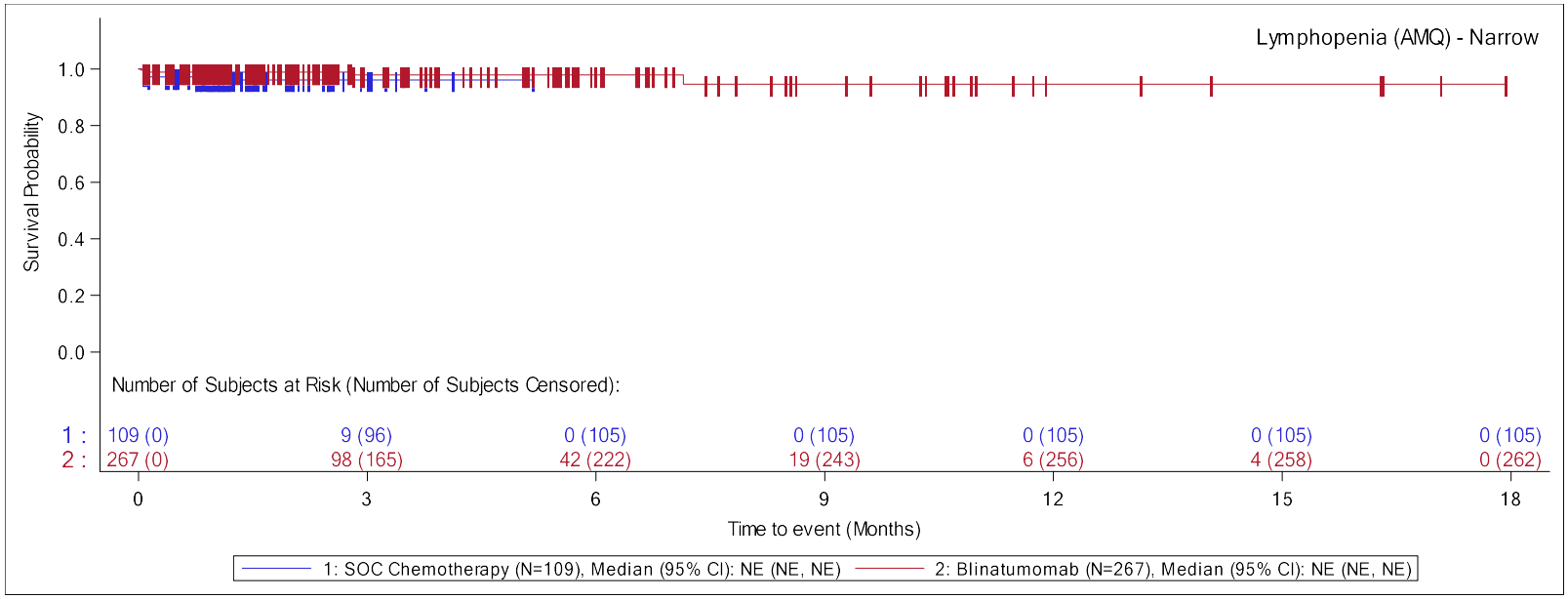
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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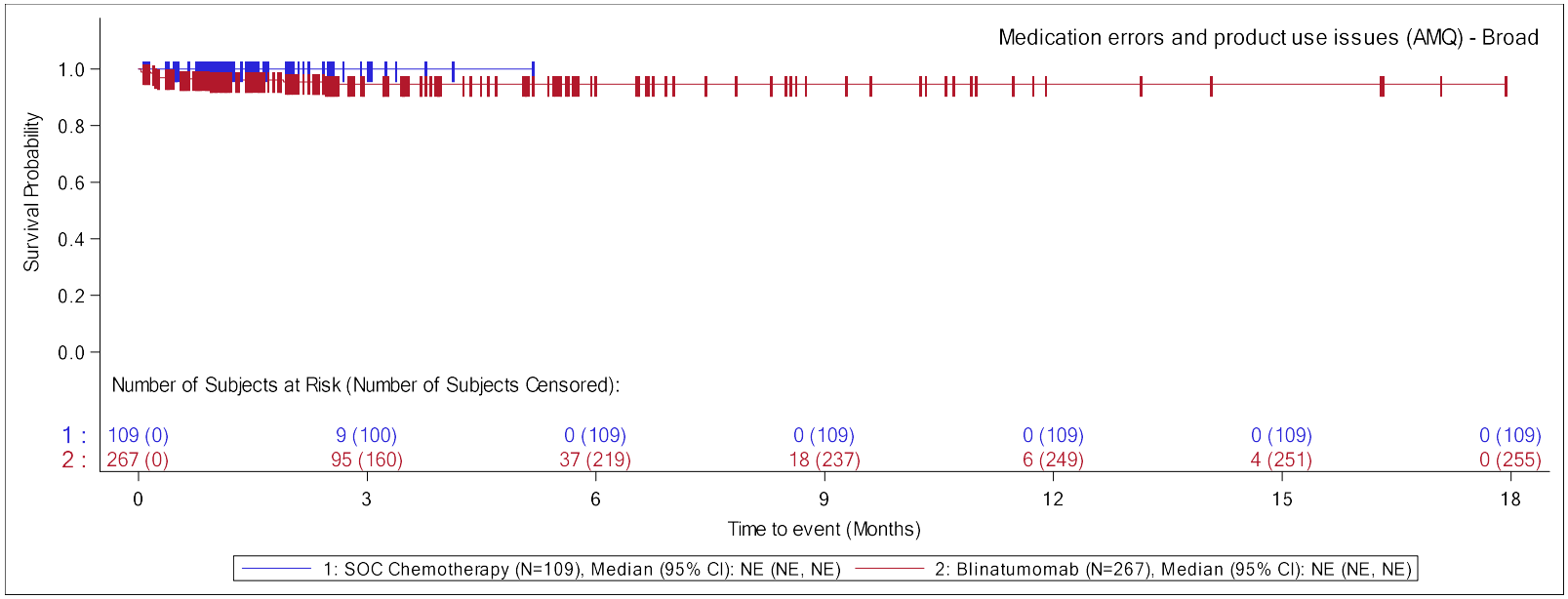
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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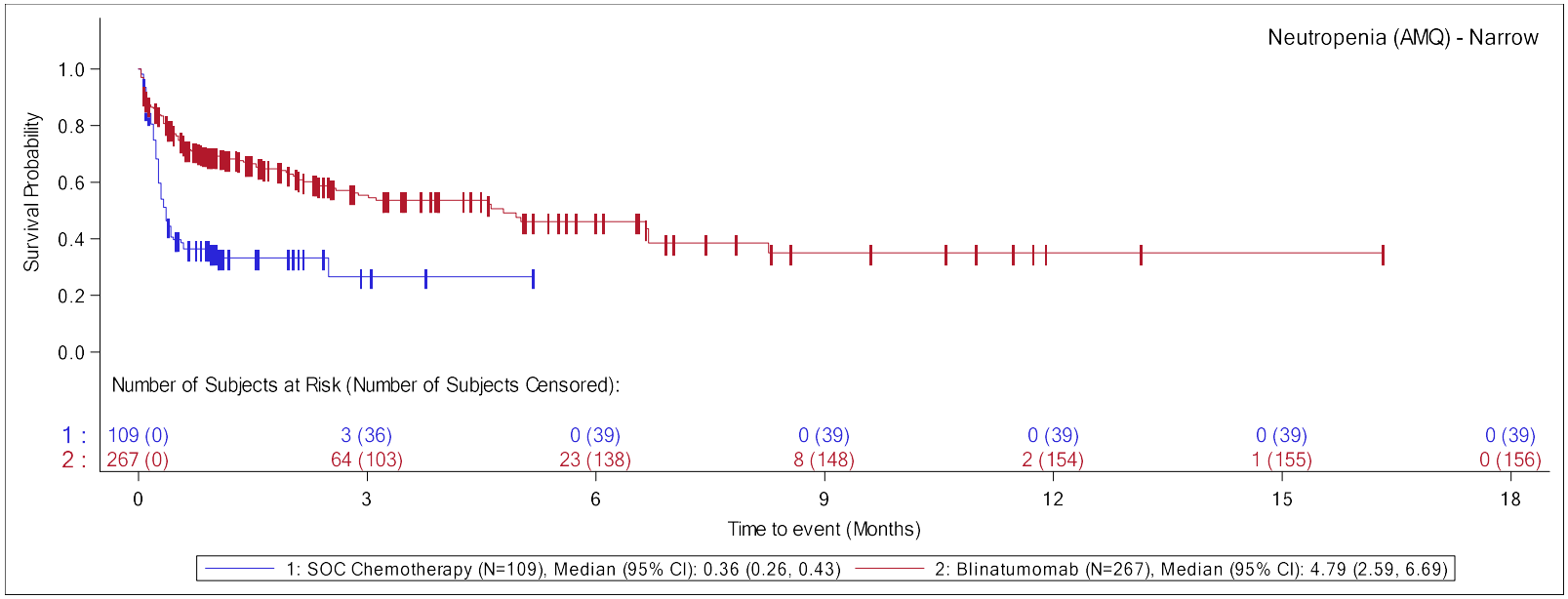
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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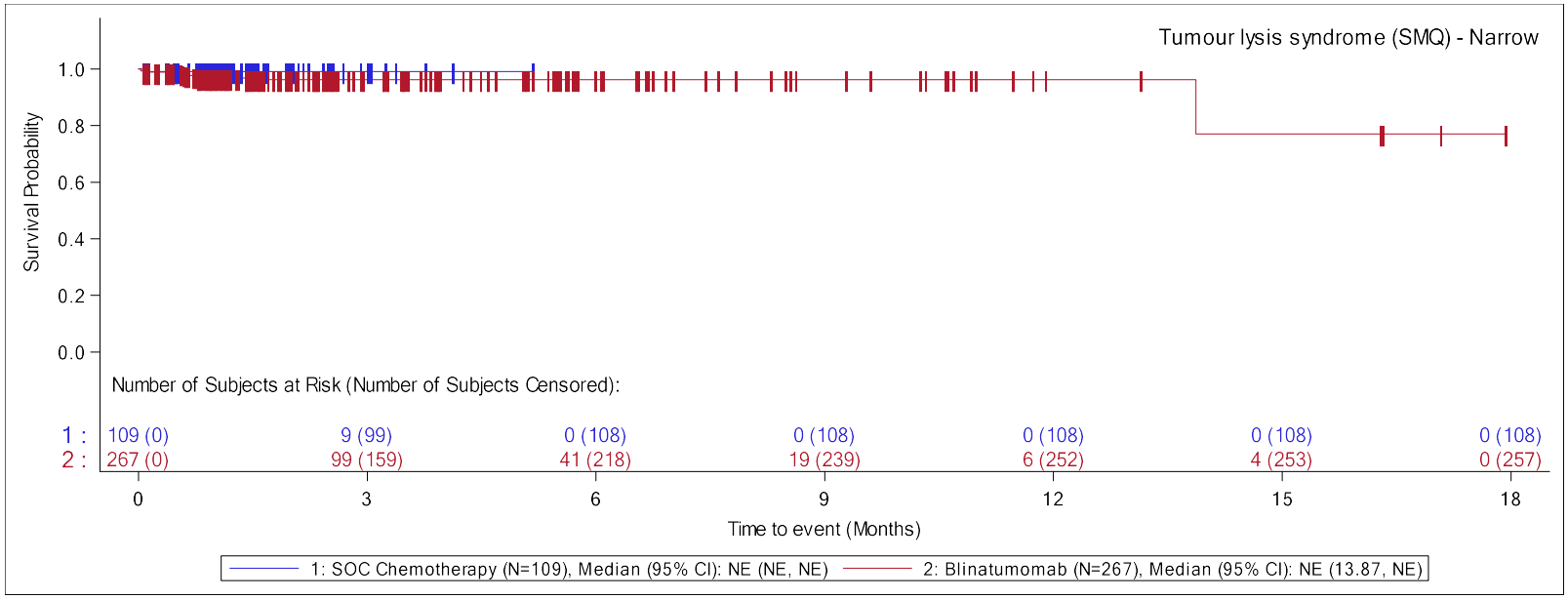
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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Anhang 4-G2.9.3: Sicherheit: SUE von besonderem Interesse

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Capillary leak syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Page 2 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			2.48
p-value			0.1738
Stratified log-rank test[c]			
Normal score[b]			2.41
p-value			0.1840

Page 3 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.15, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 0.5	0.0, 13.1	
Unstratified hazard ratio[e]			2.67
(95% CI)			(0.61, 11.67)
p-value			0.1913
Stratified hazard ratio[c,e]			2.62
(95% CI)			(0.60, 11.48)
p-value			0.2006

Page 4 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Cytokine release syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			2.68
p-value			0.0542
Stratified log-rank test[c]			
Normal score[b]			2.57
p-value			0.0590

Page 5 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 1.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Page 6 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Decreased immunoglobulins (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Haematopoietic cytopenias (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	17 (15.6)	34 (12.7)	
Unstratified log-rank test			
Normal score[b]			-6.68
p-value			0.0166
Stratified log-rank test[c]			
Normal score[b]			-6.81
p-value			0.0138

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(14.07, NE)	
Q1, Q3	1.97, NE	14.07, NE	
Min, Max	0.1, 2.8	0.1, 14.1	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.26, 0.89)
p-value			0.0188
Stratified hazard ratio[c,e]			0.47
(95% CI)			(0.26, 0.87)
p-value			0.0162

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infections and infestations (SOC)			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	33 (30.3)	75 (28.1)	
Unstratified log-rank test			
Normal score[b]			-12.05
p-value			0.0023
Stratified log-rank test[c]			
Normal score[b]			-11.91
p-value			0.0025

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	7.44	
95% CI (median)	(2.03, NE)	(5.80, NE)	
Q1, Q3	0.92, NE	2.56, NE	
Min, Max	0.0, 2.1	0.0, 10.0	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.33, 0.80)
p-value			0.0028
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.33, 0.80)
p-value			0.0030

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infusion reaction (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	3 (1.1)	
Unstratified log-rank test			
Normal score[b]			0.87
p-value			0.2674
Stratified log-rank test[c]			
Normal score[b]			0.91
p-value			0.2513

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 0.1	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Liver related investigations, signs and symptoms (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	3 (1.1)	
Unstratified log-rank test			
Normal score[b]			0.85
p-value			0.2766
Stratified log-rank test[c]			
Normal score[b]			0.85
p-value			0.2755

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.1, 0.9	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Lymphopenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Medication errors and product use issues (AMQ) - Broad			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			3.19
p-value			0.0355
Stratified log-rank test[c]			
Normal score[b]			3.26
p-value			0.0330

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 2.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Neutropenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	28 (10.5)	
Unstratified log-rank test			
Normal score[b]			-6.30
p-value			0.0137
Stratified log-rank test[c]			
Normal score[b]			-6.21
p-value			0.0153

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(14.07, NE)	
Q1, Q3	2.82, NE	14.07, NE	
Min, Max	0.1, 2.8	0.1, 14.1	
Unstratified hazard ratio[e]			0.44
(95% CI)			(0.23, 0.86)
p-value			0.0162
Stratified hazard ratio[c,e]			0.45
(95% CI)			(0.23, 0.87)
p-value			0.0181

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Tumour lysis syndrome (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	3 (1.1)	
Unstratified log-rank test			
Normal score[b]			0.74
p-value			0.3178
Stratified log-rank test[c]			
Normal score[b]			0.76
p-value			0.3063

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.6, 1.4	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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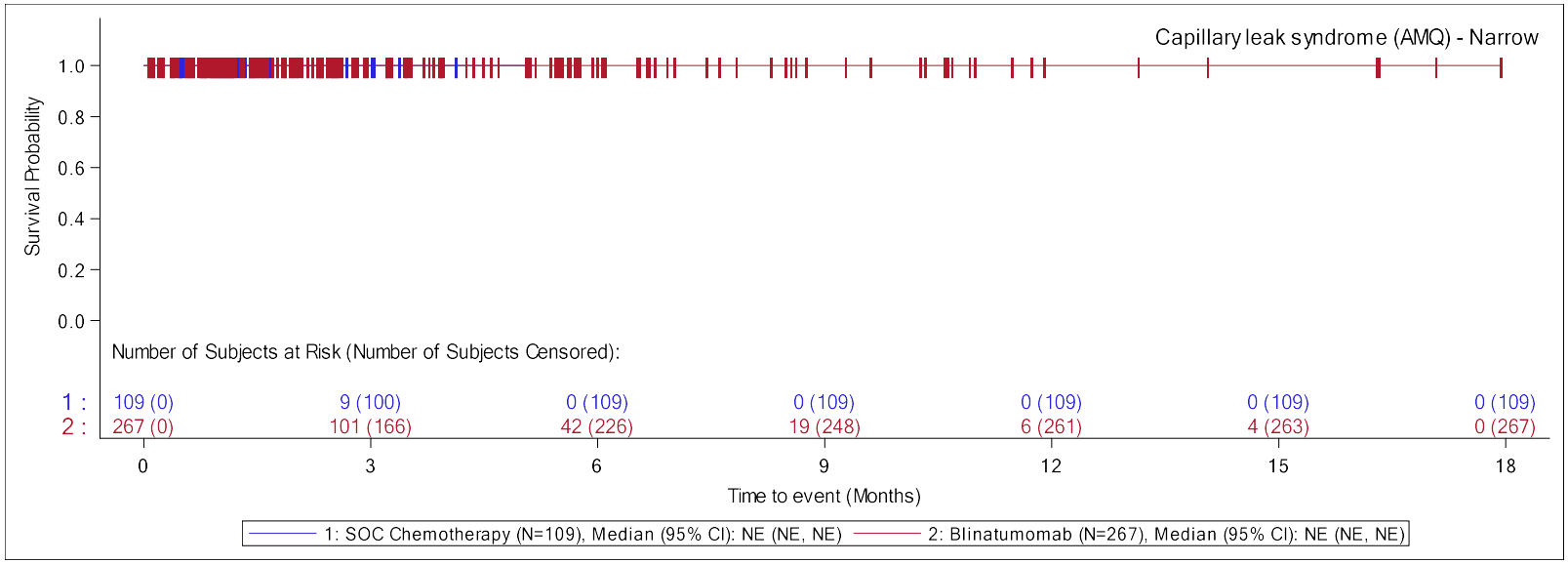
Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 16JUN2025:04:42) Source data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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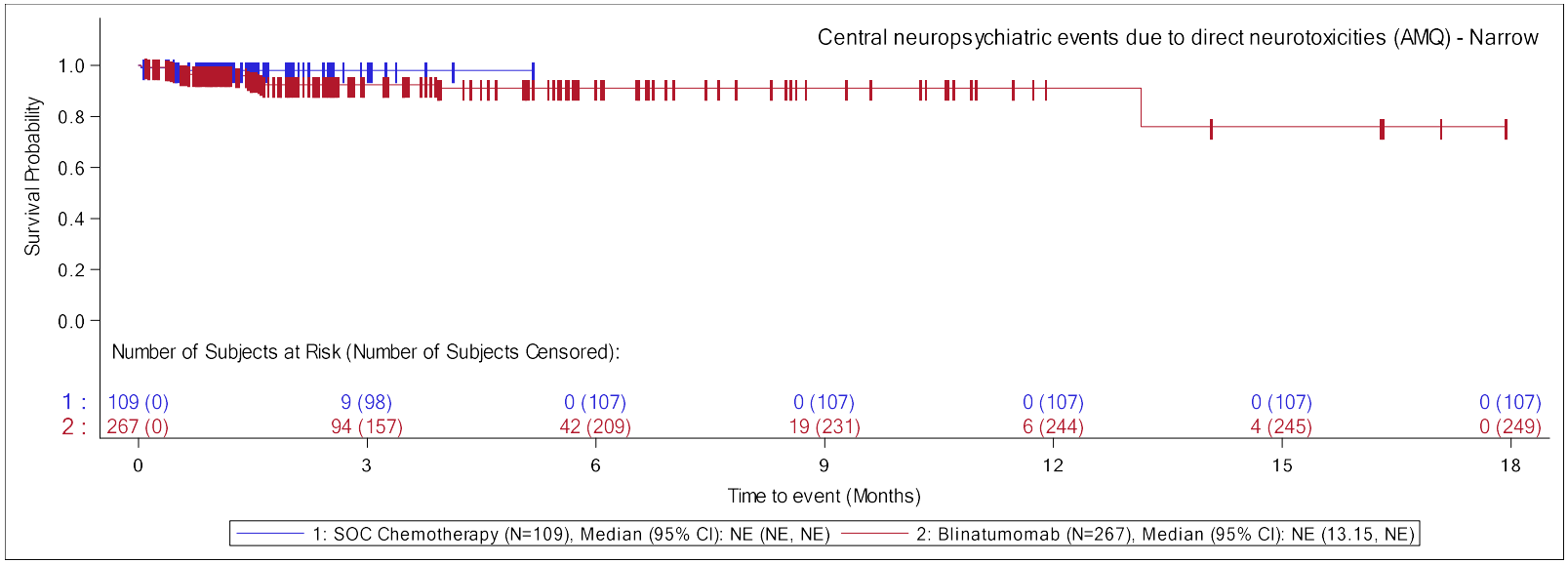
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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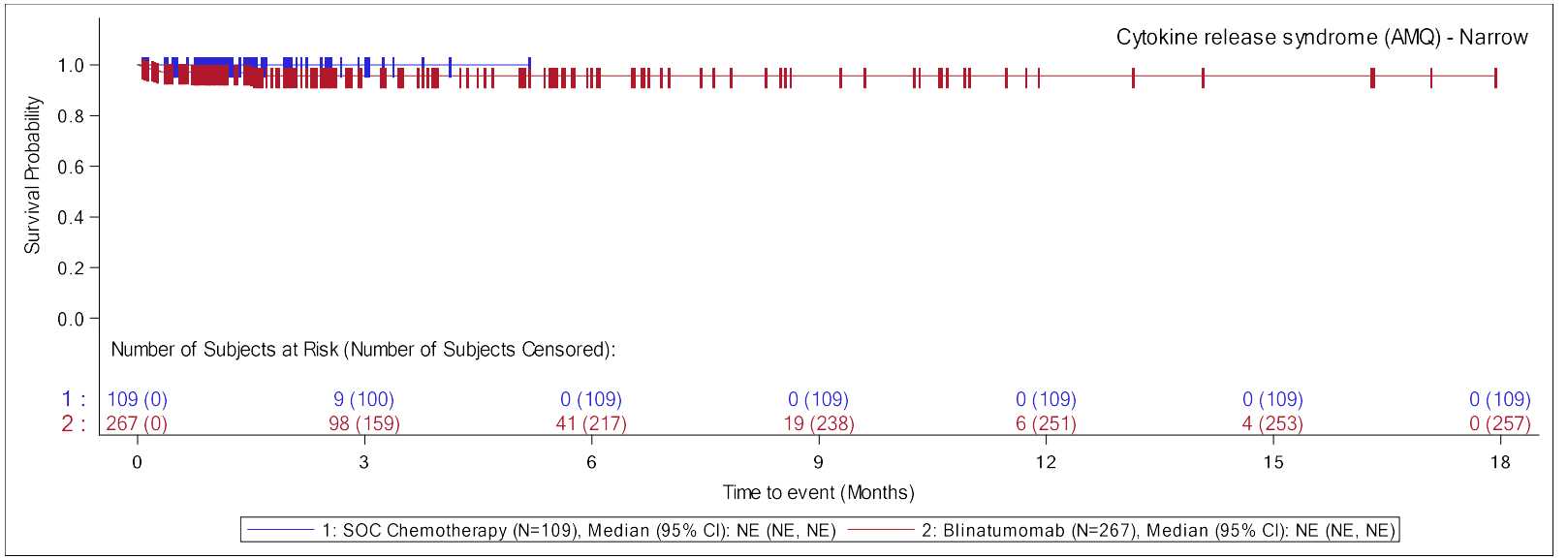
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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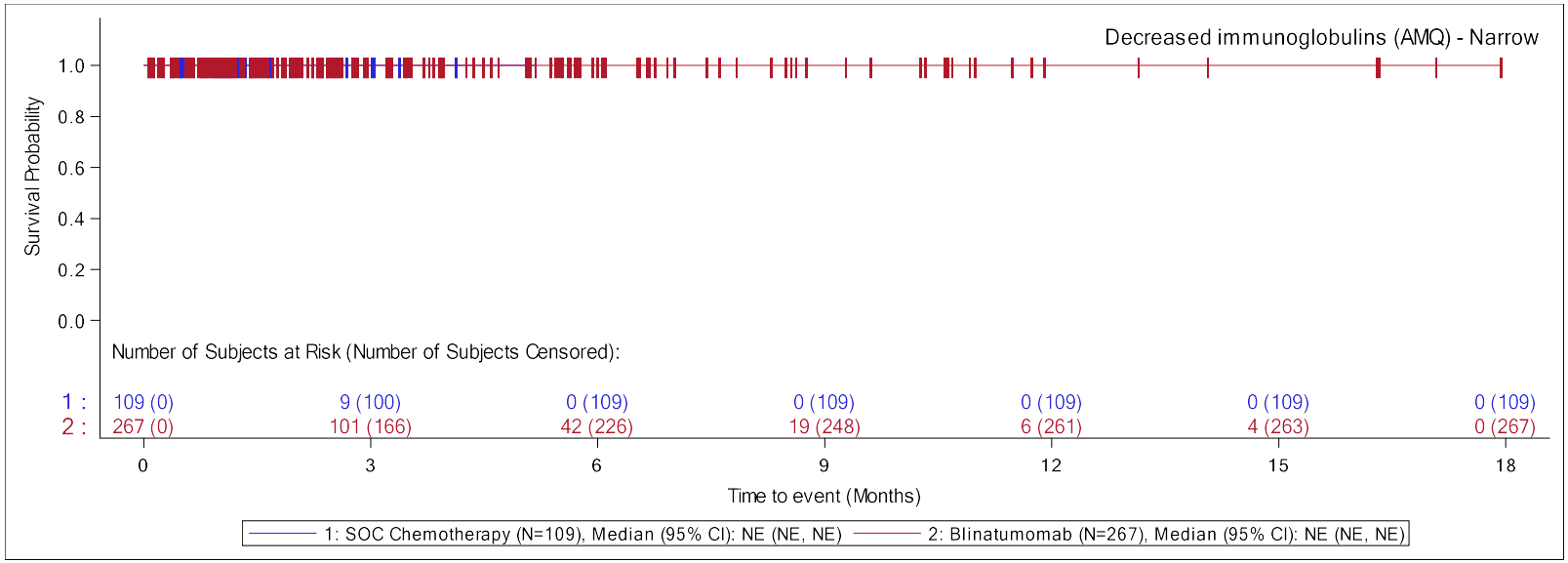
Output: f14-06-001-007-km-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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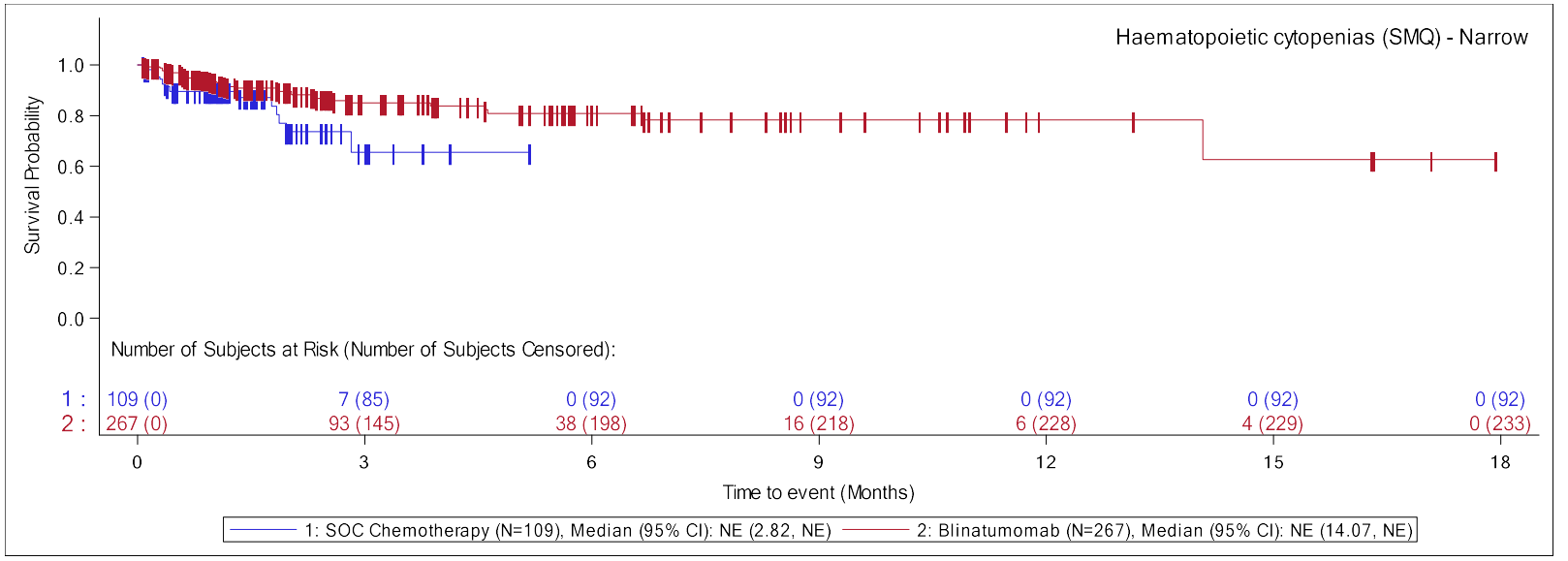
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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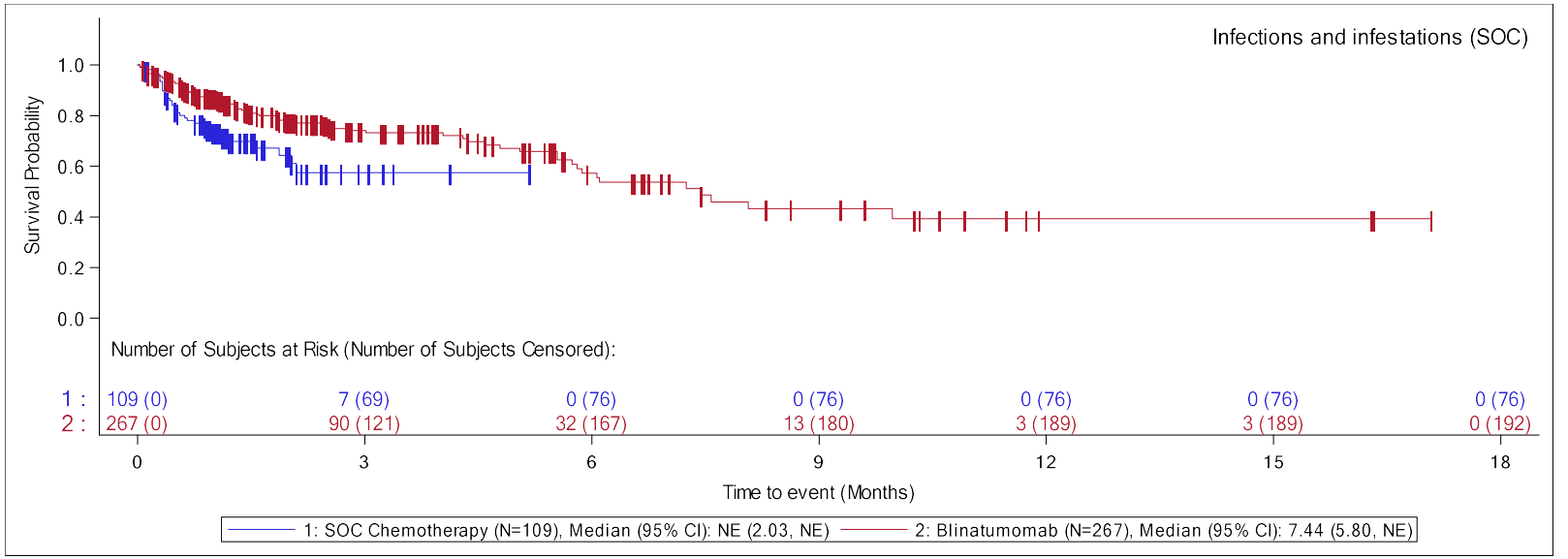
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

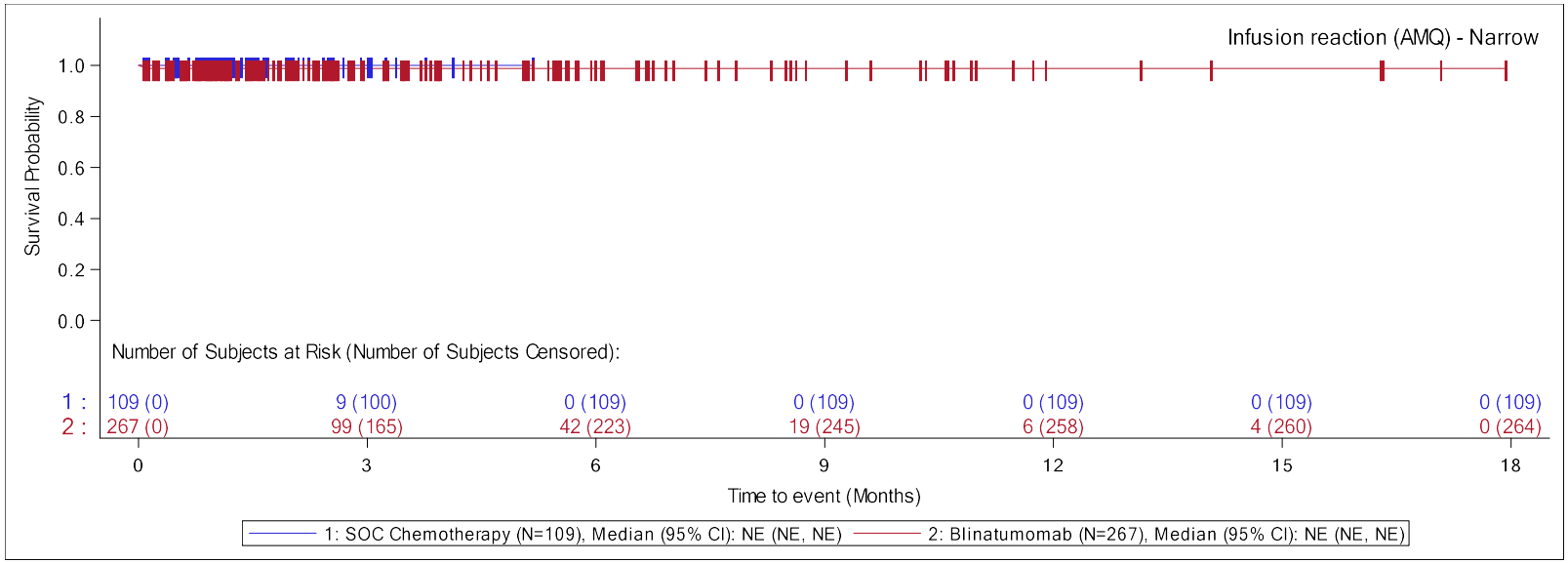

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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

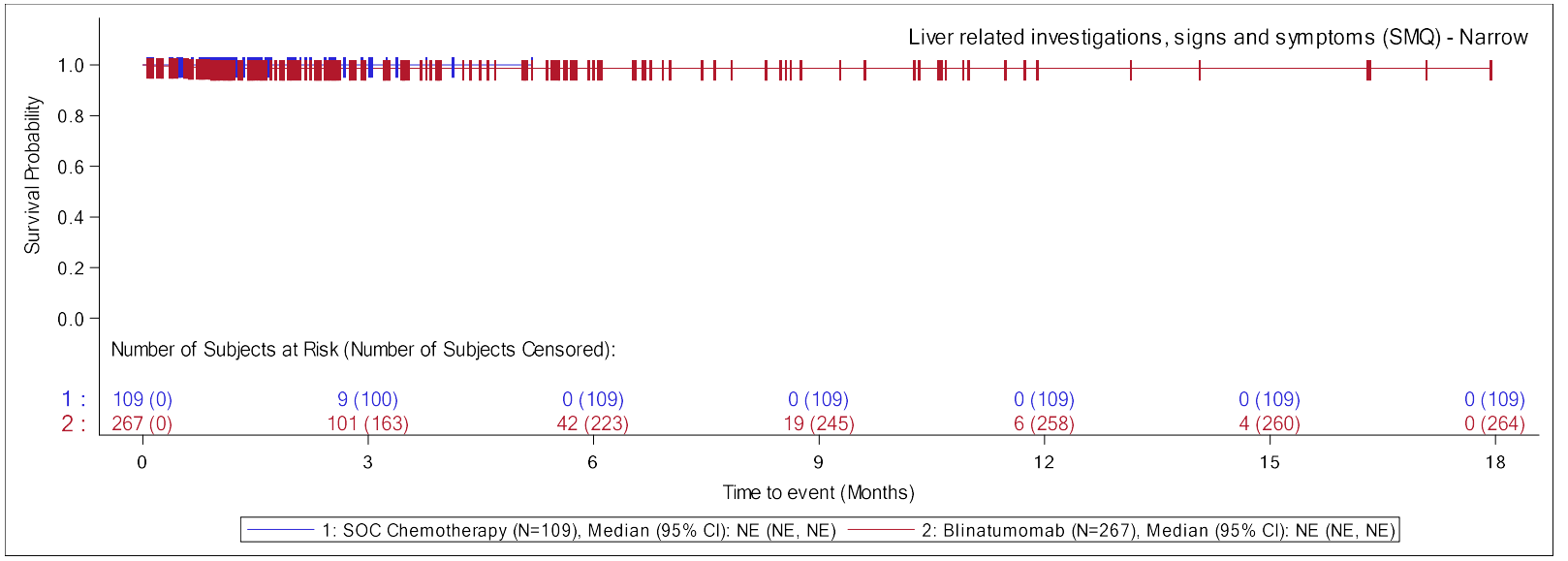

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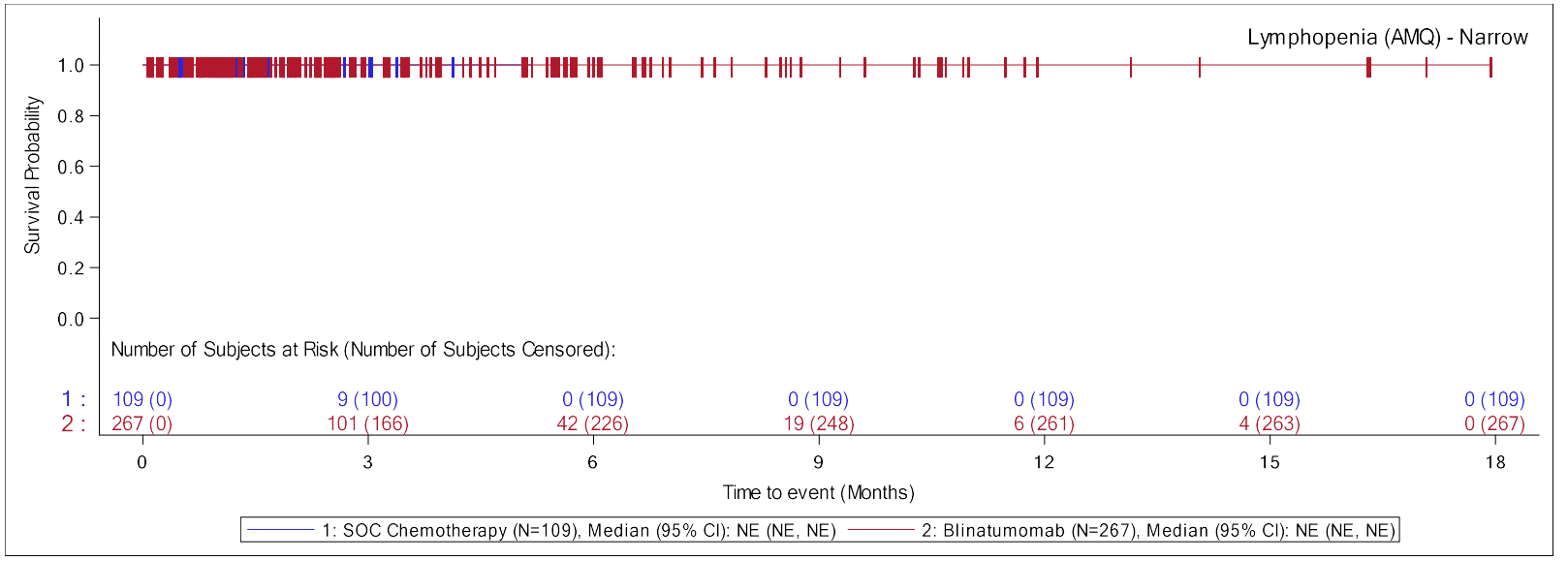
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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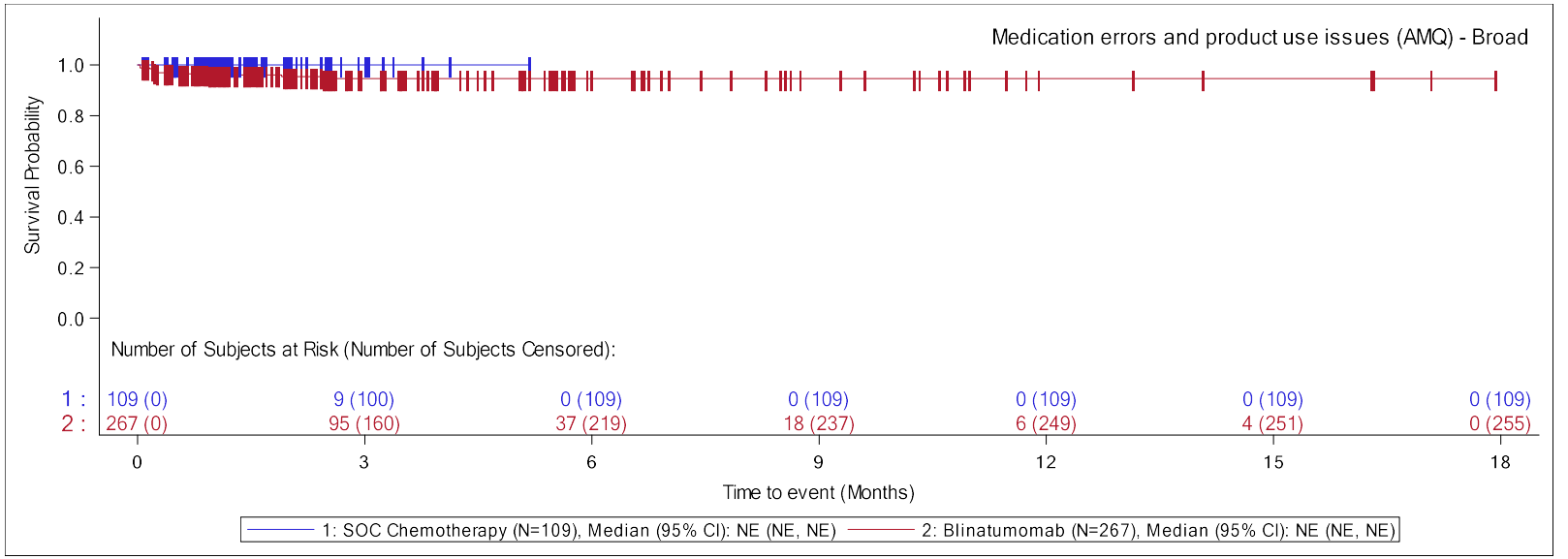
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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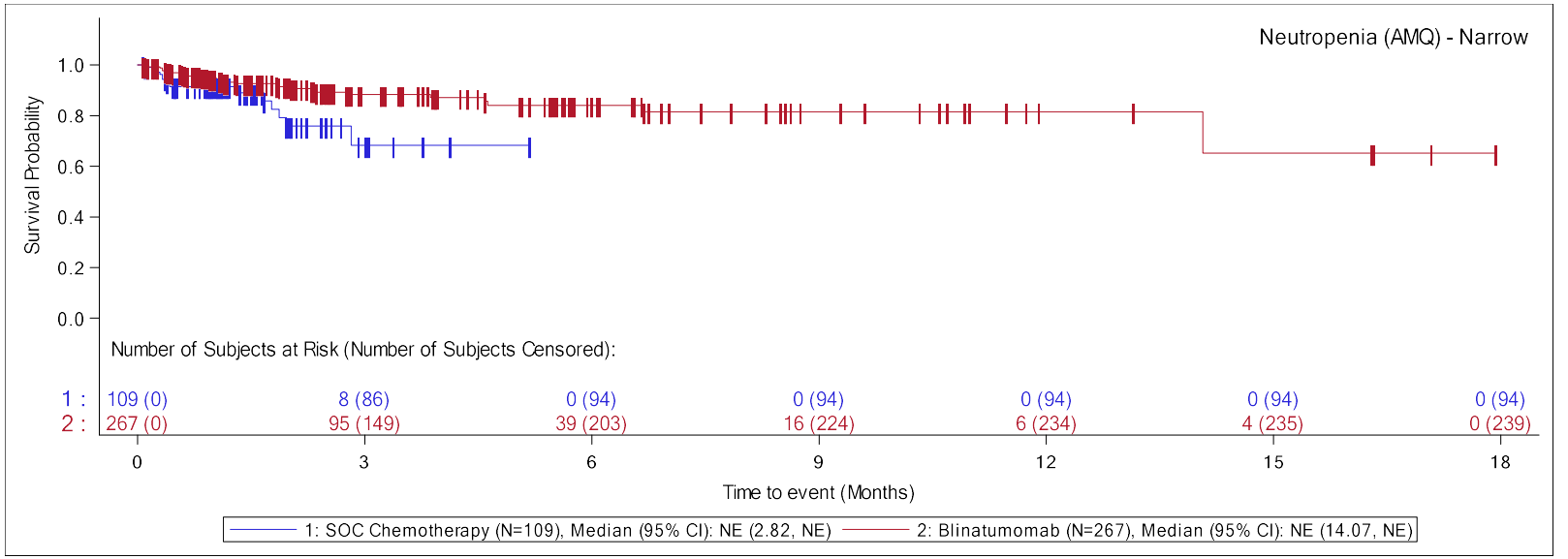
Output: f14-06-001-007-km-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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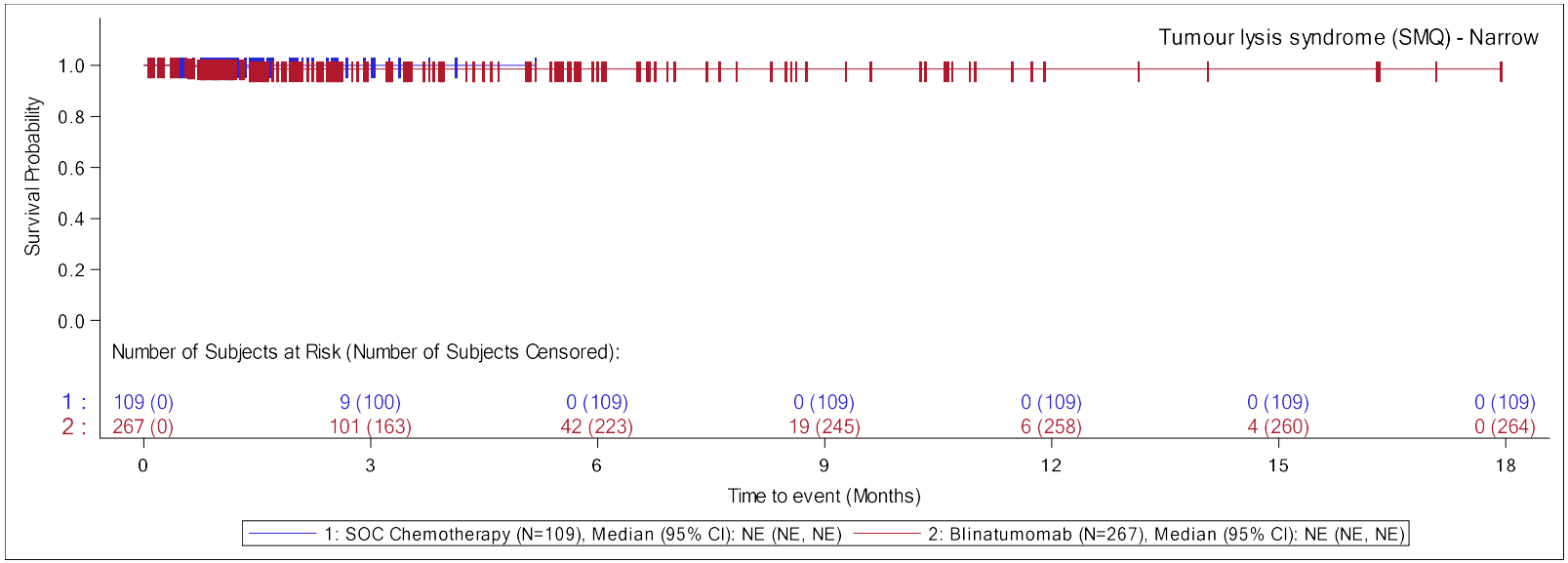
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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Output: f14-06-001-007-km-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Anhang 4-G2.9.4: Sicherheit: Schwere UE von besonderem Interesse

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Capillary leak syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Page 2 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	25 (9.4)	
Unstratified log-rank test			
Normal score[b]			-0.54
p-value			0.8294
Stratified log-rank test[c]			
Normal score[b]			-0.65
p-value			0.7928

Page 3 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.15, NE)	
Q1, Q3	NE, NE	13.15, NE	
Min, Max	0.0, 1.1	0.0, 13.1	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.42, 1.99)
p-value			0.8295
Stratified hazard ratio[c,e]			0.90
(95% CI)			(0.42, 1.96)
p-value			0.7968

Page 4 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Cytokine release syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			3.28
p-value			0.0326
Stratified log-rank test[c]			
Normal score[b]			3.17
p-value			0.0353

Page 5 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 8.3	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Decreased immunoglobulins (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	7 (2.6)	
Unstratified log-rank test			
Normal score[b]			0.56
p-value			0.4170
Stratified log-rank test[c]			
Normal score[b]			0.50
p-value			0.4449

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	1.4, 7.2	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Haematopoietic cytopenias (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	74 (67.9)	141 (52.8)	
Unstratified log-rank test			
Normal score[b]			-26.50
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-25.41
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	2.07	
95% CI (median)	(0.26, 0.36)	(1.08, 3.11)	
Q1, Q3	0.16, NE	0.26, NE	
Min, Max	0.0, 1.0	0.0, 8.3	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.39, 0.69)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.40, 0.71)
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infections and infestations (SOC)			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	57 (52.3)	91 (34.1)	
Unstratified log-rank test			
Normal score[b]			-29.03
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-29.19
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.11	6.10	
95% CI (median)	(0.62, 2.03)	(5.54, NE)	
Q1, Q3	0.39, NE	1.57, NE	
Min, Max	0.0, 2.1	0.0, 8.1	
Unstratified hazard ratio[e]			0.33
(95% CI)			(0.23, 0.48)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.22, 0.46)
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infusion reaction (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			3.77
p-value			0.0384
Stratified log-rank test[c]			
Normal score[b]			3.94
p-value			0.0329

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 8.1	
Unstratified hazard ratio[e]			6.38
(95% CI)			(0.84, 48.20)
p-value			0.0725
Stratified hazard ratio[c,e]			6.70
(95% CI)			(0.89, 50.66)
p-value			0.0652

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Liver related investigations, signs and symptoms (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	34 (12.7)	
Unstratified log-rank test			
Normal score[b]			-2.26
p-value			0.4688
Stratified log-rank test[c]			
Normal score[b]			-1.94
p-value			0.5368

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(3.02, NE)	(NE, NE)	
Q1, Q3	3.02, NE	NE, NE	
Min, Max	0.1, 3.0	0.0, 3.0	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.44, 1.46)
p-value			0.4722
Stratified hazard ratio[c,e]			0.83
(95% CI)			(0.46, 1.51)
p-value			0.5469

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Lymphopenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	4 (1.5)	
Unstratified log-rank test			
Normal score[b]			-1.98
p-value			0.0980
Stratified log-rank test[c]			
Normal score[b]			-1.90
p-value			0.1161

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.8	0.0, 7.1	
Unstratified hazard ratio[e]			0.30
(95% CI)			(0.07, 1.36)
p-value			0.1189
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.07, 1.43)
p-value			0.1362

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Medication errors and product use issues (AMQ) - Broad			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	4 (1.5)	
Unstratified log-rank test			
Normal score[b]			0.87
p-value			0.2829
Stratified log-rank test[c]			
Normal score[b]			0.94
p-value			0.2608

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 2.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Neutropenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	63 (57.8)	101 (37.8)	
Unstratified log-rank test			
Normal score[b]			-28.71
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-28.33
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.43	4.95	
95% CI (median)	(0.30, 0.95)	(3.87, NE)	
Q1, Q3	0.23, NE	0.62, NE	
Min, Max	0.0, 1.0	0.0, 8.3	
Unstratified hazard ratio[e]			0.40
(95% CI)			(0.29, 0.55)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.40
(95% CI)			(0.28, 0.55)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Tumour lysis syndrome (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	8 (3.0)	
Unstratified log-rank test			
Normal score[b]			1.45
p-value			0.2756
Stratified log-rank test[c]			
Normal score[b]			1.46
p-value			0.2705

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 1.4	
Unstratified hazard ratio[e]			3.01
(95% CI)			(0.38, 24.08)
p-value			0.3000
Stratified hazard ratio[c,e]			3.05
(95% CI)			(0.38, 24.56)
p-value			0.2949

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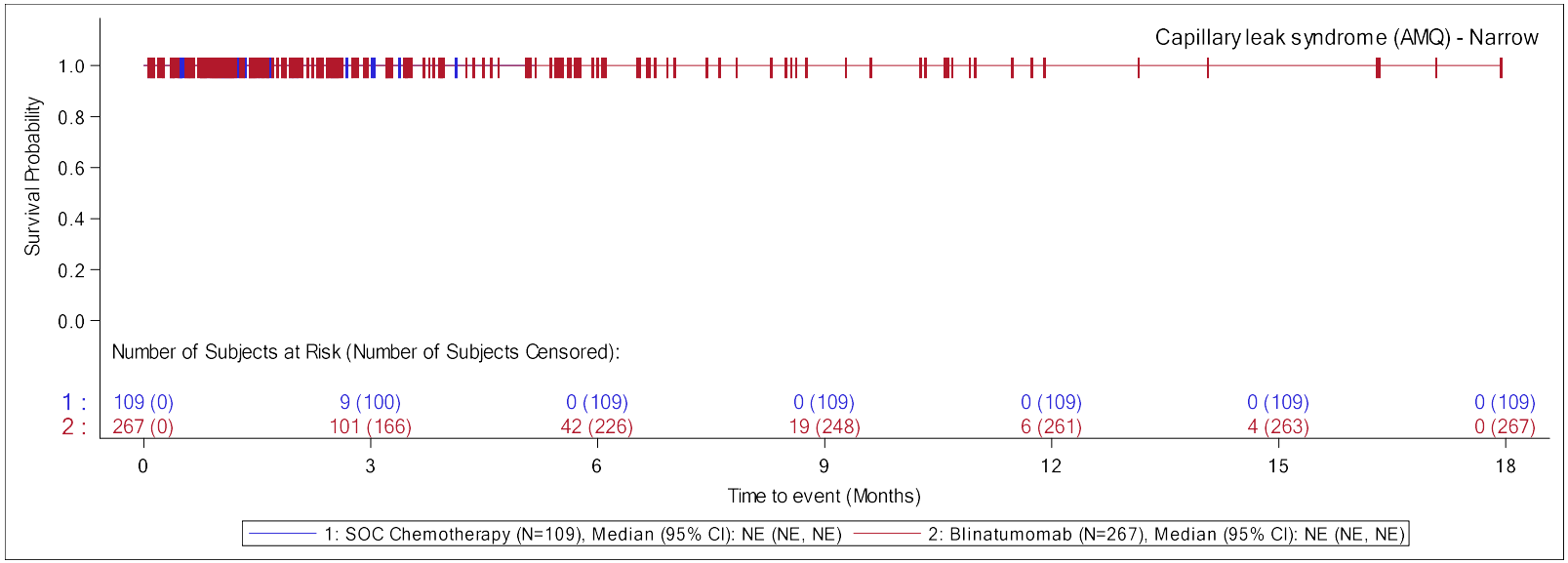
Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 16JUN2025:03:55) Source data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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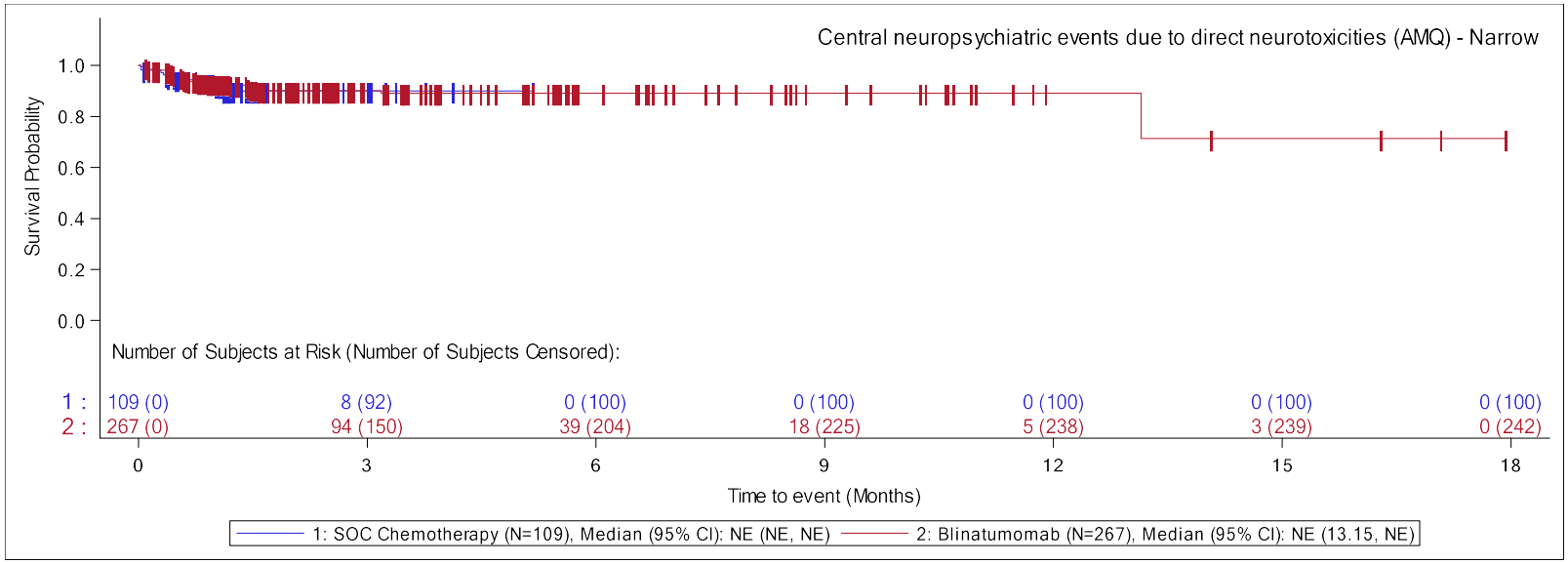
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

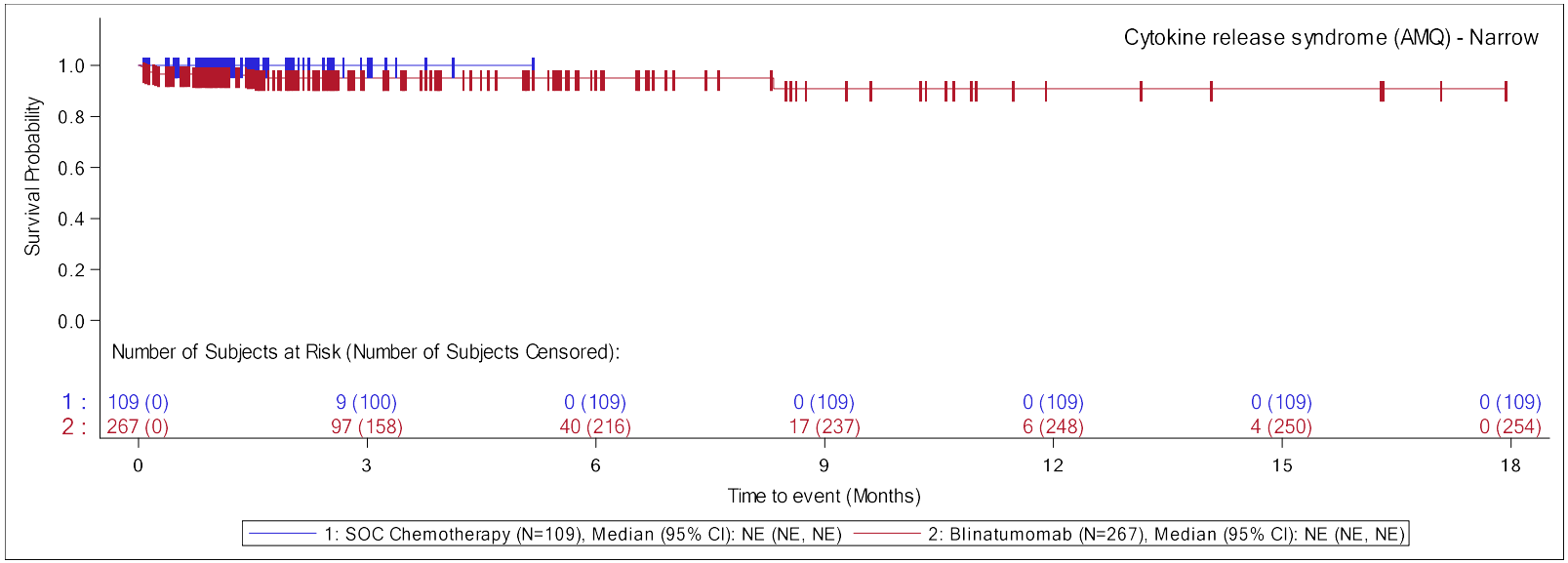
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

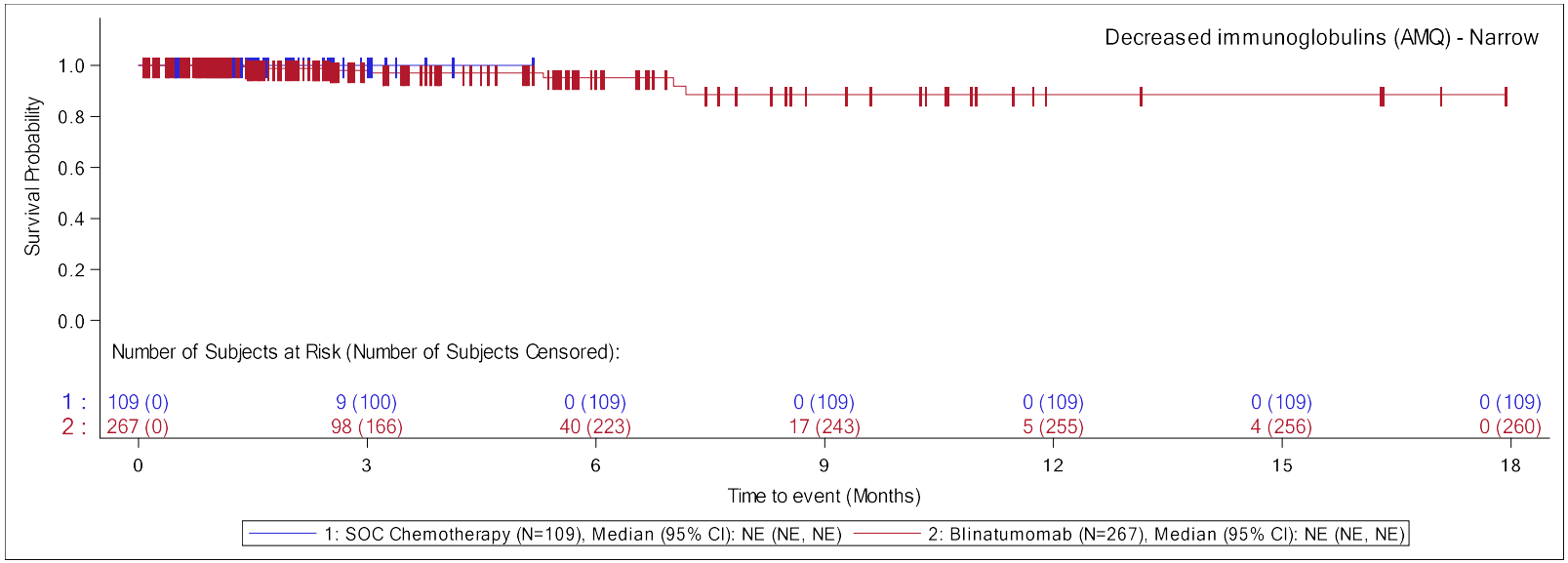
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

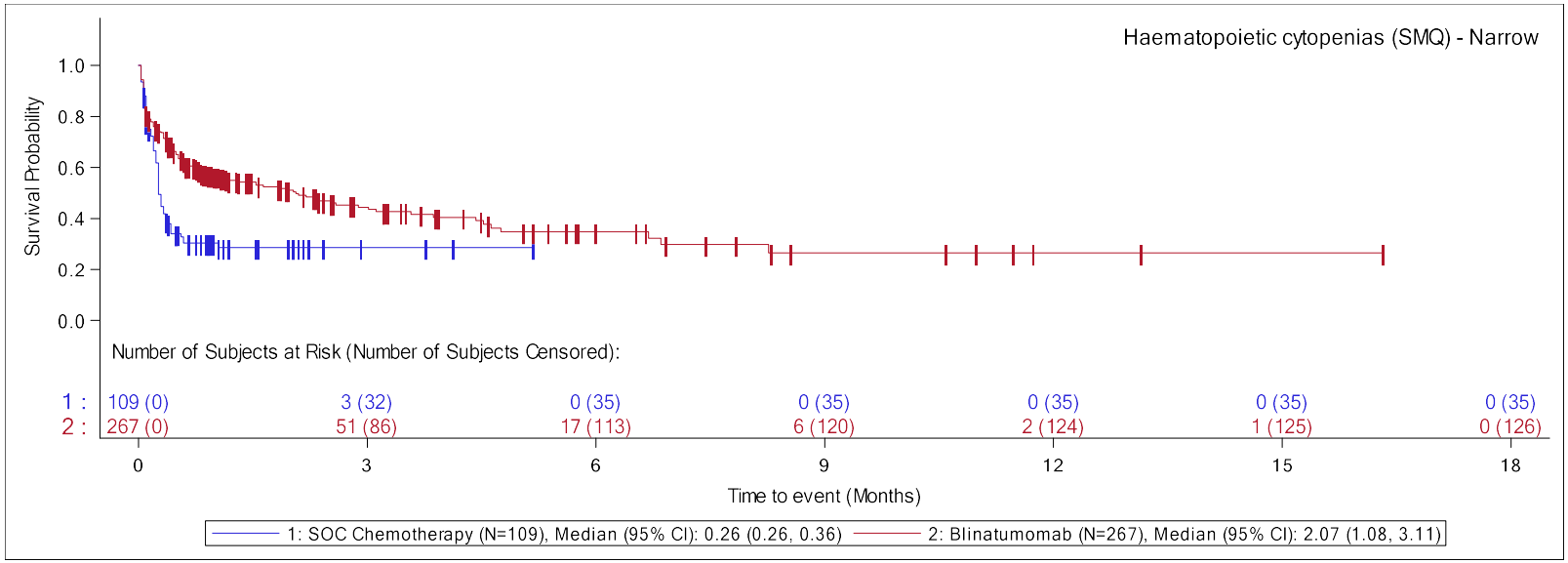
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
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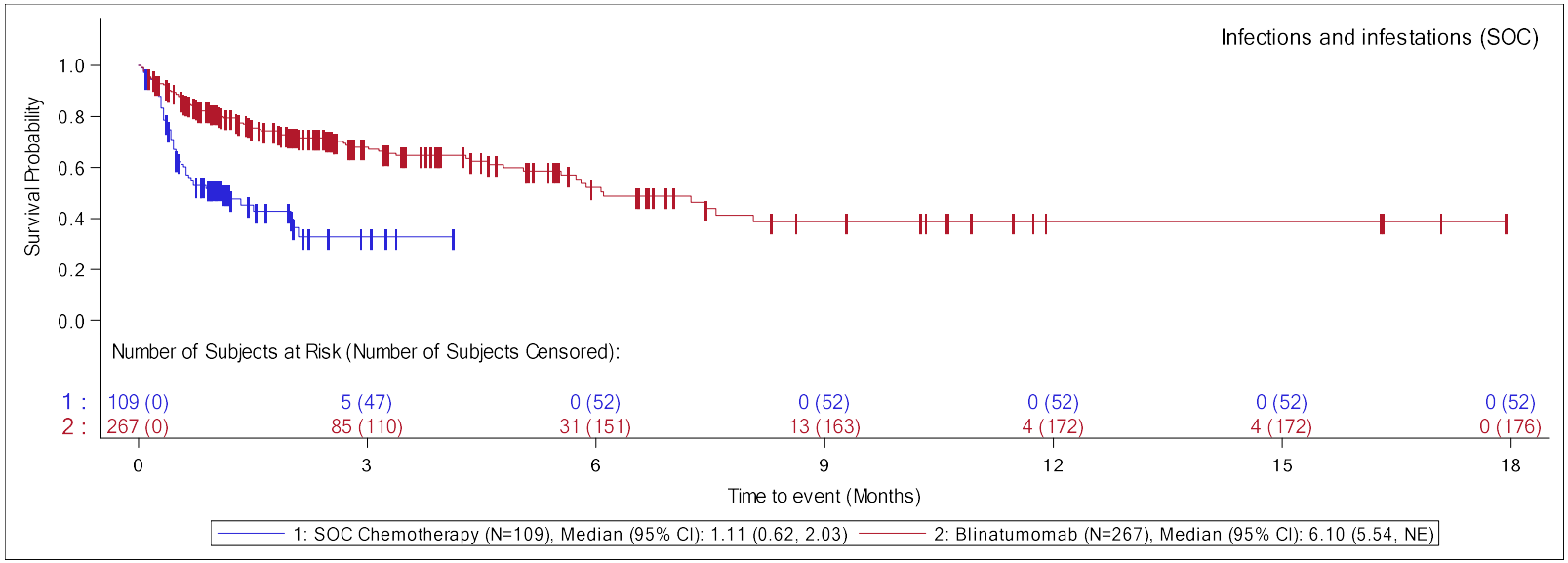
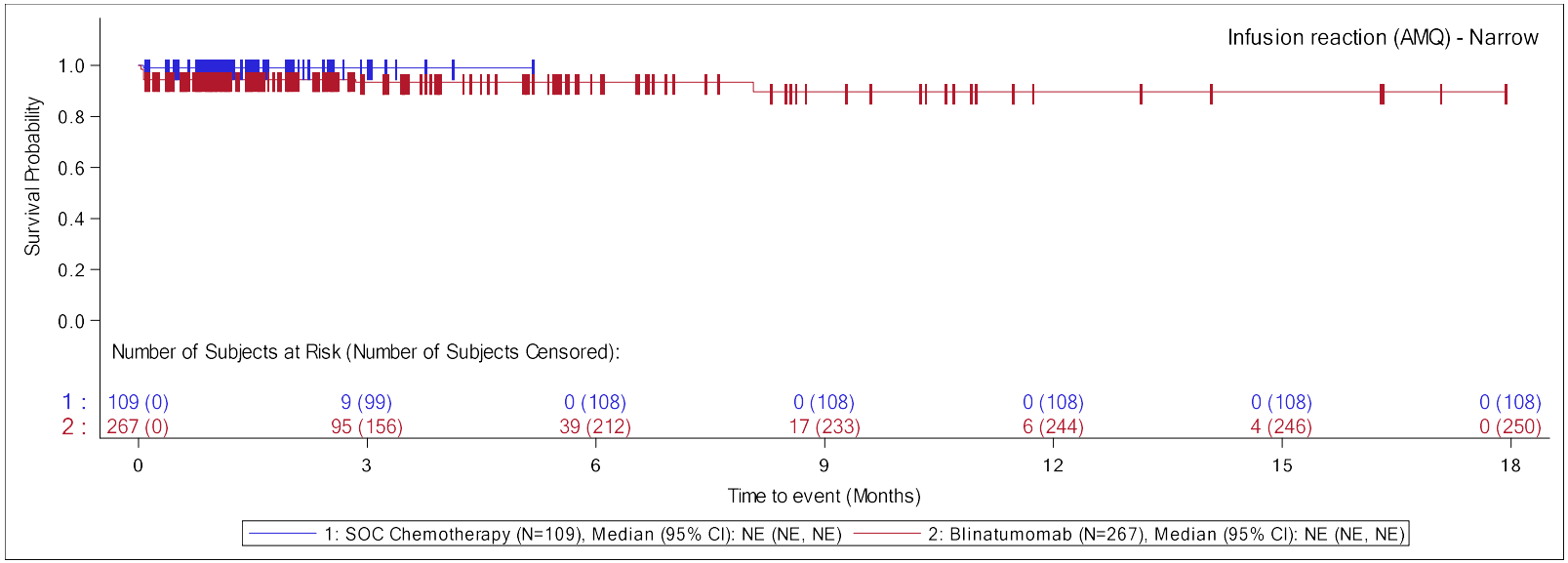
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

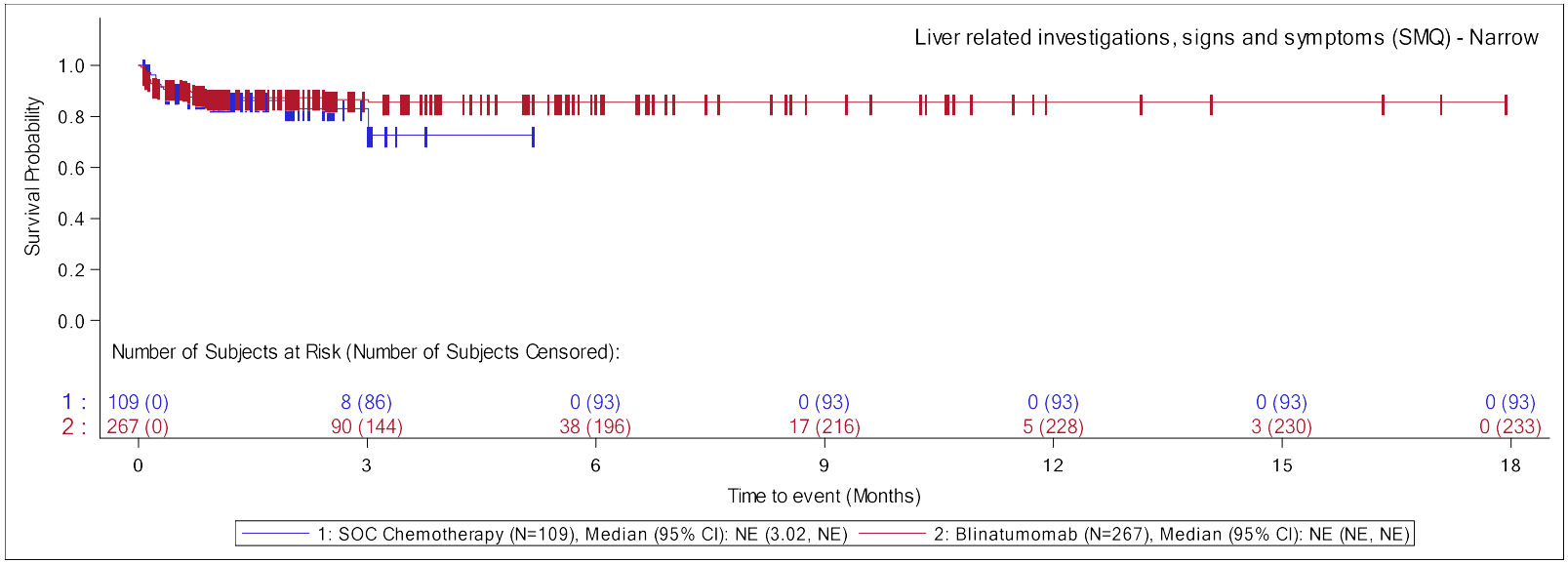
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

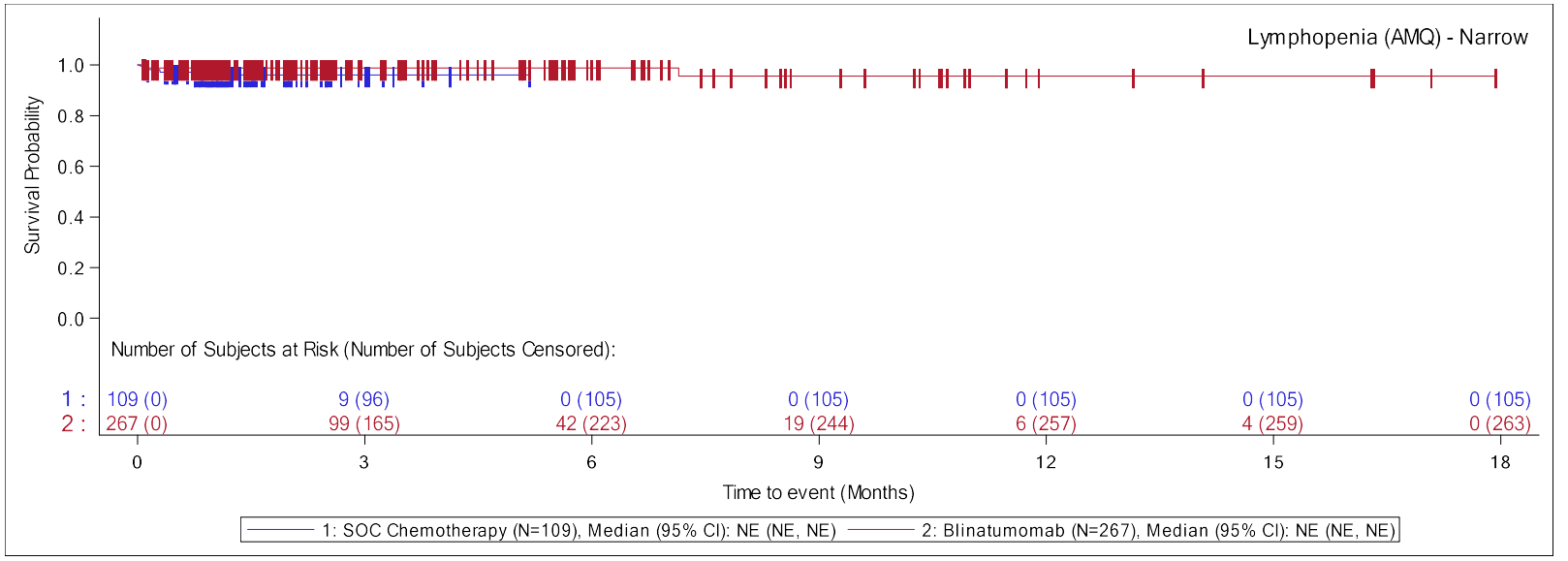
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

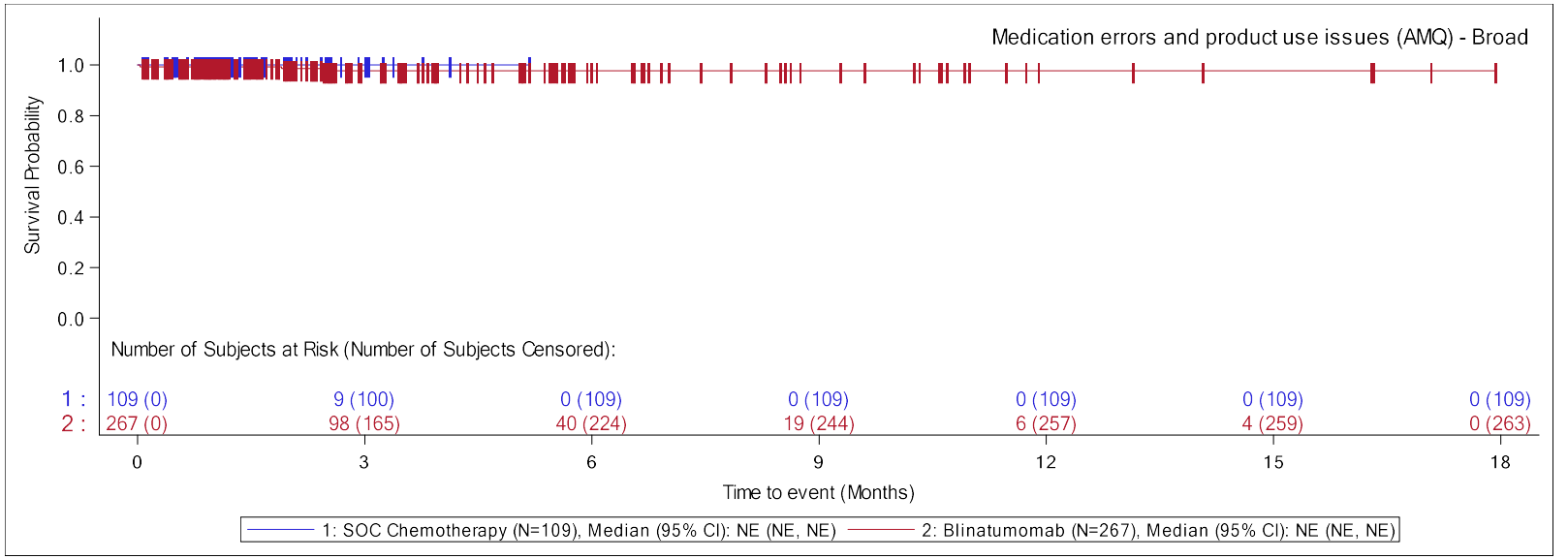
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

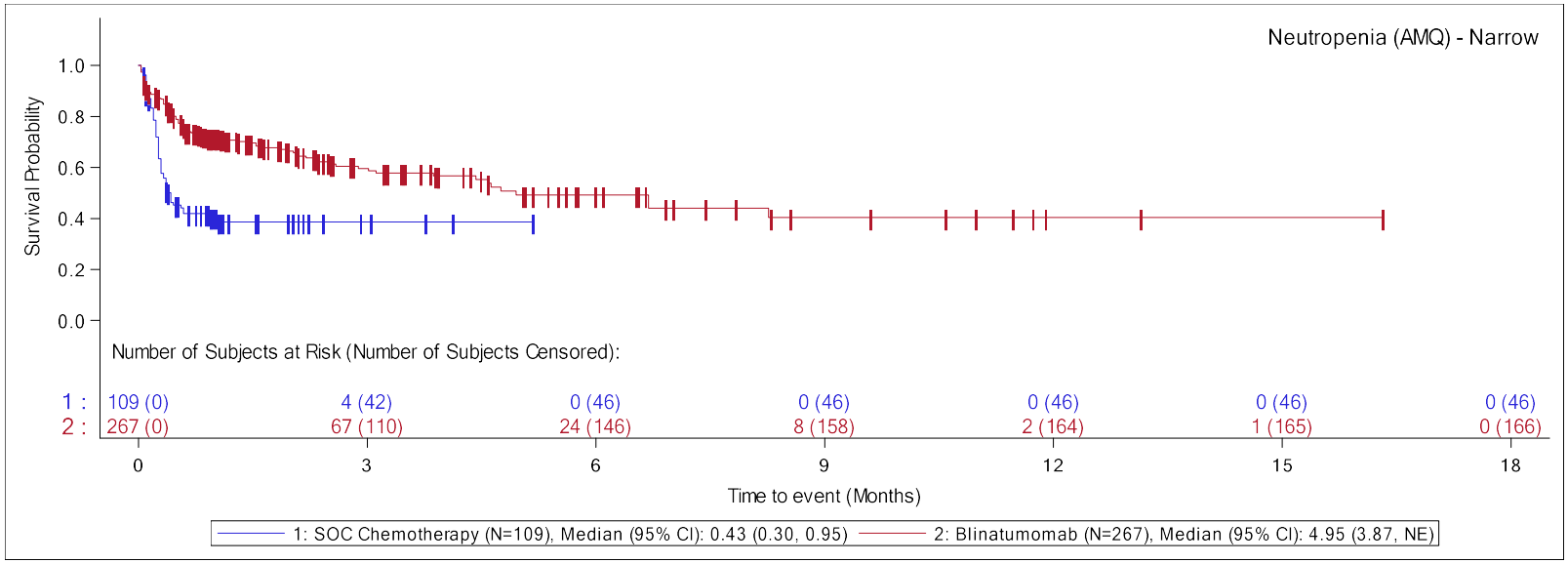
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

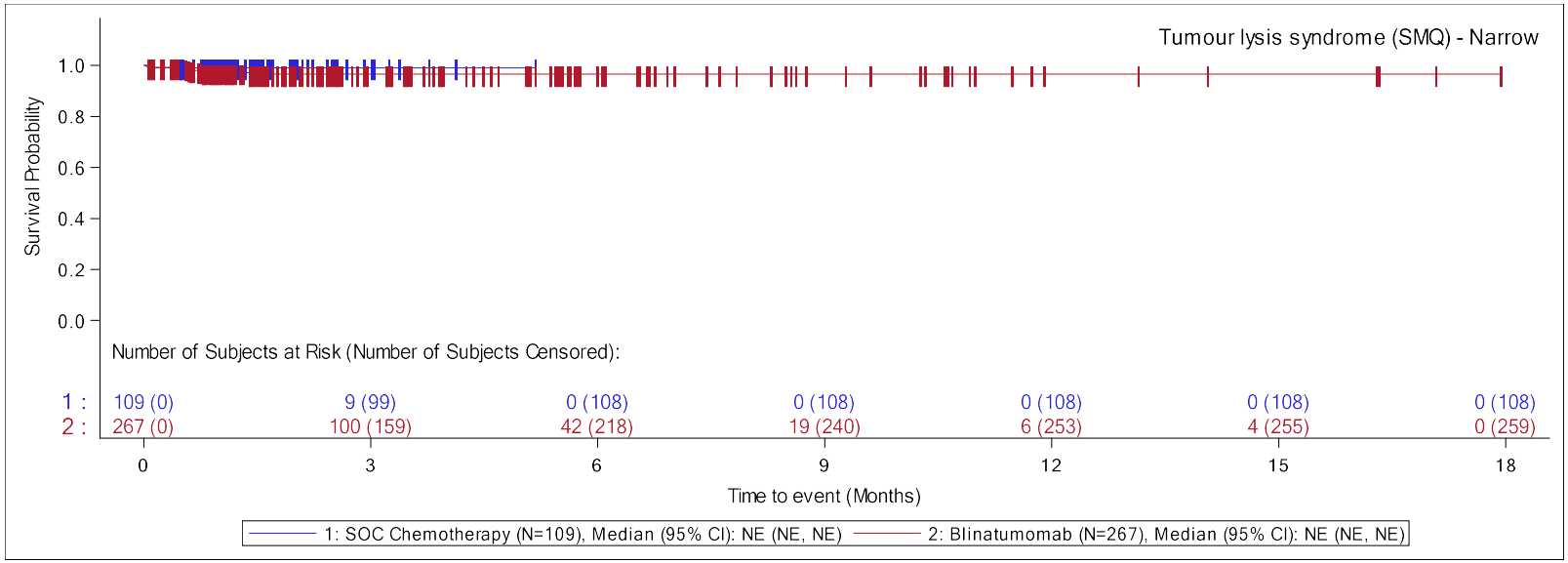
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-aesi-saf.sas
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam.adtteae

Anhang 4-G2.9.5: Sicherheit: UE nach SOC, PT

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	83 (76.1)	183 (68.5)	
Unstratified log-rank test			
Normal score[b]			-22.32
p-value			0.0006
Stratified log-rank test[c]			
Normal score[b]			-21.49
p-value			0.0009

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	0.52	
95% CI (median)	(0.20, 0.30)	(0.39, 0.79)	
Q1, Q3	0.10, 0.59	0.10, 4.52	
Min, Max	0.0, 1.9	0.0, 8.3	
Unstratified hazard ratio[e]			0.63
(95% CI)			(0.48, 0.82)
p-value			0.0007
Stratified hazard ratio[c,e]			0.64
(95% CI)			(0.49, 0.84)
p-value			0.0012

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Anaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	46 (42.2)	69 (25.8)	
Unstratified log-rank test			
Normal score[b]			-15.50
p-value			0.0008
Stratified log-rank test[c]			
Normal score[b]			-15.35
p-value			0.0009

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.93	NE	
95% CI (median)	(0.79, NE)	(11.90, NE)	
Q1, Q3	0.26, NE	0.95, NE	
Min, Max	0.0, 1.9	0.0, 11.9	
Unstratified hazard ratio[e]			0.53
(95% CI)			(0.37, 0.78)
p-value			0.0011
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.37, 0.78)
p-value			0.0011

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	43 (39.4)	64 (24.0)	
Unstratified log-rank test			
Normal score[b]			-16.45
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			-16.27
p-value			0.0002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	2.82	NE	
95% CI (median)	(1.77, NE)	(NE, NE)	
Q1, Q3	0.39, NE	2.36, NE	
Min, Max	0.0, 2.8	0.0, 6.7	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.32, 0.71)
p-value			0.0002
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.32, 0.71)
p-value			0.0003

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	33 (30.3)	53 (19.9)	
Unstratified log-rank test			
Normal score[b]			-14.53
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-14.78
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.30, NE)	(8.26, NE)	
Q1, Q3	0.30, NE	3.84, NE	
Min, Max	0.1, 2.3	0.0, 8.3	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.26, 0.65)
p-value			0.0001
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.25, 0.62)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Thrombocytopenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	32 (29.4)	47 (17.6)	
Unstratified log-rank test			
Normal score[b]			-11.19
p-value			0.0036
Stratified log-rank test[c]			
Normal score[b]			-10.65
p-value			0.0061

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.30, NE	NE, NE	
Min, Max	0.0, 2.0	0.0, 6.6	
Unstratified hazard ratio[e]			0.51
(95% CI)			(0.33, 0.81)
p-value			0.0042
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.34, 0.84)
p-value			0.0070

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Leukopenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-0.81
p-value			0.6380
Stratified log-rank test[c]			
Normal score[b]			-0.82
p-value			0.6352

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 1.8	0.0, 0.9	
Unstratified hazard ratio[e]			0.77
(95% CI)			(0.26, 2.27)
p-value			0.6381
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.26, 2.26)
p-value			0.6361

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Cardiac disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	26 (23.9)	49 (18.4)	
Unstratified log-rank test			
Normal score[b]			-6.86
p-value			0.0638
Stratified log-rank test[c]			
Normal score[b]			-6.64
p-value			0.0733

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.26, NE)	(NE, NE)	
Q1, Q3	1.64, NE	8.72, NE	
Min, Max	0.0, 2.3	0.0, 8.7	
Unstratified hazard ratio[e]			0.64
(95% CI)			(0.39, 1.03)
p-value			0.0673
Stratified hazard ratio[c,e]			0.65
(95% CI)			(0.40, 1.05)
p-value			0.0806

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Tachycardia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-2.83
p-value			0.2118
Stratified log-rank test[c]			
Normal score[b]			-2.75
p-value			0.2265

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 2.8	0.0, 3.9	
Unstratified hazard ratio[e]			0.61
(95% CI)			(0.28, 1.34)
p-value			0.2188
Stratified hazard ratio[c,e]			0.62
(95% CI)			(0.28, 1.37)
p-value			0.2383

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sinus tachycardia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-0.25
p-value			0.9009
Stratified log-rank test[c]			
Normal score[b]			-0.32
p-value			0.8745

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.2	0.0, 2.5	
Unstratified hazard ratio[e]			0.94
(95% CI)			(0.36, 2.44)
p-value			0.9018
Stratified hazard ratio[c,e]			0.93
(95% CI)			(0.36, 2.40)
p-value			0.8745

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Ear and labyrinth disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			0.37
p-value			0.8348
Stratified log-rank test[c]			
Normal score[b]			0.36
p-value			0.8385

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.54, NE)	
Q1, Q3	NE, NE	13.54, NE	
Min, Max	0.0, 0.6	0.1, 13.5	
Unstratified hazard ratio[e]			1.13
(95% CI)			(0.36, 3.51)
p-value			0.8349
Stratified hazard ratio[c,e]			1.13
(95% CI)			(0.36, 3.56)
p-value			0.8365

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Eye disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	27 (10.1)	
Unstratified log-rank test			
Normal score[b]			-5.27
p-value			0.0471
Stratified log-rank test[c]			
Normal score[b]			-5.25
p-value			0.0473

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 8.7	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.27, 1.00)
p-value			0.0507
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.26, 1.00)
p-value			0.0503

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	87 (79.8)	150 (56.2)	
Unstratified log-rank test			
Normal score[b]			-41.11
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-41.32
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.23	1.21	
95% CI (median)	(0.10, 0.26)	(0.95, 2.13)	
Q1, Q3	0.07, 0.92	0.23, 11.28	
Min, Max	0.0, 2.2	0.0, 11.3	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.29, 0.50)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.28, 0.49)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Diarrhoea			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	38 (34.9)	58 (21.7)	
Unstratified log-rank test			
Normal score[b]			-17.30
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-17.47
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.67, NE)	(11.28, NE)	
Q1, Q3	0.39, NE	2.95, NE	
Min, Max	0.0, 2.2	0.1, 11.3	
Unstratified hazard ratio[e]			0.40
(95% CI)			(0.26, 0.61)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.25, 0.59)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Nausea			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	46 (42.2)	51 (19.1)	
Unstratified log-rank test			
Normal score[b]			-25.11
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-24.67
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.61	NE	
95% CI (median)	(1.02, NE)	(NE, NE)	
Q1, Q3	0.23, NE	5.41, NE	
Min, Max	0.0, 1.8	0.0, 6.1	
Unstratified hazard ratio[e]			0.28
(95% CI)			(0.19, 0.43)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.19, 0.43)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Constipation			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	27 (24.8)	34 (12.7)	
Unstratified log-rank test			
Normal score[b]			-11.68
p-value			0.0005
Stratified log-rank test[c]			
Normal score[b]			-11.79
p-value			0.0004

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.90, NE)	(NE, NE)	
Q1, Q3	1.28, NE	NE, NE	
Min, Max	0.0, 1.9	0.0, 4.0	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.25, 0.69)
p-value			0.0007
Stratified hazard ratio[c,e]			0.40
(95% CI)			(0.24, 0.68)
p-value			0.0006

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Vomiting			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	26 (23.9)	33 (12.4)	
Unstratified log-rank test			
Normal score[b]			-15.33
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-15.79
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.44, NE	6.62, NE	
Min, Max	0.0, 1.8	0.1, 8.3	
Unstratified hazard ratio[e]			0.23
(95% CI)			(0.13, 0.41)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.21
(95% CI)			(0.12, 0.38)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Stomatitis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-7.16
p-value			0.0015
Stratified log-rank test[c]			
Normal score[b]			-6.98
p-value			0.0021

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.79, NE)	(11.80, NE)	
Q1, Q3	2.79, NE	NE, NE	
Min, Max	0.2, 2.8	0.0, 11.8	
Unstratified hazard ratio[e]			0.31
(95% CI)			(0.15, 0.66)
p-value			0.0024
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.15, 0.69)
p-value			0.0032

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Abdominal pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	19 (17.4)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			-11.04
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-10.66
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.7	0.1, 5.6	
Unstratified hazard ratio[e]			0.23
(95% CI)			(0.12, 0.46)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.25
(95% CI)			(0.13, 0.49)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Dyspepsia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-2.98
p-value			0.0849
Stratified log-rank test[c]			
Normal score[b]			-2.66
p-value			0.1340

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.8	0.1, 3.1	
Unstratified hazard ratio[e]			0.43
(95% CI)			(0.16, 1.15)
p-value			0.0936
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.18, 1.28)
p-value			0.1423

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	84 (77.1)	210 (78.7)	
Unstratified log-rank test			
Normal score[b]			2.52
p-value			0.7310
Stratified log-rank test[c]			
Normal score[b]			0.97
p-value			0.8922

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.33	0.20	
95% CI (median)	(0.23, 0.39)	(0.13, 0.33)	
Q1, Q3	0.13, 1.11	0.07, 1.54	
Min, Max	0.0, 2.3	0.0, 7.0	
Unstratified hazard ratio[e]			1.07
(95% CI)			(0.83, 1.38)
p-value			0.5924
Stratified hazard ratio[c,e]			1.05
(95% CI)			(0.81, 1.36)
p-value			0.7154

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	49 (45.0)	159 (59.6)	
Unstratified log-rank test			
Normal score[b]			15.92
p-value			0.0123
Stratified log-rank test[c]			
Normal score[b]			16.17
p-value			0.0105

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.70	0.69	
95% CI (median)	(1.08, 2.62)	(0.36, 1.34)	
Q1, Q3	0.39, NE	0.07, NE	
Min, Max	0.0, 2.6	0.0, 7.0	
Unstratified hazard ratio[e]			1.54
(95% CI)			(1.12, 2.12)
p-value			0.0087
Stratified hazard ratio[c,e]			1.56
(95% CI)			(1.13, 2.16)
p-value			0.0071

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Oedema peripheral			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	39 (14.6)	
Unstratified log-rank test			
Normal score[b]			-1.89
p-value			0.5559
Stratified log-rank test[c]			
Normal score[b]			-1.88
p-value			0.5550

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.1, 6.3	
Unstratified hazard ratio[e]			0.84
(95% CI)			(0.47, 1.51)
p-value			0.5561
Stratified hazard ratio[c,e]			0.84
(95% CI)			(0.46, 1.51)
p-value			0.5581

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Fatigue			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	34 (12.7)	
Unstratified log-rank test			
Normal score[b]			-2.60
p-value			0.3653
Stratified log-rank test[c]			
Normal score[b]			-2.66
p-value			0.3523

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.0, 6.6	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.39, 1.41)
p-value			0.3667
Stratified hazard ratio[c,e]			0.74
(95% CI)			(0.39, 1.40)
p-value			0.3541

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Asthenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	21 (7.9)	
Unstratified log-rank test			
Normal score[b]			-3.29
p-value			0.1682
Stratified log-rank test[c]			
Normal score[b]			-3.05
p-value			0.2046

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.7	0.0, 6.9	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.28, 1.25)
p-value			0.1728
Stratified hazard ratio[c,e]			0.62
(95% CI)			(0.29, 1.31)
p-value			0.2082

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Chills			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			-4.81
p-value			0.0347
Stratified log-rank test[c]			
Normal score[b]			-4.63
p-value			0.0422

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 2.0	0.0, 10.0	
Unstratified hazard ratio[e]			0.45
(95% CI)			(0.21, 0.96)
p-value			0.0400
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.21, 0.99)
p-value			0.0483

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-1.03
p-value			0.5919
Stratified log-rank test[c]			
Normal score[b]			-1.02
p-value			0.5941

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 2.6	0.1, 3.7	
Unstratified hazard ratio[e]			0.77
(95% CI)			(0.29, 2.02)
p-value			0.5909
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.29, 2.03)
p-value			0.5950

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Mucosal inflammation			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	9 (3.4)	
Unstratified log-rank test			
Normal score[b]			-8.23
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-8.22
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.7	0.1, 3.5	
Unstratified hazard ratio[e]			0.20
(95% CI)			(0.08, 0.47)
p-value			0.0003
Stratified hazard ratio[c,e]			0.19
(95% CI)			(0.08, 0.47)
p-value			0.0003

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Hepatobiliary disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	30 (11.2)	
Unstratified log-rank test			
Normal score[b]			-3.57
p-value			0.2158
Stratified log-rank test[c]			
Normal score[b]			-3.46
p-value			0.2305

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.2	0.0, 3.0	
Unstratified hazard ratio[e]			0.67
(95% CI)			(0.36, 1.26)
p-value			0.2184
Stratified hazard ratio[c,e]			0.68
(95% CI)			(0.36, 1.28)
p-value			0.2334

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	63 (23.6)	
Unstratified log-rank test			
Normal score[b]			12.58
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			12.30
p-value			0.0003

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(7.74, NE)	
Q1, Q3	NE, NE	3.02, NE	
Min, Max	0.2, 1.1	0.0, 8.3	
Unstratified hazard ratio[e]			5.49
(95% CI)			(1.99, 15.17)
p-value			0.0010
Stratified hazard ratio[c,e]			5.38
(95% CI)			(1.95, 14.86)
p-value			0.0012

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Cytokine release syndrome			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	38 (14.2)	
Unstratified log-rank test			
Normal score[b]			11.18
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			10.98
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 1.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypogammaglobulinaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			1.09
p-value			0.3970
Stratified log-rank test[c]			
Normal score[b]			0.99
p-value			0.4266

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 0.2	0.6, 8.3	
Unstratified hazard ratio[e]			2.38
(95% CI)			(0.30, 18.84)
p-value			0.4111
Stratified hazard ratio[c,e]			2.28
(95% CI)			(0.28, 18.32)
p-value			0.4391

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	79 (72.5)	171 (64.0)	
Unstratified log-rank test			
Normal score[b]			-29.98
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-30.29
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.49	1.31	
95% CI (median)	(0.39, 0.62)	(1.05, 1.90)	
Q1, Q3	0.30, 1.51	0.39, 4.69	
Min, Max	0.0, 2.1	0.0, 8.1	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.38, 0.66)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.37, 0.65)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Upper respiratory tract infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			1.76
p-value			0.2284
Stratified log-rank test[c]			
Normal score[b]			1.74
p-value			0.2258

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.4, 0.4	0.3, 7.6	
Unstratified hazard ratio[e]			3.29
(95% CI)			(0.42, 25.52)
p-value			0.2550
Stratified hazard ratio[c,e]			3.33
(95% CI)			(0.42, 26.16)
p-value			0.2524

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Device related infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-1.78
p-value			0.3117
Stratified log-rank test[c]			
Normal score[b]			-1.71
p-value			0.3326

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.7	0.2, 7.6	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.22, 1.64)
p-value			0.3164
Stratified hazard ratio[c,e]			0.61
(95% CI)			(0.22, 1.68)
p-value			0.3369

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pneumonia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-9.20
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-9.15
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.8	0.0, 8.3	
Unstratified hazard ratio[e]			0.22
(95% CI)			(0.10, 0.48)
p-value			0.0001
Stratified hazard ratio[c,e]			0.22
(95% CI)			(0.10, 0.49)
p-value			0.0002

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Oral herpes			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-3.53
p-value			0.0772
Stratified log-rank test[c]			
Normal score[b]			-3.54
p-value			0.0755

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 0.6	0.1, 4.7	
Unstratified hazard ratio[e]			0.47
(95% CI)			(0.20, 1.11)
p-value			0.0837
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.19, 1.11)
p-value			0.0827

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sepsis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-3.42
p-value			0.0660
Stratified log-rank test[c]			
Normal score[b]			-3.25
p-value			0.0832

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.1, 8.1	
Unstratified hazard ratio[e]			0.44
(95% CI)			(0.18, 1.08)
p-value			0.0733
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.18, 1.14)
p-value			0.0915

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Nasopharyngitis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			1.27
p-value			0.2049
Stratified log-rank test[c]			
Normal score[b]			1.31
p-value			0.1971

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.1, 9.2	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Urinary tract infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			0.83
p-value			0.5668
Stratified log-rank test[c]			
Normal score[b]			0.88
p-value			0.5349

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.0	0.1, 6.7	
Unstratified hazard ratio[e]			1.56
(95% CI)			(0.34, 7.26)
p-value			0.5692
Stratified hazard ratio[c,e]			1.63
(95% CI)			(0.34, 7.75)
p-value			0.5374

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Injury, poisoning and procedural complications			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	38 (14.2)	
Unstratified log-rank test			
Normal score[b]			0.73
p-value			0.7940
Stratified log-rank test[c]			
Normal score[b]			1.34
p-value			0.6407

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 2.7	0.0, 5.9	
Unstratified hazard ratio[e]			1.10
(95% CI)			(0.54, 2.24)
p-value			0.7941
Stratified hazard ratio[c,e]			1.18
(95% CI)			(0.58, 2.41)
p-value			0.6411

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Investigations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	40 (36.7)	111 (41.6)	
Unstratified log-rank test			
Normal score[b]			0.41
p-value			0.9382
Stratified log-rank test[c]			
Normal score[b]			1.21
p-value			0.8193

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	5.31	
95% CI (median)	(1.41, NE)	(2.85, NE)	
Q1, Q3	0.26, NE	0.26, NE	
Min, Max	0.0, 1.6	0.0, 5.7	
Unstratified hazard ratio[e]			1.02
(95% CI)			(0.71, 1.46)
p-value			0.9307
Stratified hazard ratio[c,e]			1.05
(95% CI)			(0.73, 1.51)
p-value			0.7992

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Alanine aminotransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	24 (9.0)	
Unstratified log-rank test			
Normal score[b]			-1.39
p-value			0.5947
Stratified log-rank test[c]			
Normal score[b]			-1.75
p-value			0.4959

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 3.0	0.0, 1.5	
Unstratified hazard ratio[e]			0.82
(95% CI)			(0.40, 1.69)
p-value			0.5972
Stratified hazard ratio[c,e]			0.78
(95% CI)			(0.38, 1.61)
p-value			0.5082

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Platelet count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			-5.46
p-value			0.0192
Stratified log-rank test[c]			
Normal score[b]			-5.25
p-value			0.0250

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.2	0.0, 6.7	
Unstratified hazard ratio[e]			0.42
(95% CI)			(0.20, 0.89)
p-value			0.0230
Stratified hazard ratio[c,e]			0.43
(95% CI)			(0.20, 0.92)
p-value			0.0293

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Aspartate aminotransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-3.09
p-value			0.1630
Stratified log-rank test[c]			
Normal score[b]			-3.45
p-value			0.1119

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 3.0	0.1, 0.7	
Unstratified hazard ratio[e]			0.57
(95% CI)			(0.25, 1.27)
p-value			0.1705
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.24, 1.19)
p-value			0.1235

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: White blood cell count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-0.92
p-value			0.6303
Stratified log-rank test[c]			
Normal score[b]			-0.76
p-value			0.6906

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 5.7	
Unstratified hazard ratio[e]			0.79
(95% CI)			(0.30, 2.09)
p-value			0.6351
Stratified hazard ratio[c,e]			0.82
(95% CI)			(0.31, 2.19)
p-value			0.6959

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Gamma-glutamyltransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			0.50
p-value			0.7809
Stratified log-rank test[c]			
Normal score[b]			0.20
p-value			0.9094

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 1.5	
Unstratified hazard ratio[e]			1.17
(95% CI)			(0.38, 3.64)
p-value			0.7819
Stratified hazard ratio[c,e]			1.07
(95% CI)			(0.34, 3.33)
p-value			0.9106

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Blood bilirubin increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-3.78
p-value			0.0519
Stratified log-rank test[c]			
Normal score[b]			-3.67
p-value			0.0609

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.3	0.1, 3.0	
Unstratified hazard ratio[e]			0.42
(95% CI)			(0.17, 1.03)
p-value			0.0592
Stratified hazard ratio[c,e]			0.44
(95% CI)			(0.18, 1.06)
p-value			0.0682

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutrophil count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-5.85
p-value			0.0025
Stratified log-rank test[c]			
Normal score[b]			-5.74
p-value			0.0032

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 5.5	
Unstratified hazard ratio[e]			0.27
(95% CI)			(0.11, 0.67)
p-value			0.0047
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.12, 0.69)
p-value			0.0056

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Transaminases increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			2.62
p-value			0.0539
Stratified log-rank test[c]			
Normal score[b]			2.74
p-value			0.0458

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[a] Events are first onset of treatment emergent adverse event.
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[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.1, 5.7	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	57 (52.3)	113 (42.3)	
Unstratified log-rank test			
Normal score[b]			-13.50
p-value			0.0142
Stratified log-rank test[c]			
Normal score[b]			-12.64
p-value			0.0218

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.82	NE	
95% CI (median)	(0.49, 2.82)	(1.90, NE)	
Q1, Q3	0.23, NE	0.20, NE	
Min, Max	0.0, 2.8	0.0, 6.5	
Unstratified hazard ratio[e]			0.67
(95% CI)			(0.49, 0.93)
p-value			0.0151
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.50, 0.95)
p-value			0.0239

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypokalaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	30 (27.5)	45 (16.9)	
Unstratified log-rank test			
Normal score[b]			-11.39
p-value			0.0019
Stratified log-rank test[c]			
Normal score[b]			-11.39
p-value			0.0018

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.75, NE	7.28, NE	
Min, Max	0.1, 1.7	0.0, 7.3	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.30, 0.77)
p-value			0.0024
Stratified hazard ratio[c,e]			0.47
(95% CI)			(0.29, 0.76)
p-value			0.0021

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypomagnesaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	18 (16.5)	29 (10.9)	
Unstratified log-rank test			
Normal score[b]			-5.93
p-value			0.0445
Stratified log-rank test[c]			
Normal score[b]			-5.93
p-value			0.0435

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 2.0	0.0, 5.5	
Unstratified hazard ratio[e]			0.55
(95% CI)			(0.30, 0.99)
p-value			0.0480
Stratified hazard ratio[c,e]			0.54
(95% CI)			(0.30, 0.99)
p-value			0.0478

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hyperglycaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			-0.93
p-value			0.6968
Stratified log-rank test[c]			
Normal score[b]			-1.04
p-value			0.6608

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 2.0	
Unstratified hazard ratio[e]			0.86
(95% CI)			(0.39, 1.88)
p-value			0.6988
Stratified hazard ratio[c,e]			0.84
(95% CI)			(0.38, 1.85)
p-value			0.6587

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Decreased appetite			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-8.46
p-value			0.0001
Stratified log-rank test[c]			
Normal score[b]			-8.07
p-value			0.0004

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	2.82, NE	NE, NE	
Min, Max	0.1, 2.8	0.0, 7.6	
Unstratified hazard ratio[e]			0.26
(95% CI)			(0.13, 0.55)
p-value			0.0004
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.14, 0.59)
p-value			0.0008

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypoalbuminaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-4.55
p-value			0.0354
Stratified log-rank test[c]			
Normal score[b]			-4.77
p-value			0.0249

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.8	0.0, 1.4	
Unstratified hazard ratio[e]			0.43
(95% CI)			(0.19, 0.96)
p-value			0.0407
Stratified hazard ratio[c,e]			0.40
(95% CI)			(0.18, 0.92)
p-value			0.0298

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypophosphataemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-1.12
p-value			0.5478
Stratified log-rank test[c]			
Normal score[b]			-1.23
p-value			0.5096

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.6	0.0, 4.9	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.28, 1.99)
p-value			0.5499
Stratified hazard ratio[c,e]			0.72
(95% CI)			(0.27, 1.93)
p-value			0.5114

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypocalcaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-4.00
p-value			0.0349
Stratified log-rank test[c]			
Normal score[b]			-3.82
p-value			0.0453

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.2	0.1, 6.5	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.15, 0.97)
p-value			0.0423
Stratified hazard ratio[c,e]			0.40
(95% CI)			(0.16, 1.01)
p-value			0.0530

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Tumour lysis syndrome			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			1.75
p-value			0.2142
Stratified log-rank test[c]			
Normal score[b]			1.71
p-value			0.2200

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.87, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 13.9	
Unstratified hazard ratio[e]			3.42
(95% CI)			(0.43, 27.05)
p-value			0.2434
Stratified hazard ratio[c,e]			3.39
(95% CI)			(0.43, 26.90)
p-value			0.2484

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Musculoskeletal and connective tissue disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	37 (33.9)	110 (41.2)	
Unstratified log-rank test			
Normal score[b]			-2.22
p-value			0.6590
Stratified log-rank test[c]			
Normal score[b]			-1.41
p-value			0.7778

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	3.84	
95% CI (median)	(1.54, NE)	(2.92, 8.23)	
Q1, Q3	0.66, NE	0.75, NE	
Min, Max	0.0, 1.7	0.0, 8.2	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.63, 1.34)
p-value			0.6563
Stratified hazard ratio[c,e]			0.94
(95% CI)			(0.64, 1.38)
p-value			0.7597

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Back pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	35 (13.1)	
Unstratified log-rank test			
Normal score[b]			-0.70
p-value			0.7920
Stratified log-rank test[c]			
Normal score[b]			-0.50
p-value			0.8491

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	8.49, NE	
Min, Max	0.0, 1.5	0.1, 8.5	
Unstratified hazard ratio[e]			0.91
(95% CI)			(0.44, 1.87)
p-value			0.7919
Stratified hazard ratio[c,e]			0.93
(95% CI)			(0.45, 1.93)
p-value			0.8450

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Bone pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	30 (11.2)	
Unstratified log-rank test			
Normal score[b]			0.55
p-value			0.8264
Stratified log-rank test[c]			
Normal score[b]			0.70
p-value			0.7800

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.9	0.0, 8.6	
Unstratified hazard ratio[e]			1.09
(95% CI)			(0.49, 2.44)
p-value			0.8249
Stratified hazard ratio[c,e]			1.12
(95% CI)			(0.50, 2.51)
p-value			0.7774

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pain in extremity			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	25 (9.4)	
Unstratified log-rank test			
Normal score[b]			-1.07
p-value			0.6366
Stratified log-rank test[c]			
Normal score[b]			-0.83
p-value			0.7151

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.6	0.0, 10.2	
Unstratified hazard ratio[e]			0.82
(95% CI)			(0.36, 1.88)
p-value			0.6383
Stratified hazard ratio[c,e]			0.86
(95% CI)			(0.37, 1.97)
p-value			0.7172

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Myalgia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			-0.20
p-value			0.9227
Stratified log-rank test[c]			
Normal score[b]			-0.34
p-value			0.8677

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.3	0.1, 5.9	
Unstratified hazard ratio[e]			0.95
(95% CI)			(0.37, 2.45)
p-value			0.9219
Stratified hazard ratio[c,e]			0.92
(95% CI)			(0.36, 2.39)
p-value			0.8667

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Arthralgia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-0.98
p-value			0.5677
Stratified log-rank test[c]			
Normal score[b]			-1.07
p-value			0.5277

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.2, 8.0	
Unstratified hazard ratio[e]			0.73
(95% CI)			(0.25, 2.14)
p-value			0.5691
Stratified hazard ratio[c,e]			0.71
(95% CI)			(0.24, 2.09)
p-value			0.5296

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Muscle spasms			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	3 (2.8)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-0.16
p-value			0.9132
Stratified log-rank test[c]			
Normal score[b]			-0.21
p-value			0.8819

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 2.7	0.1, 9.9	
Unstratified hazard ratio[e]			0.93
(95% CI)			(0.24, 3.55)
p-value			0.9132
Stratified hazard ratio[c,e]			0.90
(95% CI)			(0.24, 3.47)
p-value			0.8820

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Musculoskeletal pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	3 (2.8)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-0.18
p-value			0.9028
Stratified log-rank test[c]			
Normal score[b]			-0.65
p-value			0.6193

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.18, NE)	
Q1, Q3	NE, NE	13.18, NE	
Min, Max	0.0, 0.1	0.1, 13.2	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.24, 3.50)
p-value			0.9025
Stratified hazard ratio[c,e]			0.70
(95% CI)			(0.18, 2.83)
p-value			0.6209

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	44 (40.4)	140 (52.4)	
Unstratified log-rank test			
Normal score[b]			6.81
p-value			0.2515
Stratified log-rank test[c]			
Normal score[b]			6.13
p-value			0.2984

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	1.54	
95% CI (median)	(1.11, NE)	(1.08, 2.85)	
Q1, Q3	0.39, NE	0.30, NE	
Min, Max	0.0, 1.6	0.0, 6.2	
Unstratified hazard ratio[e]			1.22
(95% CI)			(0.87, 1.72)
p-value			0.2492
Stratified hazard ratio[c,e]			1.20
(95% CI)			(0.85, 1.69)
p-value			0.2927

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Headache			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	31 (28.4)	77 (28.8)	
Unstratified log-rank test			
Normal score[b]			-3.66
p-value			0.4070
Stratified log-rank test[c]			
Normal score[b]			-3.93
p-value			0.3690

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(6.66, NE)	
Q1, Q3	0.75, NE	1.44, NE	
Min, Max	0.0, 1.3	0.0, 7.9	
Unstratified hazard ratio[e]			0.84
(95% CI)			(0.55, 1.28)
p-value			0.4111
Stratified hazard ratio[c,e]			0.82
(95% CI)			(0.54, 1.26)
p-value			0.3697

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Tremor			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	26 (9.7)	
Unstratified log-rank test			
Normal score[b]			7.35
p-value			0.0013
Stratified log-rank test[c]			
Normal score[b]			7.44
p-value			0.0011

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 3.8	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Dizziness			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-1.60
p-value			0.4557
Stratified log-rank test[c]			
Normal score[b]			-1.32
p-value			0.5421

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 8.3	
Unstratified hazard ratio[e]			0.72
(95% CI)			(0.31, 1.70)
p-value			0.4576
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.32, 1.81)
p-value			0.5439

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Somnolence			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			3.00
p-value			0.0774
Stratified log-rank test[c]			
Normal score[b]			2.93
p-value			0.0820

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.5, 0.5	0.1, 2.6	
Unstratified hazard ratio[e]			5.16
(95% CI)			(0.68, 39.41)
p-value			0.1135
Stratified hazard ratio[c,e]			5.07
(95% CI)			(0.66, 38.78)
p-value			0.1178

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Paraesthesia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			2.39
p-value			0.1276
Stratified log-rank test[c]			
Normal score[b]			2.53
p-value			0.1117

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(12.39, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 0.3	0.0, 12.4	
Unstratified hazard ratio[e]			4.30
(95% CI)			(0.56, 33.21)
p-value			0.1623
Stratified hazard ratio[c,e]			4.54
(95% CI)			(0.59, 35.12)
p-value			0.1471

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Psychiatric disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	21 (19.3)	69 (25.8)	
Unstratified log-rank test			
Normal score[b]			1.75
p-value			0.6648
Stratified log-rank test[c]			
Normal score[b]			2.03
p-value			0.6117

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	2.23, NE	
Min, Max	0.0, 1.4	0.0, 6.2	
Unstratified hazard ratio[e]			1.12
(95% CI)			(0.68, 1.83)
p-value			0.6644
Stratified hazard ratio[c,e]			1.14
(95% CI)			(0.69, 1.88)
p-value			0.6181

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Insomnia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	28 (10.5)	
Unstratified log-rank test			
Normal score[b]			-0.94
p-value			0.7149
Stratified log-rank test[c]			
Normal score[b]			-1.07
p-value			0.6698

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.3	0.0, 9.7	
Unstratified hazard ratio[e]			0.87
(95% CI)			(0.42, 1.83)
p-value			0.7181
Stratified hazard ratio[c,e]			0.85
(95% CI)			(0.40, 1.80)
p-value			0.6705

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Anxiety			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-1.54
p-value			0.3939
Stratified log-rank test[c]			
Normal score[b]			-1.33
p-value			0.4652

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 5.1	
Unstratified hazard ratio[e]			0.65
(95% CI)			(0.24, 1.76)
p-value			0.3960
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.25, 1.88)
p-value			0.4675

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Renal and urinary disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	24 (22.0)	35 (13.1)	
Unstratified log-rank test			
Normal score[b]			-11.26
p-value			0.0003
Stratified log-rank test[c]			
Normal score[b]			-11.32
p-value			0.0002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.59, NE)	(NE, NE)	
Q1, Q3	1.28, NE	NE, NE	
Min, Max	0.1, 2.9	0.0, 5.3	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.22, 0.65)
p-value			0.0004
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.22, 0.65)
p-value			0.0004

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Acute kidney injury			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-3.74
p-value			0.0363
Stratified log-rank test[c]			
Normal score[b]			-3.78
p-value			0.0334

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 2.9	0.0, 3.2	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.15, 0.97)
p-value			0.0433
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.15, 0.96)
p-value			0.0401

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Reproductive system and breast disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	3 (2.8)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			0.40
p-value			0.8000
Stratified log-rank test[c]			
Normal score[b]			0.70
p-value			0.6702

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.6	0.1, 4.7	
Unstratified hazard ratio[e]			1.18
(95% CI)			(0.33, 4.28)
p-value			0.8006
Stratified hazard ratio[c,e]			1.32
(95% CI)			(0.36, 4.79)
p-value			0.6712

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	36 (33.0)	99 (37.1)	
Unstratified log-rank test			
Normal score[b]			-6.39
p-value			0.1715
Stratified log-rank test[c]			
Normal score[b]			-6.26
p-value			0.1761

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	5.25	
95% CI (median)	(2.79, NE)	(3.61, 7.15)	
Q1, Q3	0.59, NE	1.21, NE	
Min, Max	0.0, 2.8	0.0, 7.8	
Unstratified hazard ratio[e]			0.76
(95% CI)			(0.51, 1.13)
p-value			0.1723
Stratified hazard ratio[c,e]			0.76
(95% CI)			(0.51, 1.13)
p-value			0.1763

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Cough			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	39 (14.6)	
Unstratified log-rank test			
Normal score[b]			3.27
p-value			0.2119
Stratified log-rank test[c]			
Normal score[b]			3.28
p-value			0.2082

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	5.97, NE	
Min, Max	0.1, 2.0	0.0, 6.2	
Unstratified hazard ratio[e]			1.74
(95% CI)			(0.72, 4.17)
p-value			0.2179
Stratified hazard ratio[c,e]			1.75
(95% CI)			(0.72, 4.21)
p-value			0.2145

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Epistaxis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-2.52
p-value			0.2448
Stratified log-rank test[c]			
Normal score[b]			-2.32
p-value			0.2880

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 9.2	
Unstratified hazard ratio[e]			0.61
(95% CI)			(0.27, 1.41)
p-value			0.2486
Stratified hazard ratio[c,e]			0.64
(95% CI)			(0.28, 1.47)
p-value			0.2914

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Dyspnoea			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-2.20
p-value			0.2878
Stratified log-rank test[c]			
Normal score[b]			-1.98
p-value			0.3420

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.1, 3.1	
Unstratified hazard ratio[e]			0.63
(95% CI)			(0.27, 1.49)
p-value			0.2915
Stratified hazard ratio[c,e]			0.66
(95% CI)			(0.28, 1.57)
p-value			0.3454

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Oropharyngeal pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-3.74
p-value			0.0178
Stratified log-rank test[c]			
Normal score[b]			-3.88
p-value			0.0106

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 5.9	
Unstratified hazard ratio[e]			0.31
(95% CI)			(0.11, 0.86)
p-value			0.0236
Stratified hazard ratio[c,e]			0.27
(95% CI)			(0.09, 0.79)
p-value			0.0167

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Productive cough			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			0.45
p-value			0.6751
Stratified log-rank test[c]			
Normal score[b]			0.35
p-value			0.7421

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(14.23, NE)	
Q1, Q3	NE, NE	14.23, NE	
Min, Max	2.1, 2.1	0.0, 14.2	
Unstratified hazard ratio[e]			1.57
(95% CI)			(0.19, 13.10)
p-value			0.6775
Stratified hazard ratio[c,e]			1.42
(95% CI)			(0.17, 11.74)
p-value			0.7436

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Skin and subcutaneous tissue disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	41 (37.6)	89 (33.3)	
Unstratified log-rank test			
Normal score[b]			-10.80
p-value			0.0218
Stratified log-rank test[c]			
Normal score[b]			-10.94
p-value			0.0191

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	2.72	NE	
95% CI (median)	(1.25, NE)	(3.84, NE)	
Q1, Q3	0.49, NE	0.95, NE	
Min, Max	0.0, 2.7	0.0, 6.0	
Unstratified hazard ratio[e]			0.64
(95% CI)			(0.44, 0.94)
p-value			0.0226
Stratified hazard ratio[c,e]			0.64
(95% CI)			(0.43, 0.93)
p-value			0.0209

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Rash			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			-5.16
p-value			0.0315
Stratified log-rank test[c]			
Normal score[b]			-5.11
p-value			0.0316

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.7	0.1, 3.8	
Unstratified hazard ratio[e]			0.46
(95% CI)			(0.22, 0.95)
p-value			0.0357
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.22, 0.95)
p-value			0.0363

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hyperhidrosis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			1.10
p-value			0.4618
Stratified log-rank test[c]			
Normal score[b]			1.33
p-value			0.3845

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.4, 1.0	0.0, 3.7	
Unstratified hazard ratio[e]			1.76
(95% CI)			(0.38, 8.16)
p-value			0.4678
Stratified hazard ratio[c,e]			1.95
(95% CI)			(0.42, 9.01)
p-value			0.3931

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Vascular disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	28 (25.7)	62 (23.2)	
Unstratified log-rank test			
Normal score[b]			-7.14
p-value			0.0663
Stratified log-rank test[c]			
Normal score[b]			-6.90
p-value			0.0746

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	13.38	
95% CI (median)	(NE, NE)	(10.10, NE)	
Q1, Q3	1.21, NE	3.21, 13.87	
Min, Max	0.1, 1.5	0.0, 13.9	
Unstratified hazard ratio[e]			0.65
(95% CI)			(0.41, 1.03)
p-value			0.0687
Stratified hazard ratio[c,e]			0.66
(95% CI)			(0.41, 1.04)
p-value			0.0758

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypotension			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	32 (12.0)	
Unstratified log-rank test			
Normal score[b]			-1.84
p-value			0.5152
Stratified log-rank test[c]			
Normal score[b]			-1.83
p-value			0.5168

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.0, 5.5	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.42, 1.55)
p-value			0.5162
Stratified hazard ratio[c,e]			0.80
(95% CI)			(0.41, 1.56)
p-value			0.5157

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypertension			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			-3.01
p-value			0.1512
Stratified log-rank test[c]			
Normal score[b]			-2.95
p-value			0.1592

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.87, NE)	
Q1, Q3	NE, NE	13.87, NE	
Min, Max	0.1, 1.0	0.0, 13.9	
Unstratified hazard ratio[e]			0.55
(95% CI)			(0.24, 1.26)
p-value			0.1572
Stratified hazard ratio[c,e]			0.55
(95% CI)			(0.24, 1.28)
p-value			0.1647

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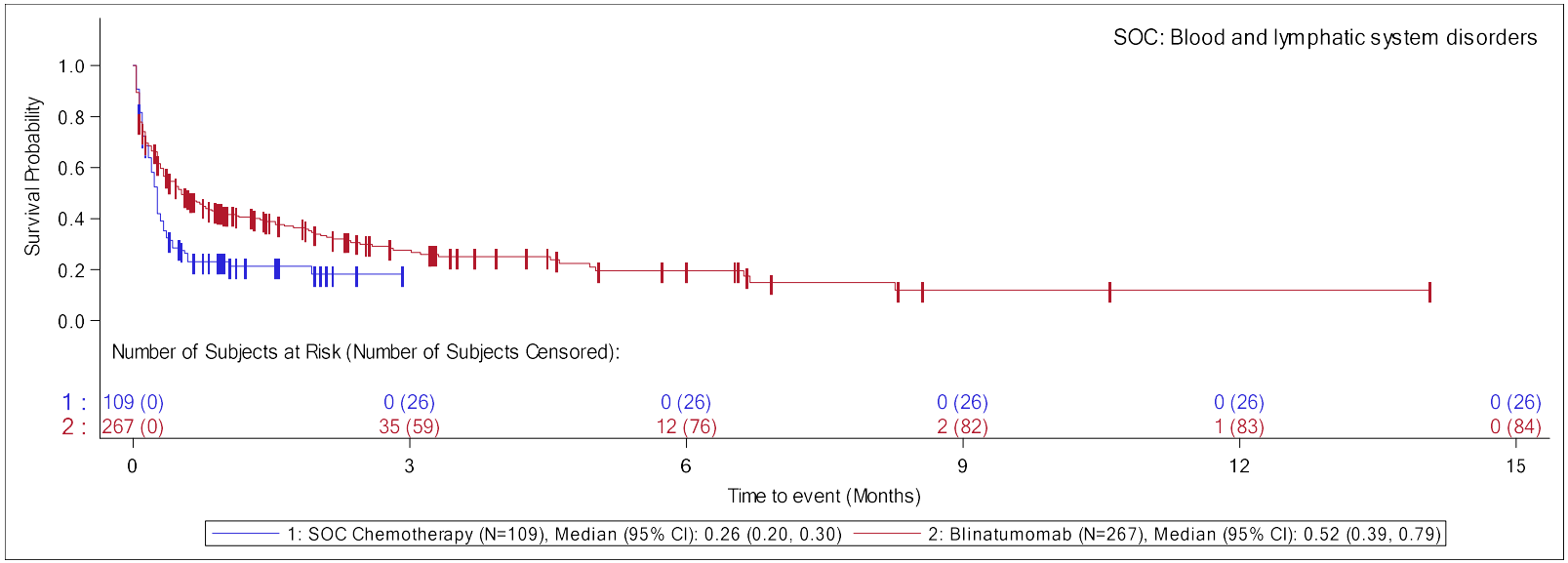
Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:54) Source data: adam_pa.adsl, adam_pa.adae

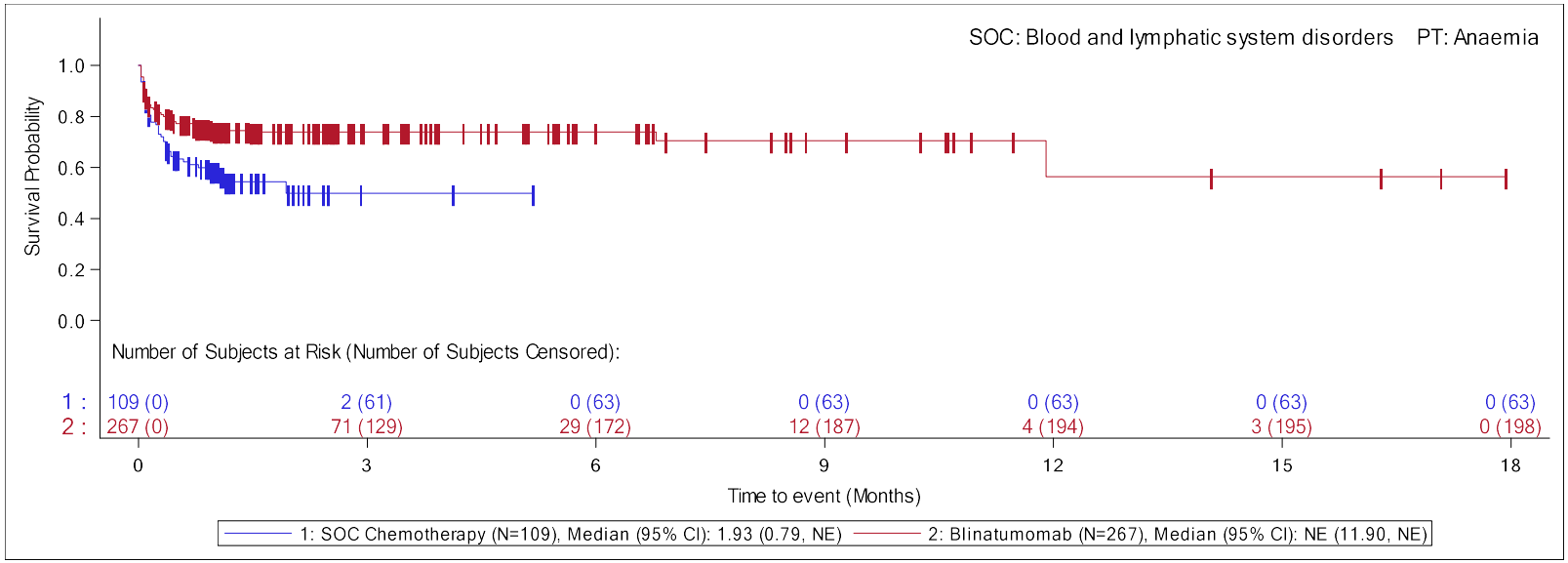
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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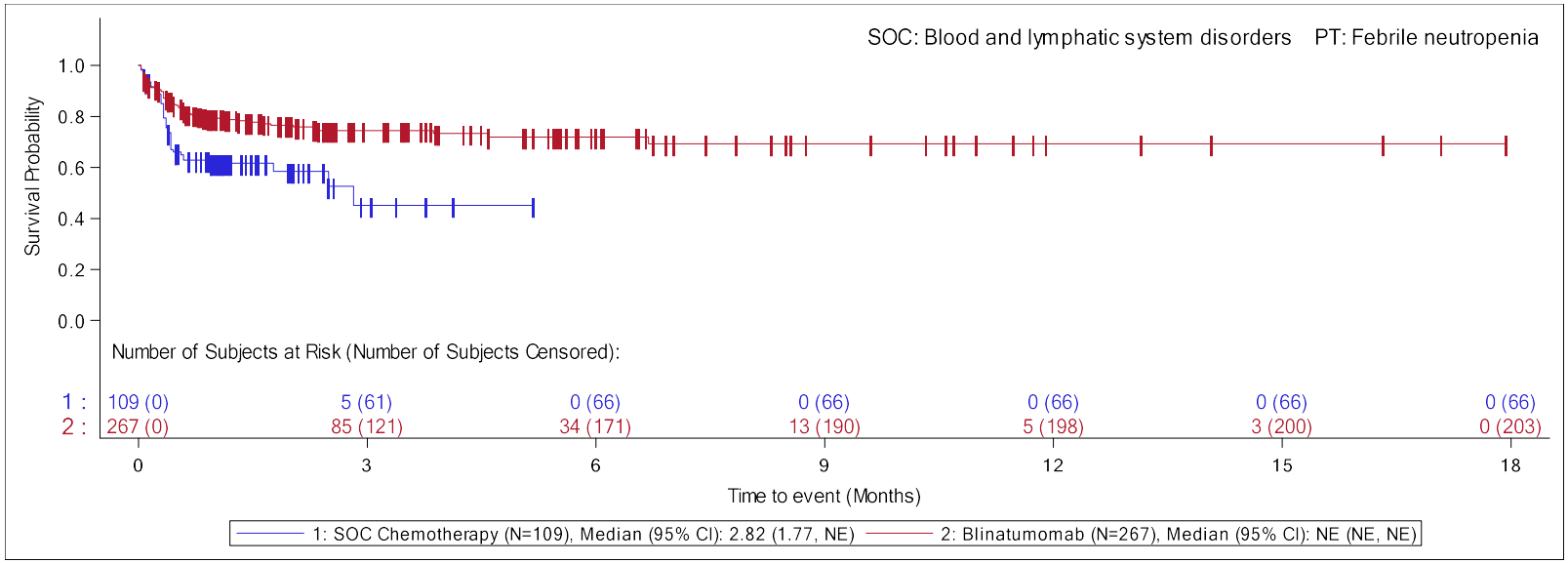

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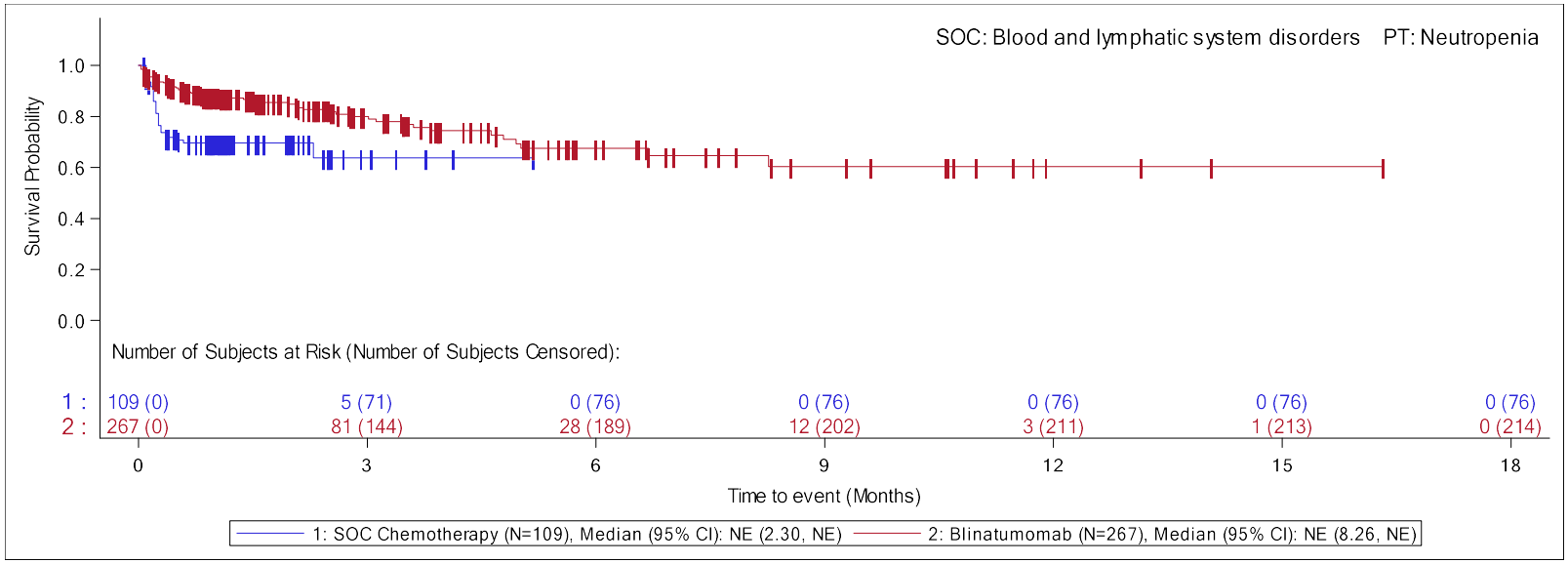

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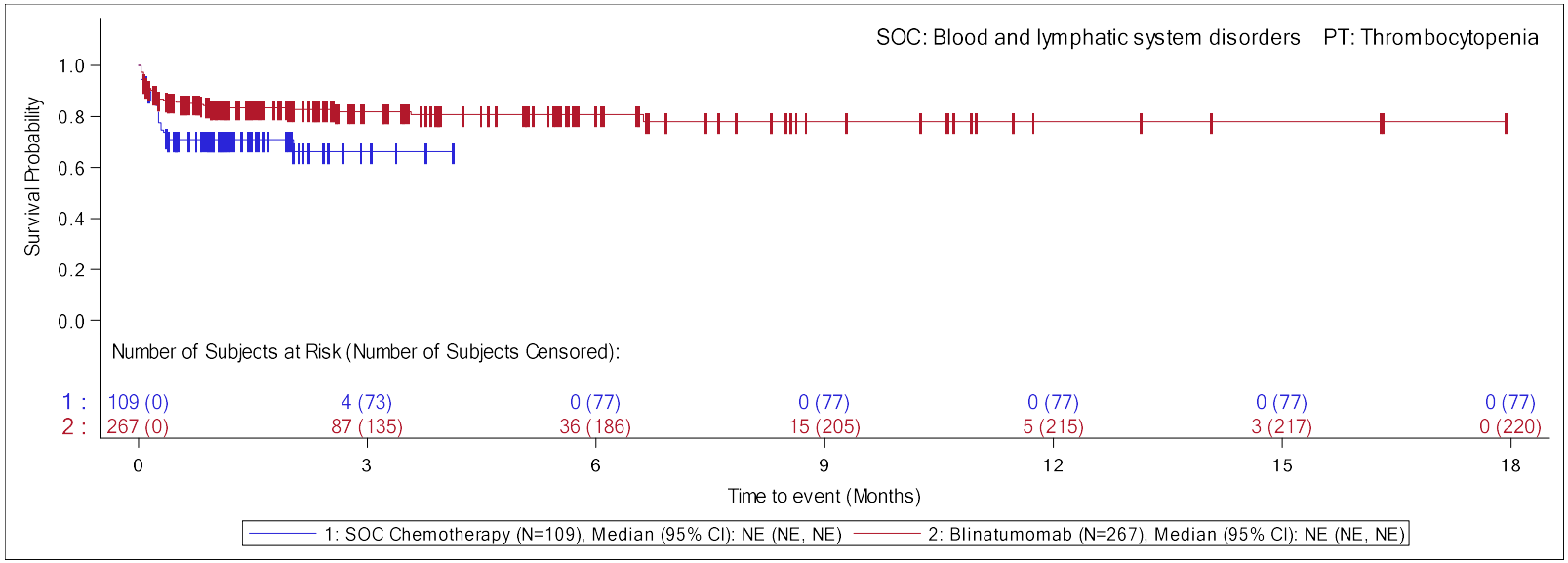

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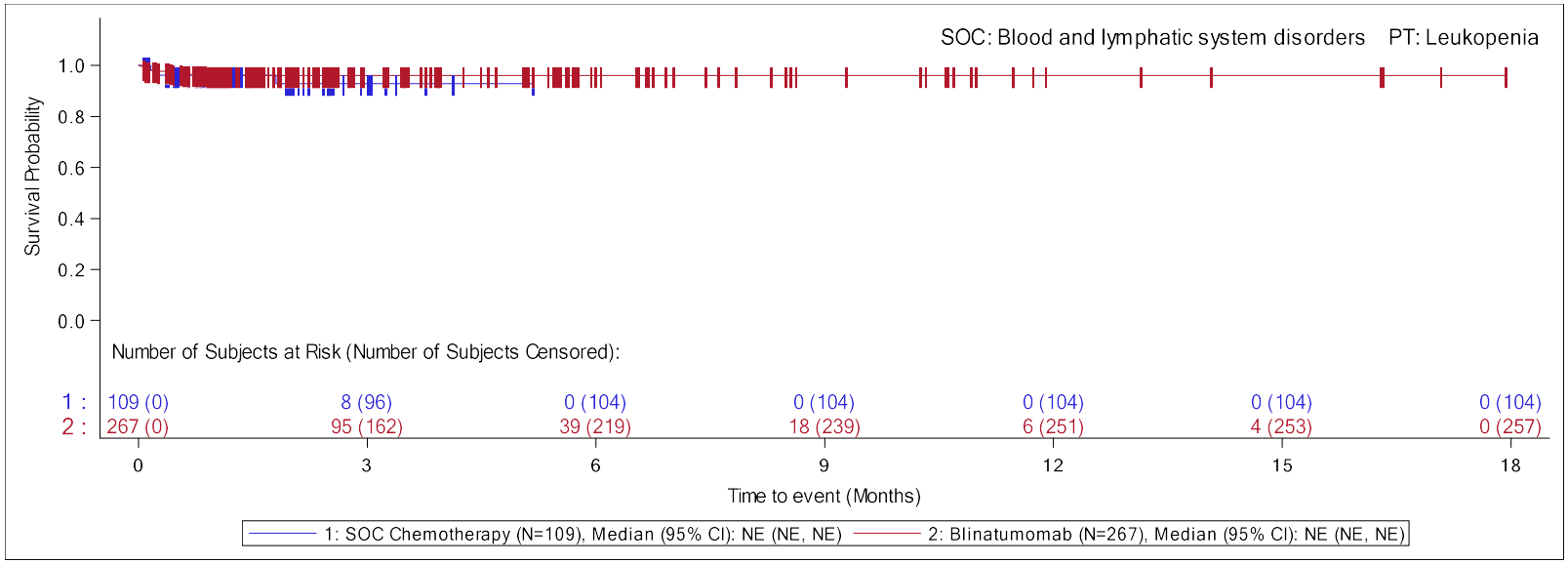

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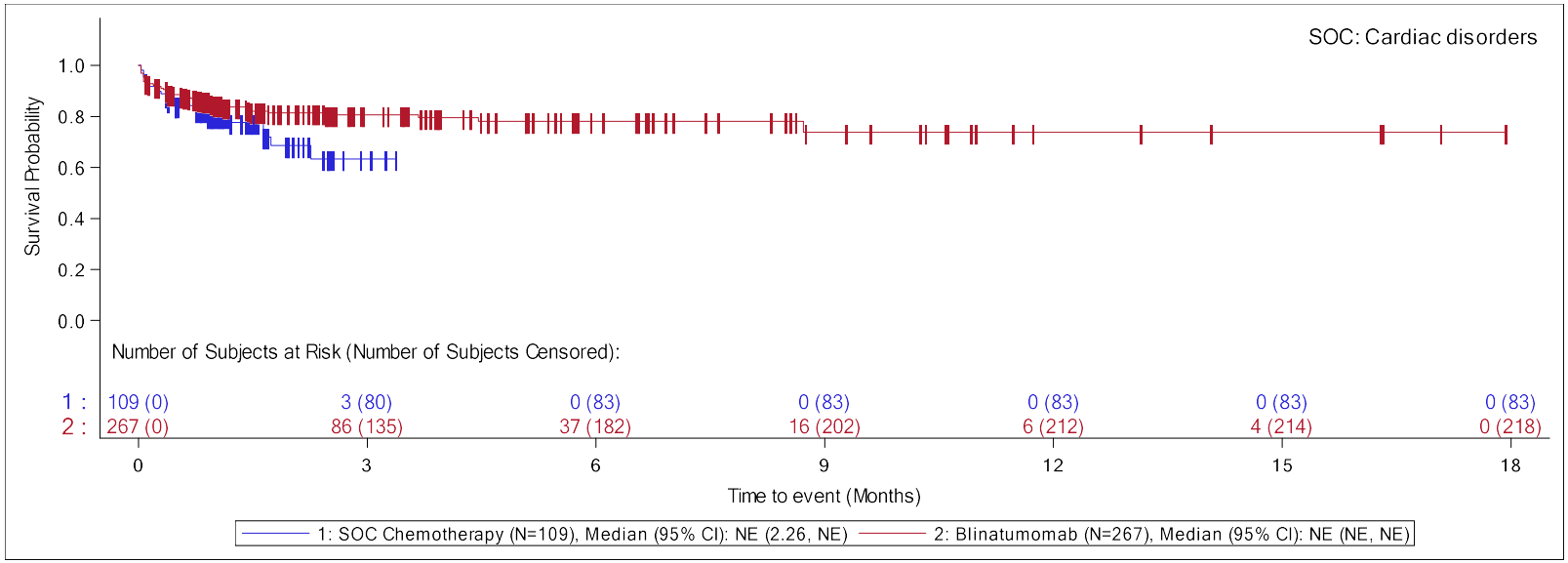

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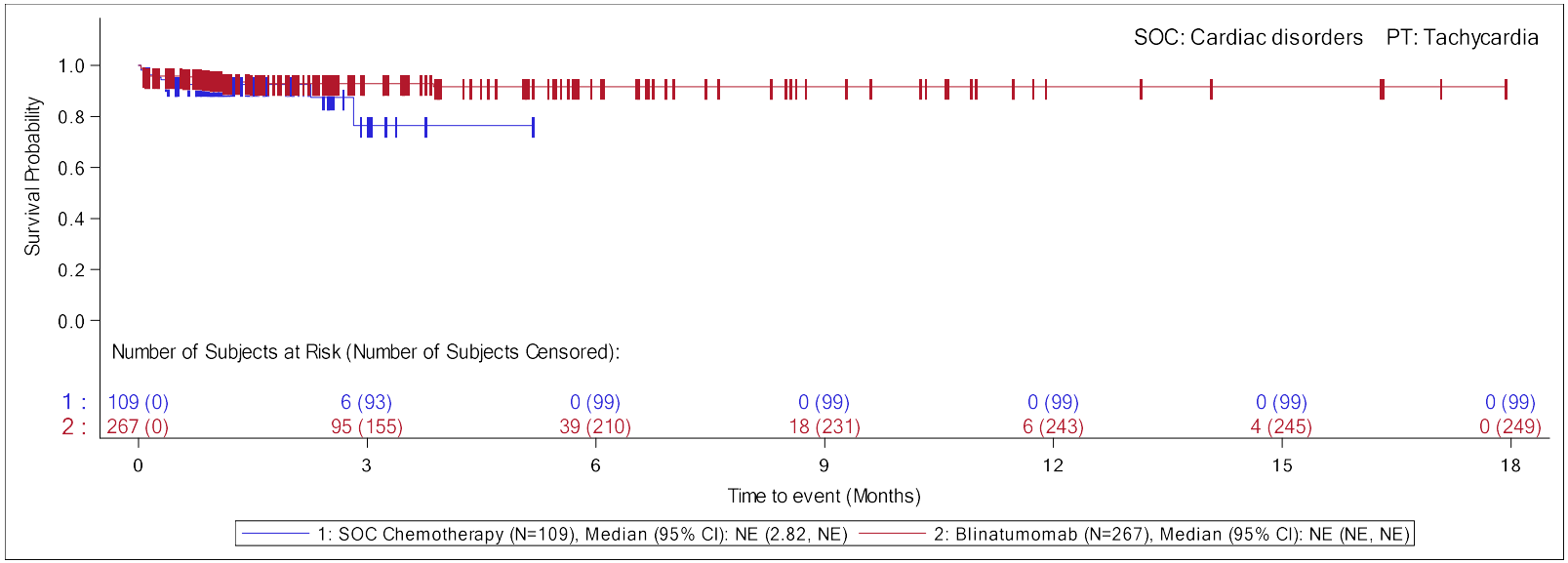

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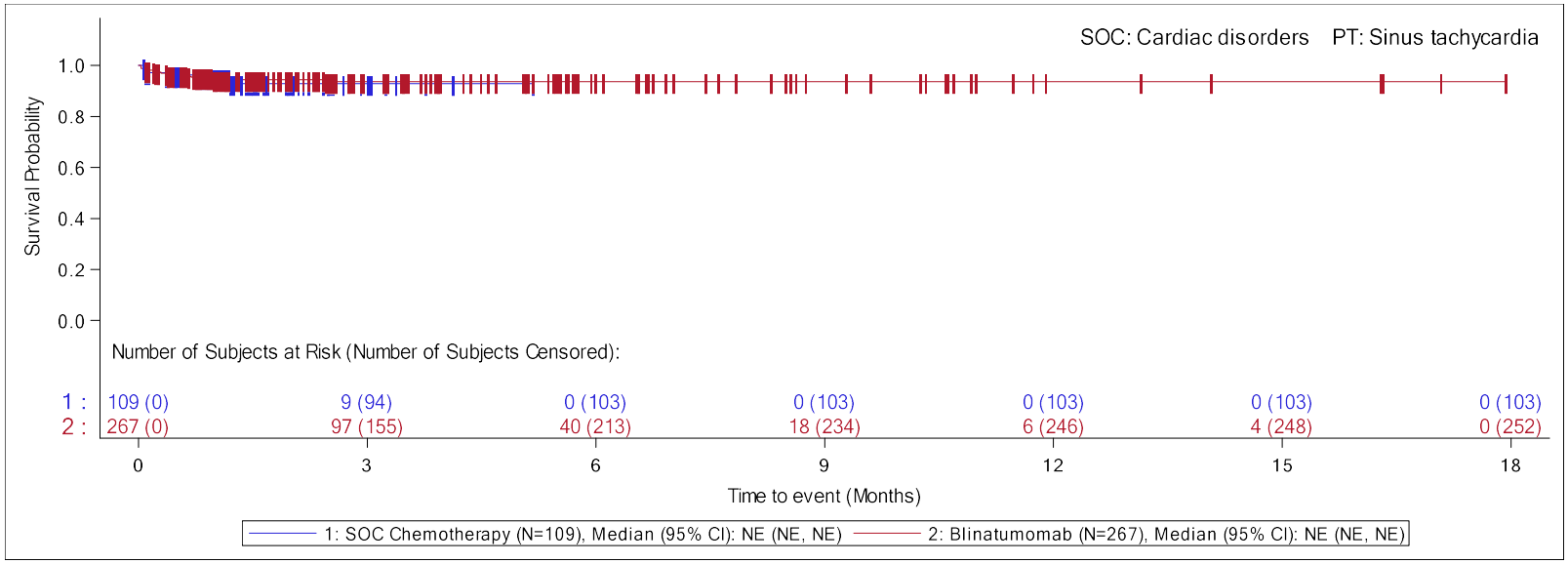

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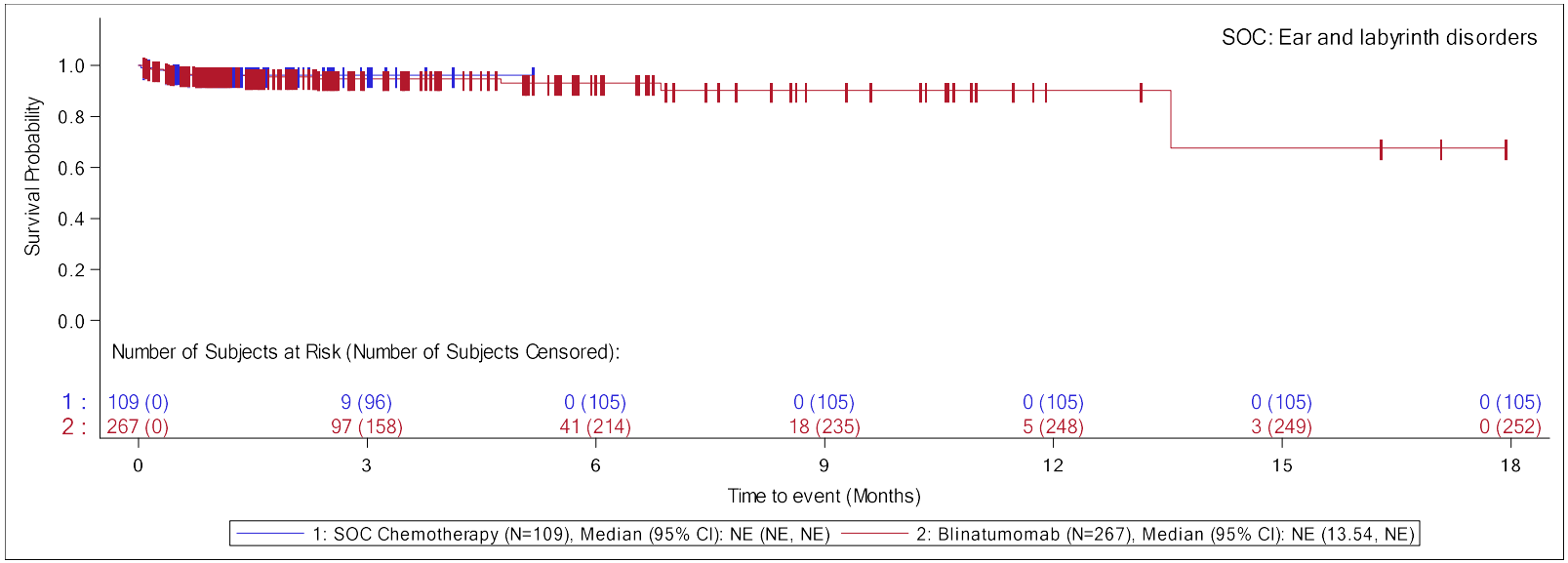

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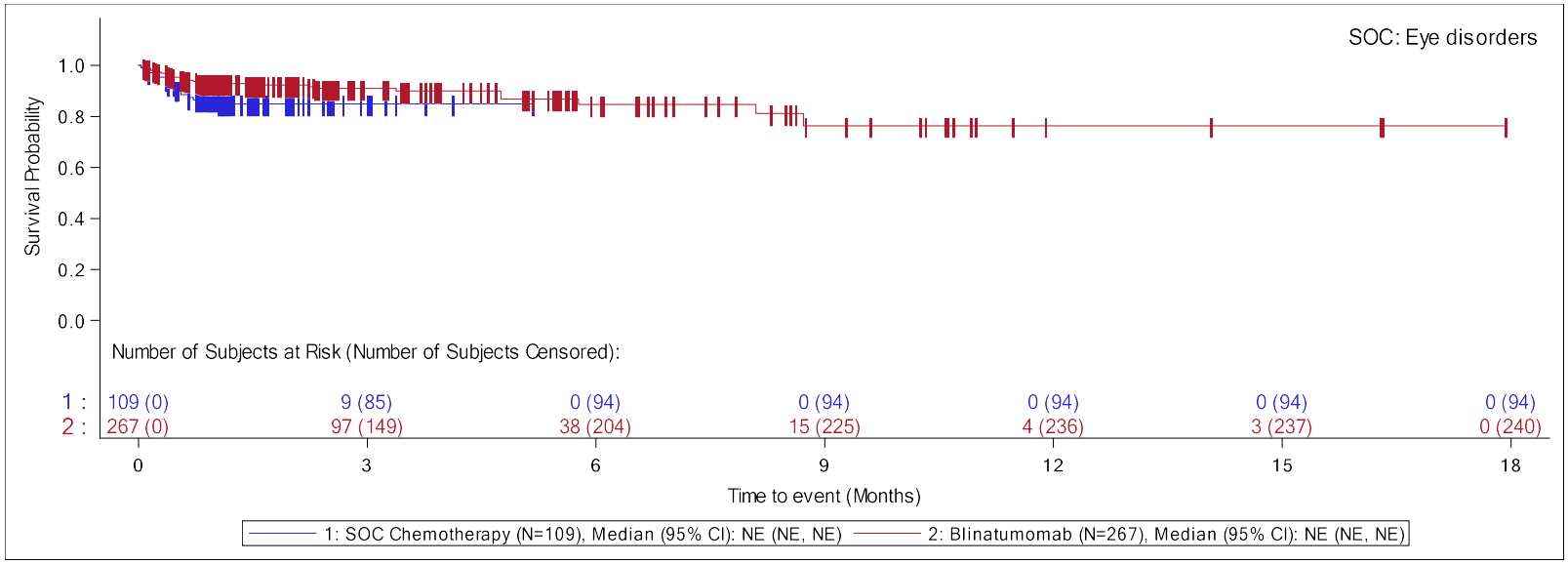

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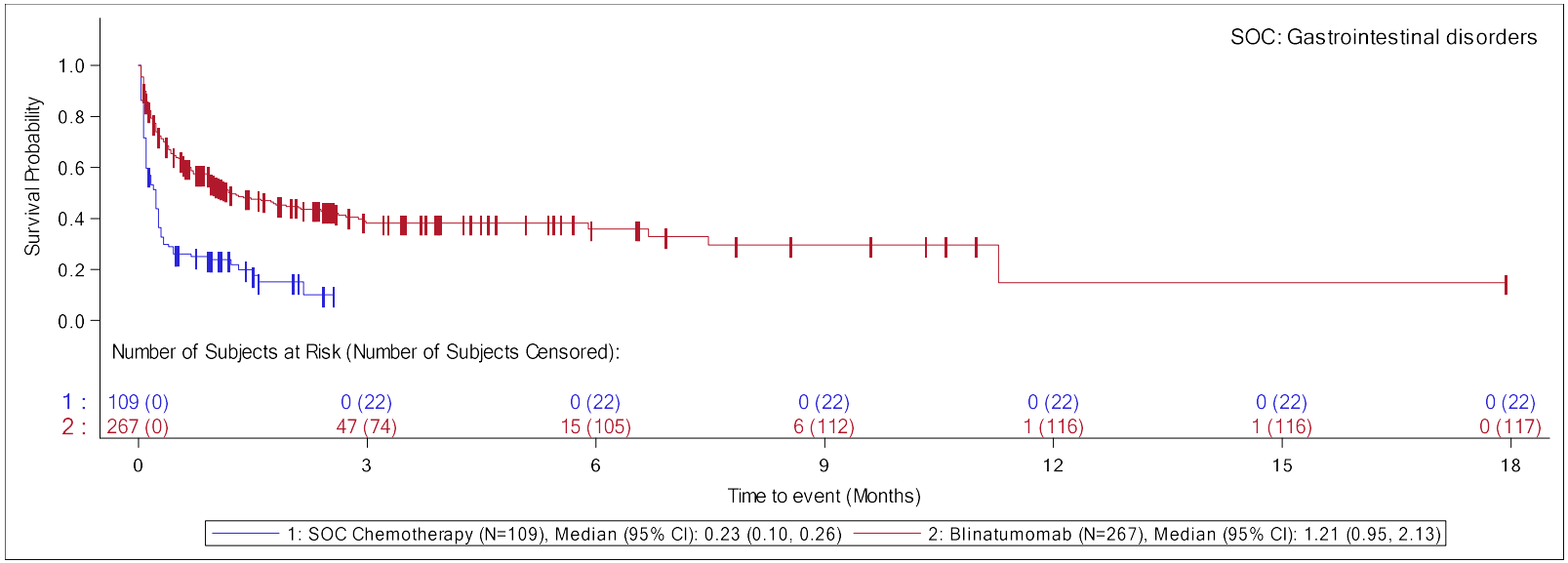

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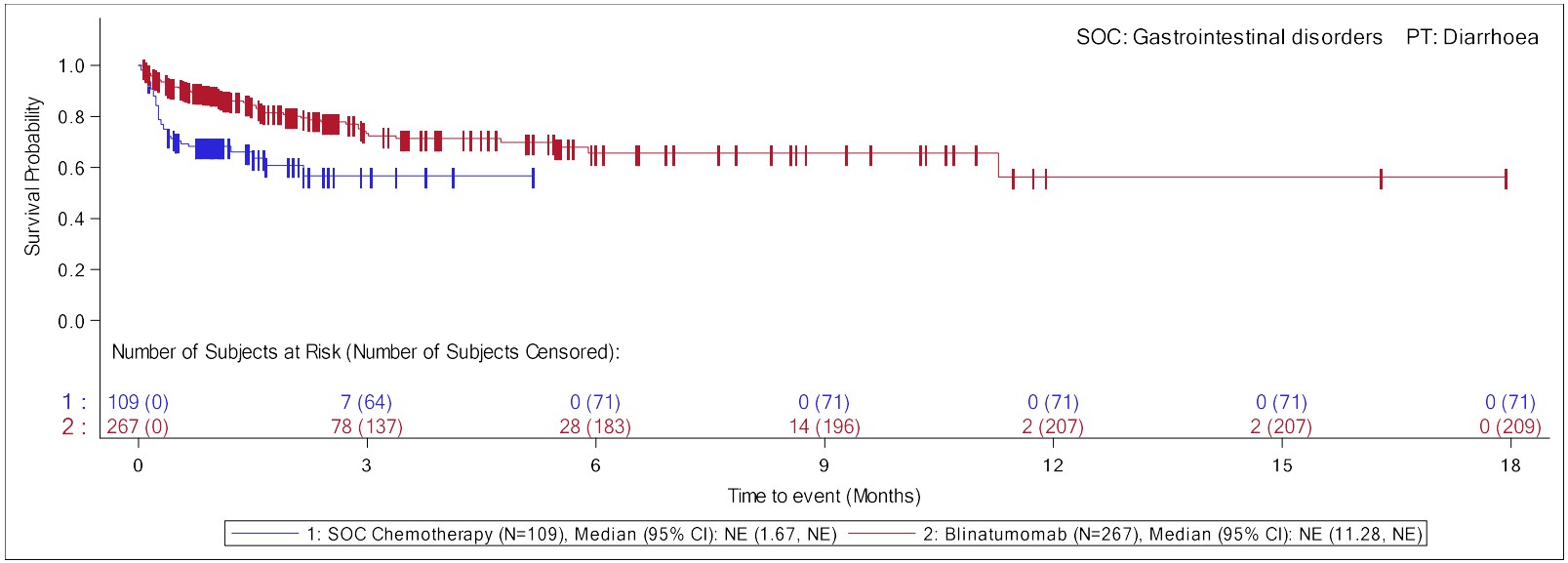

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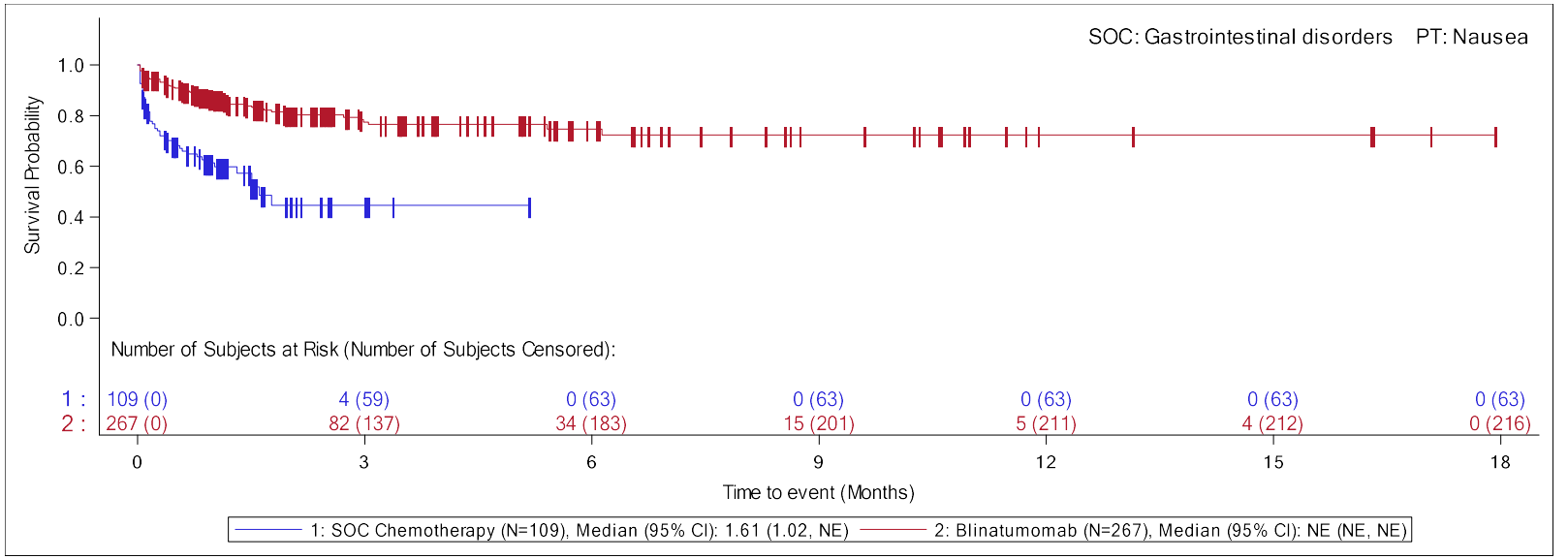

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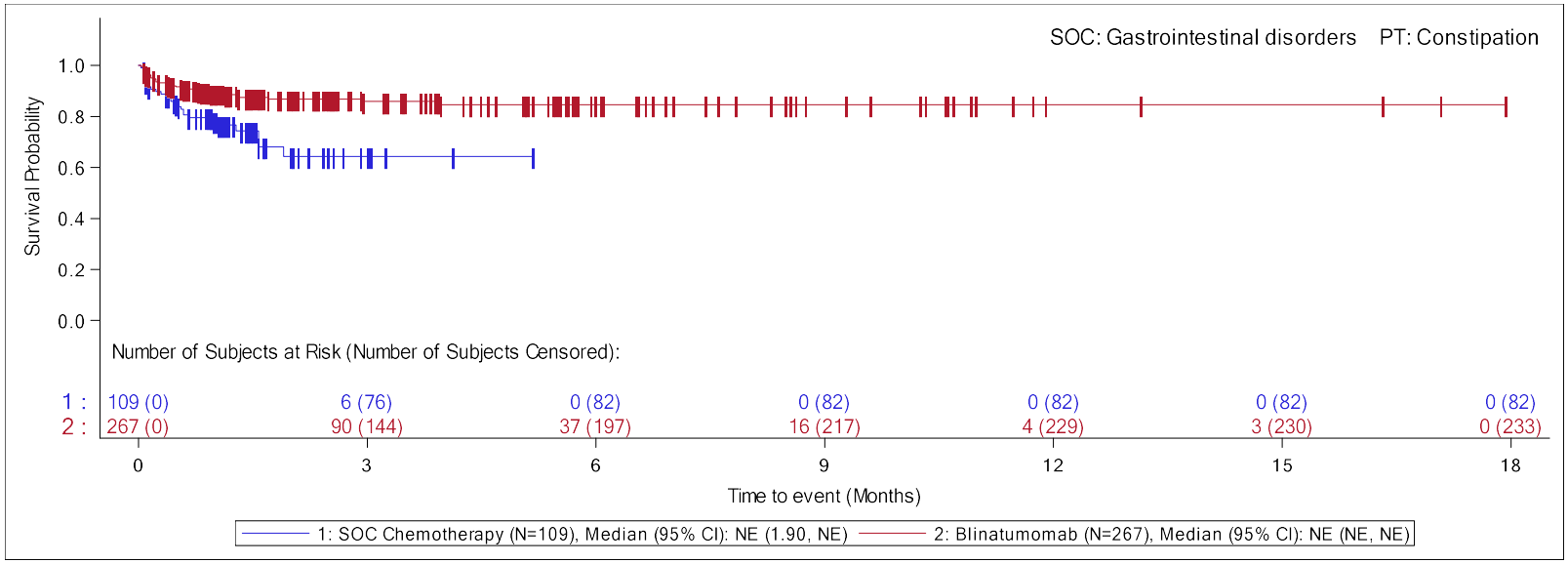

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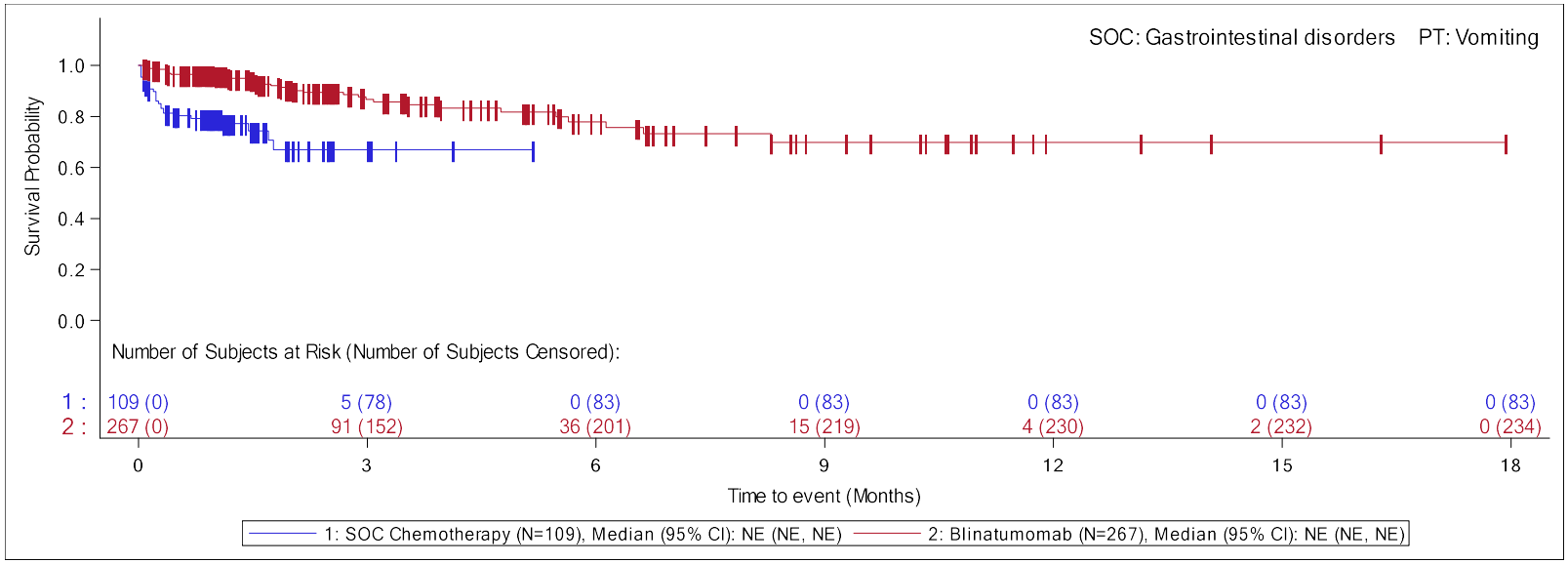

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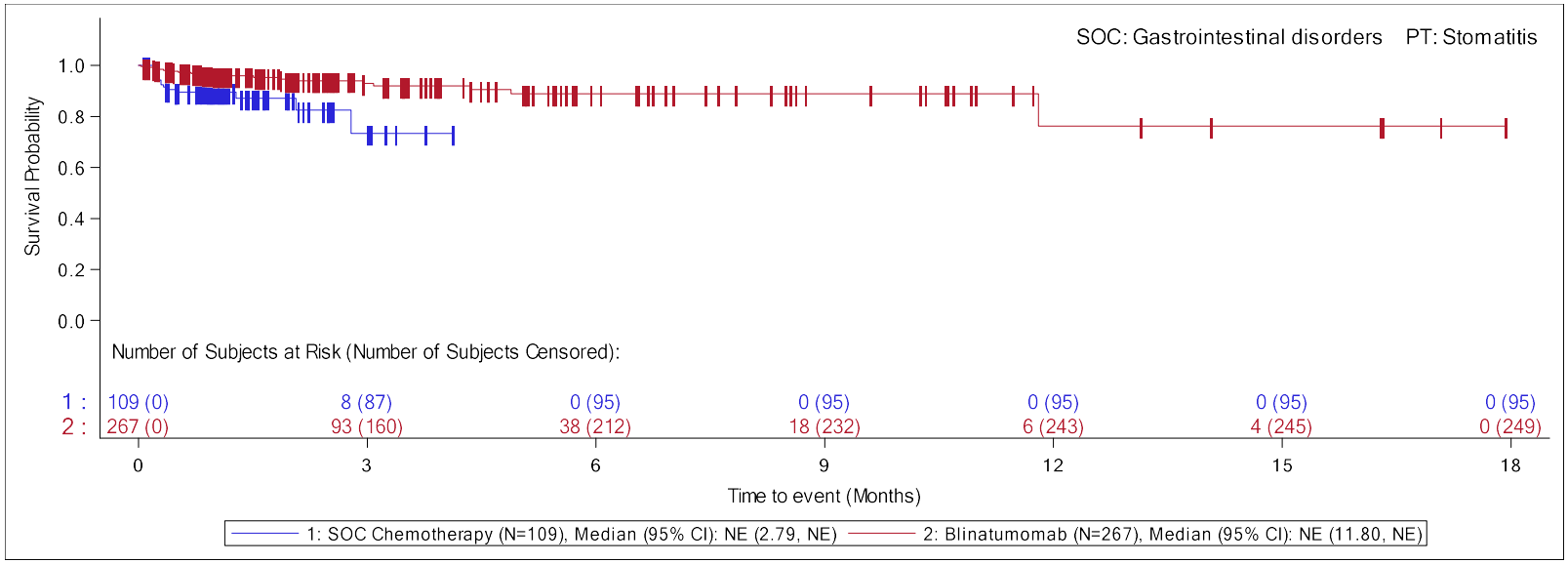

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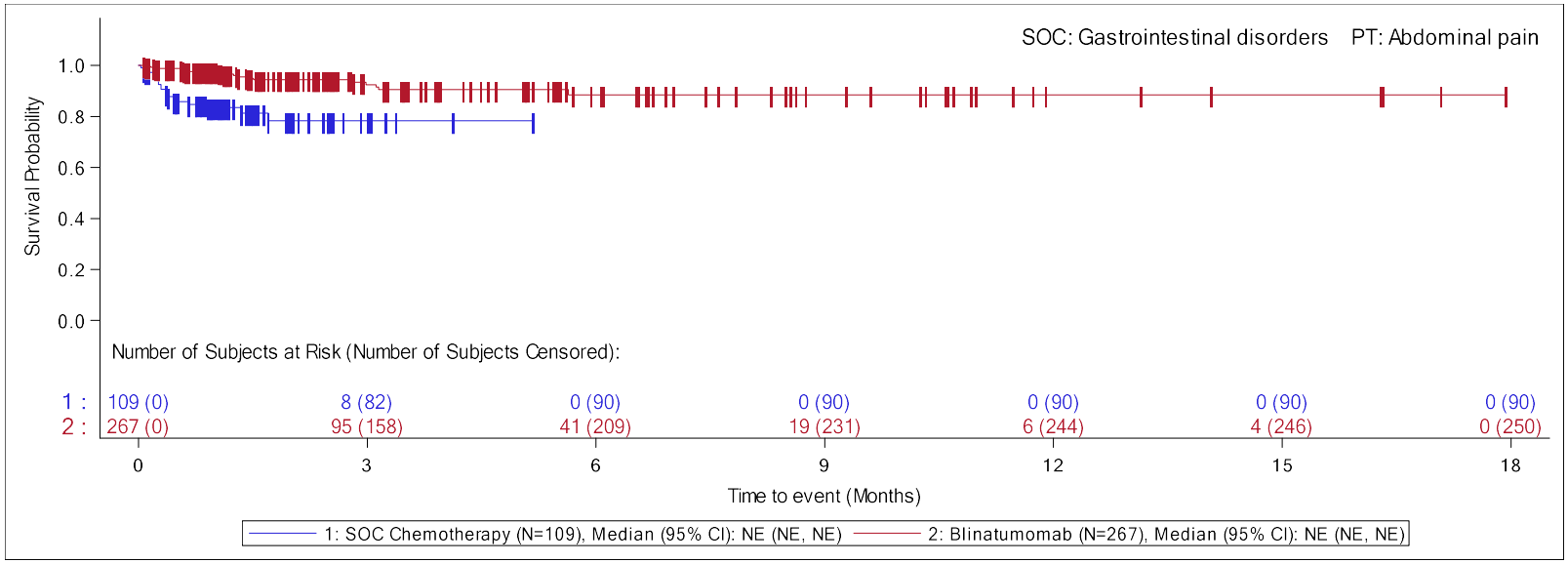

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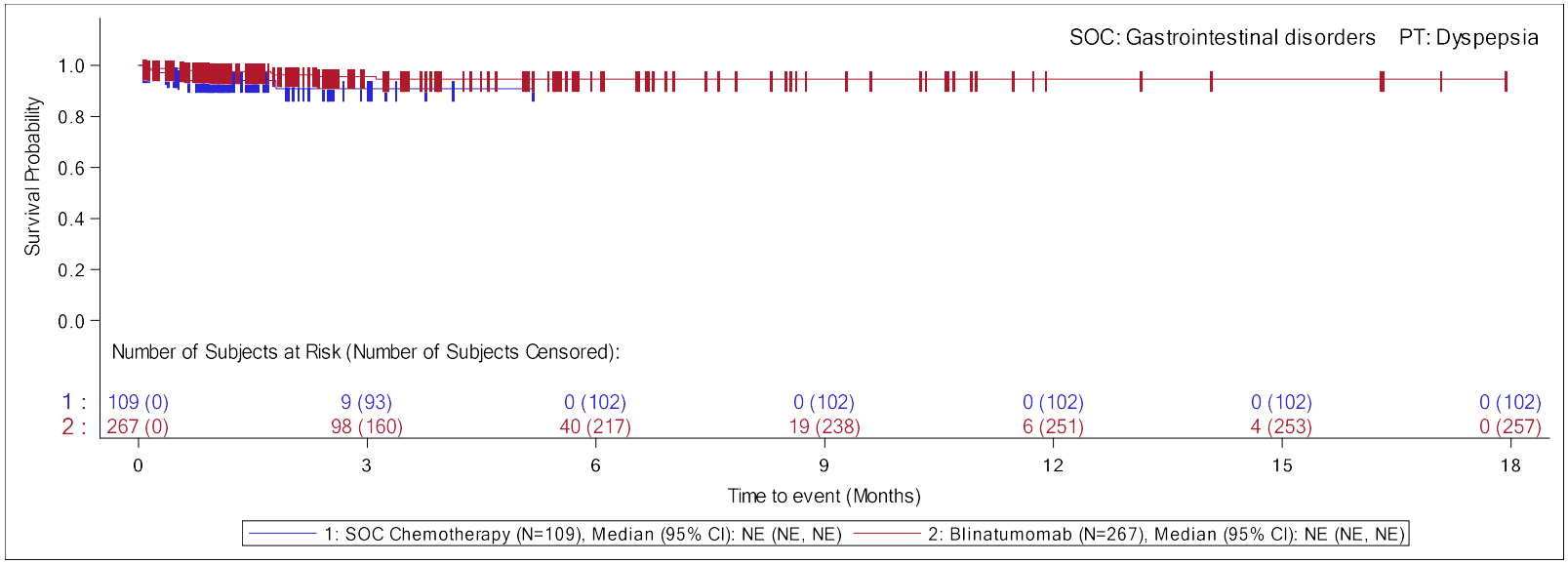

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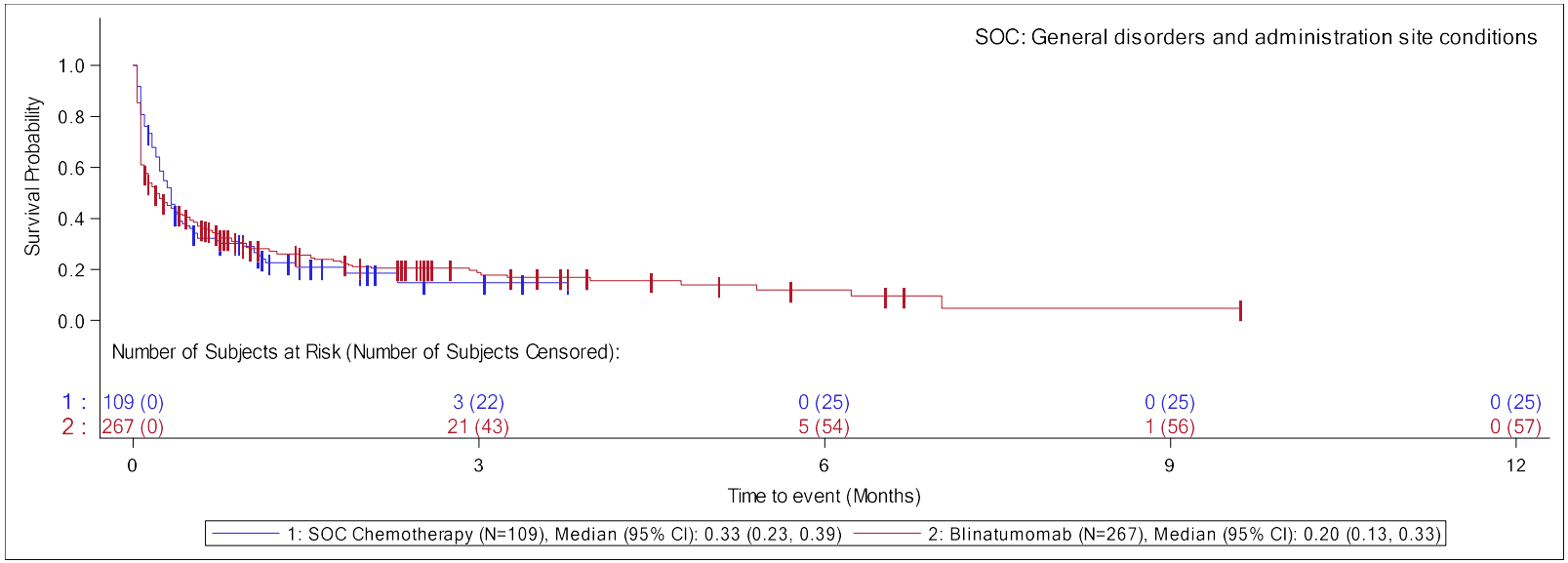

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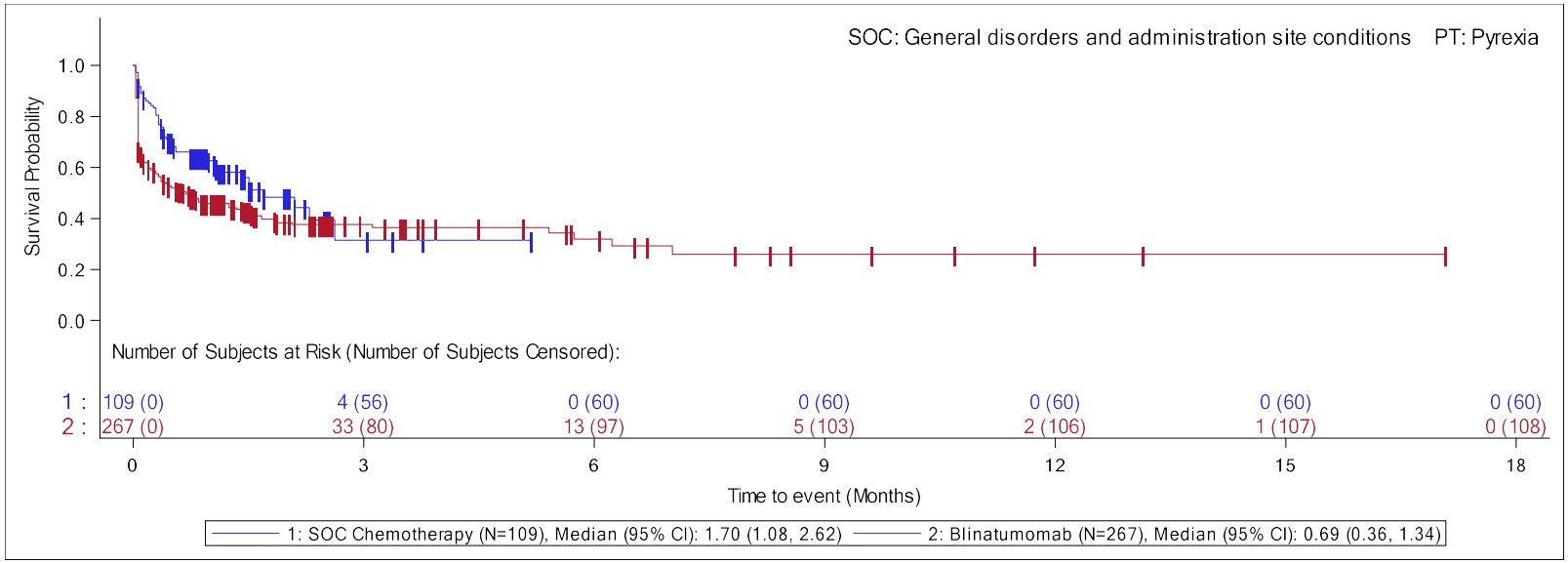

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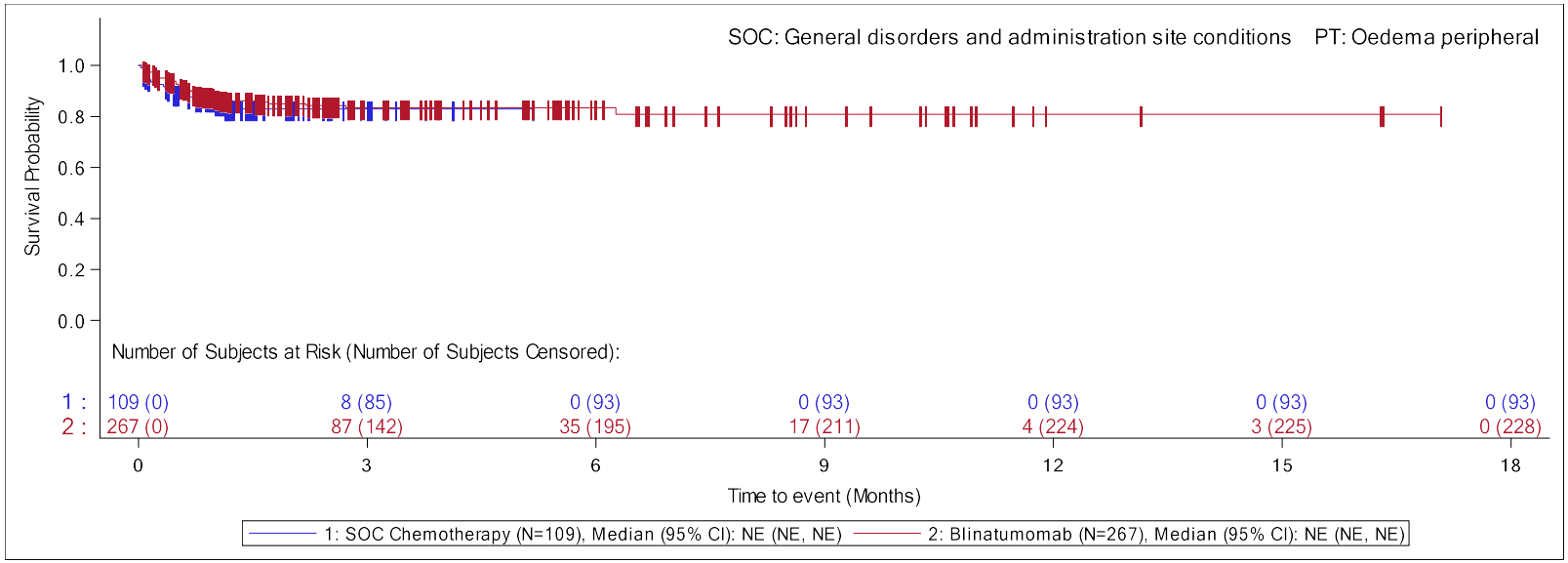

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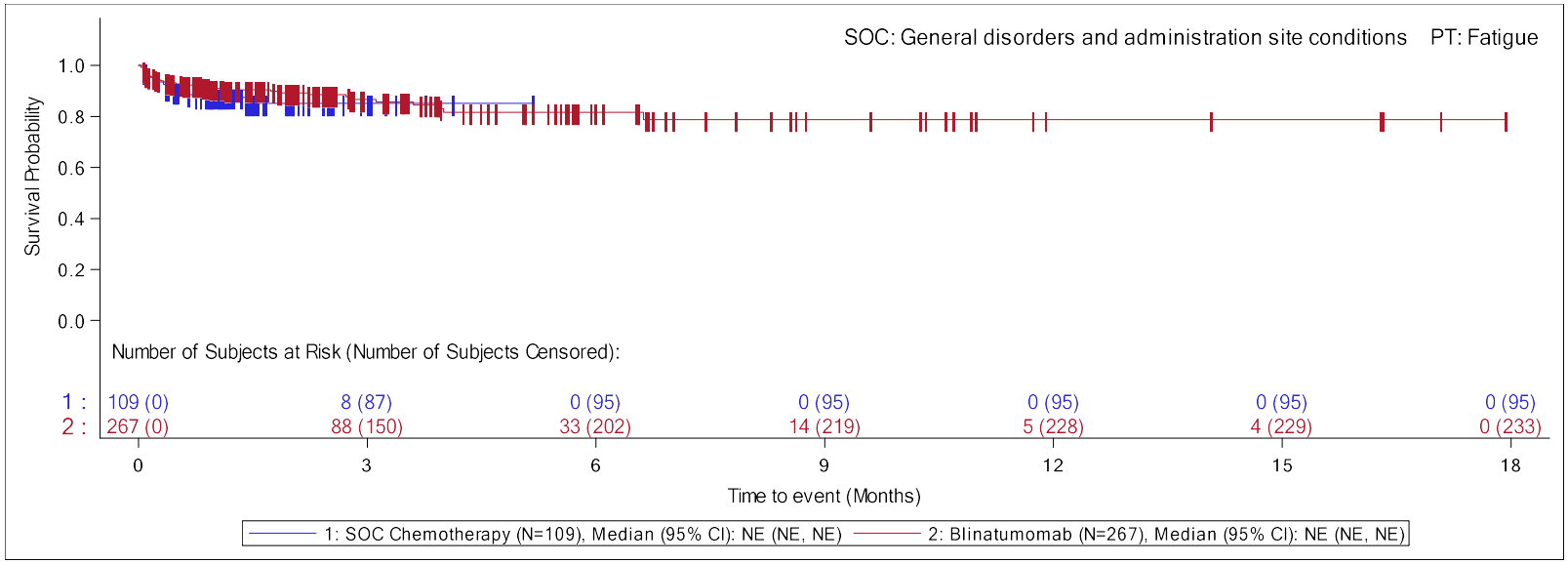

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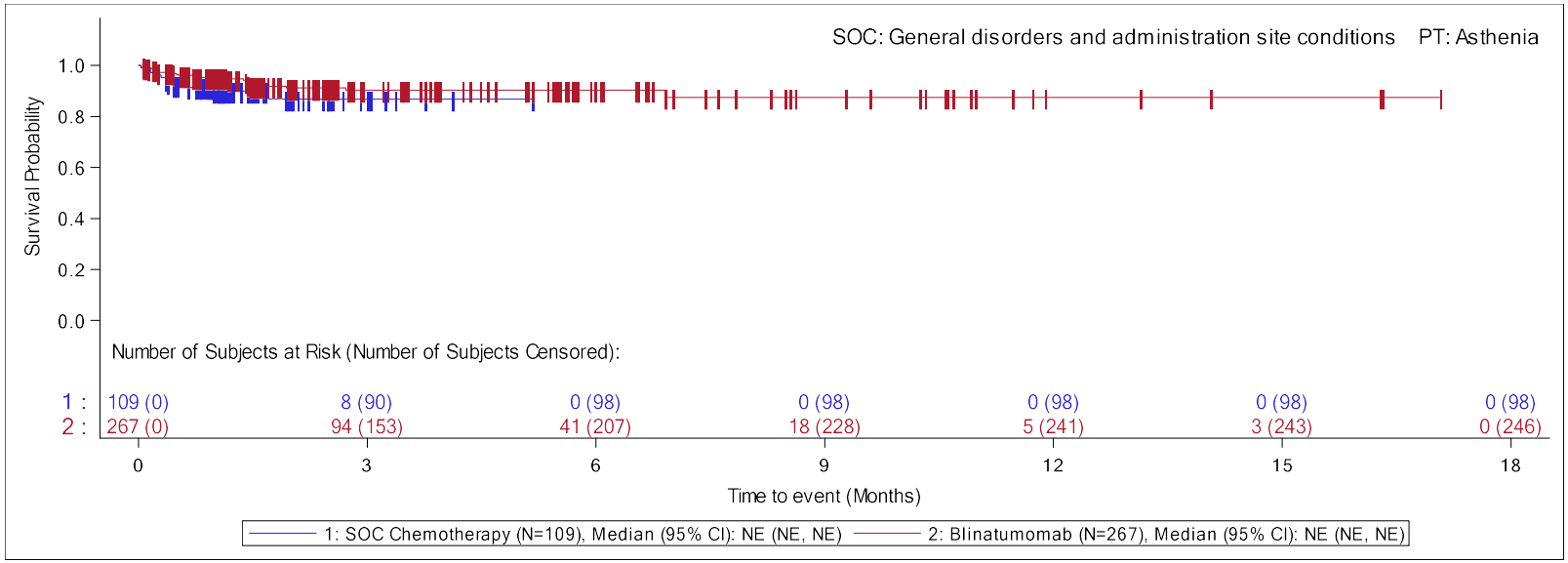

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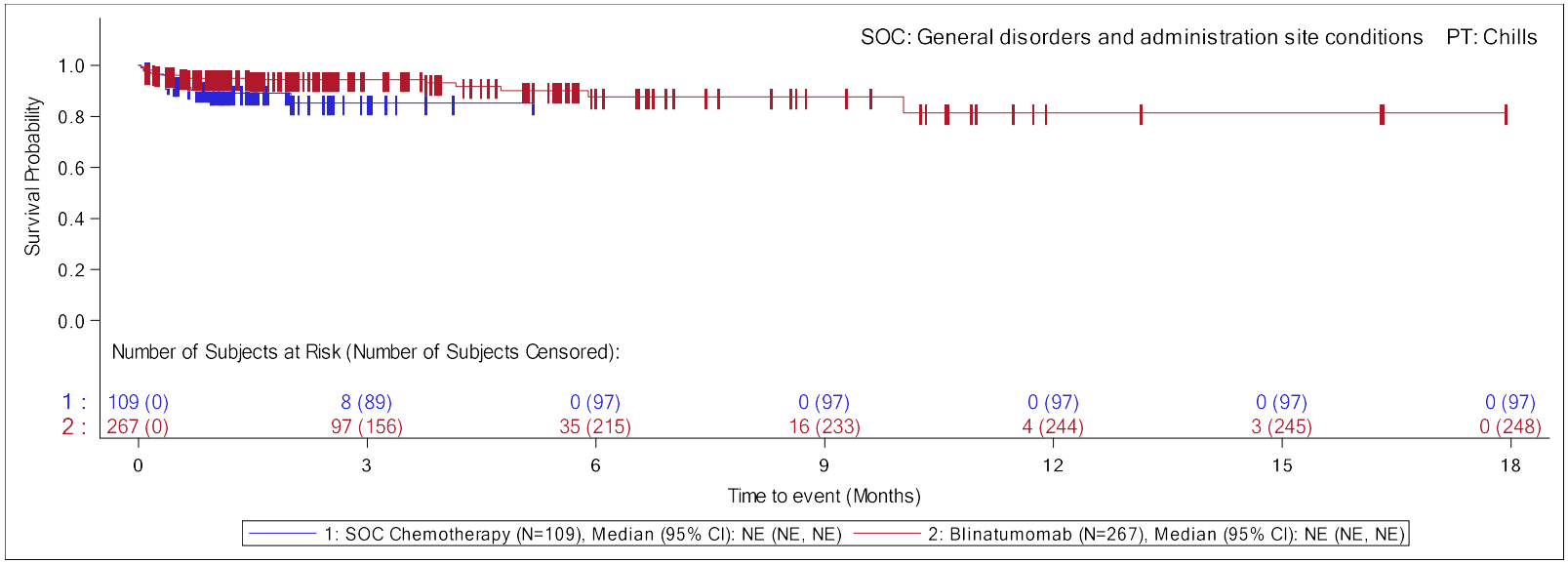

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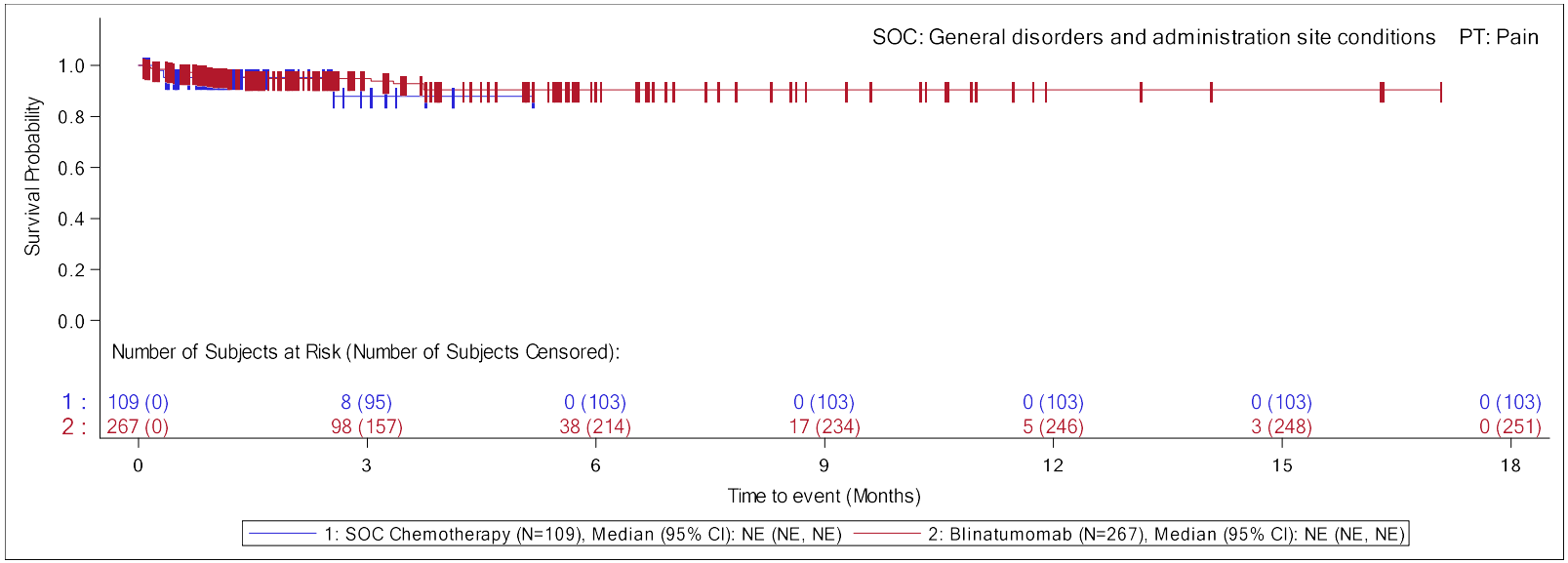
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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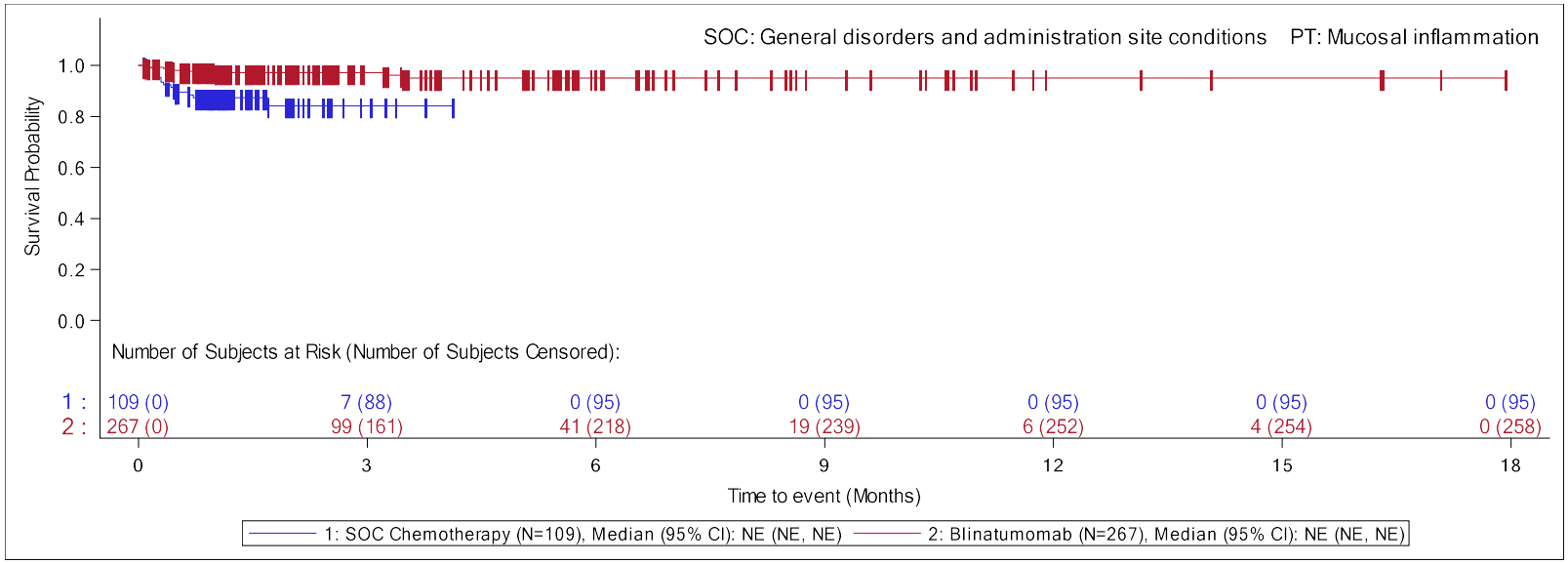

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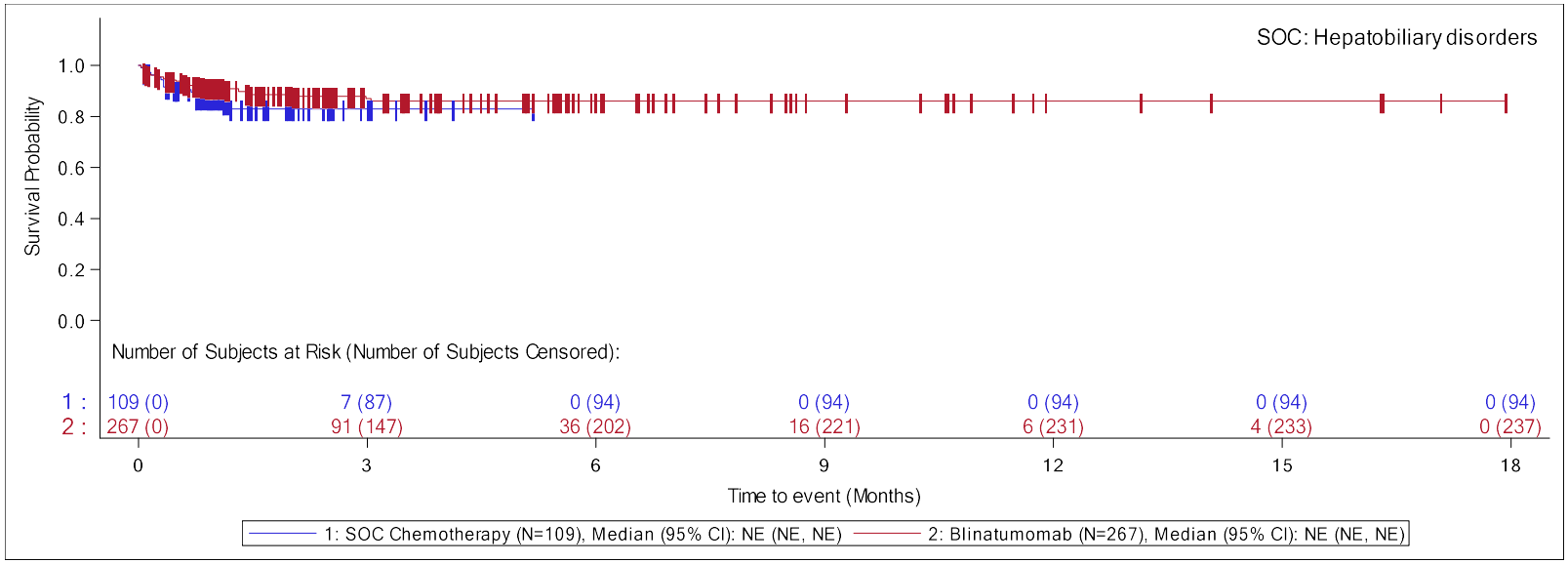

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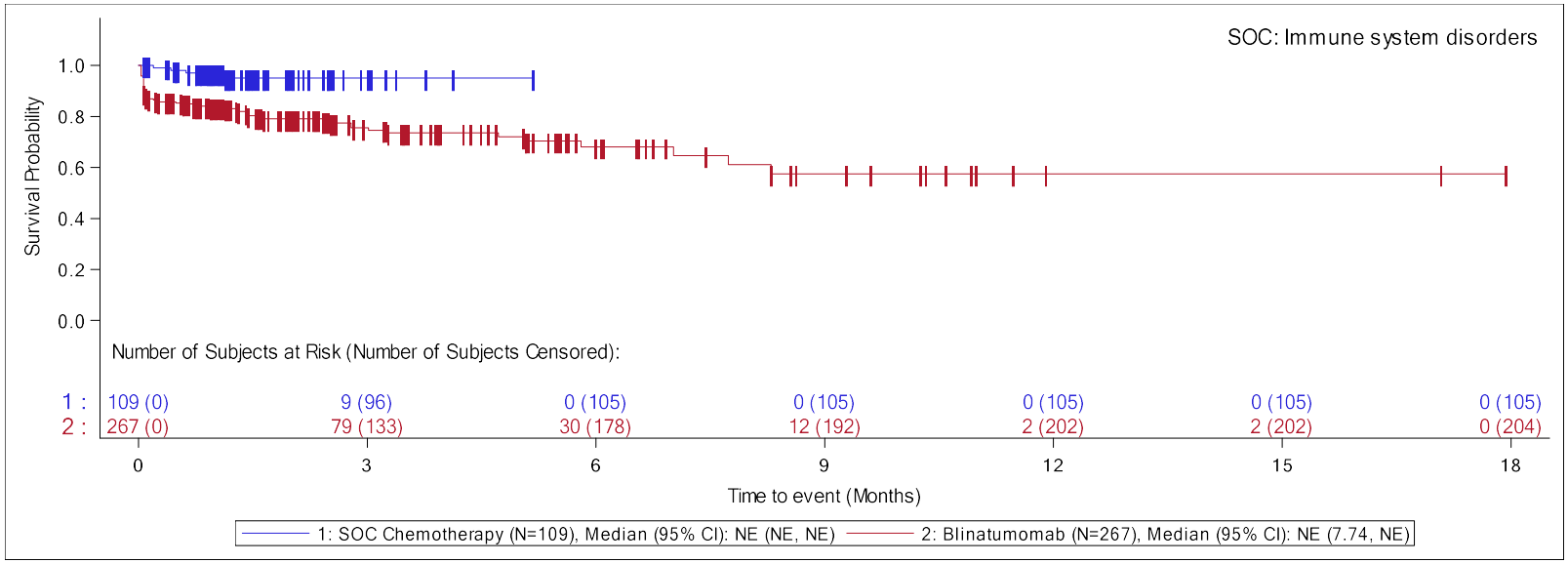

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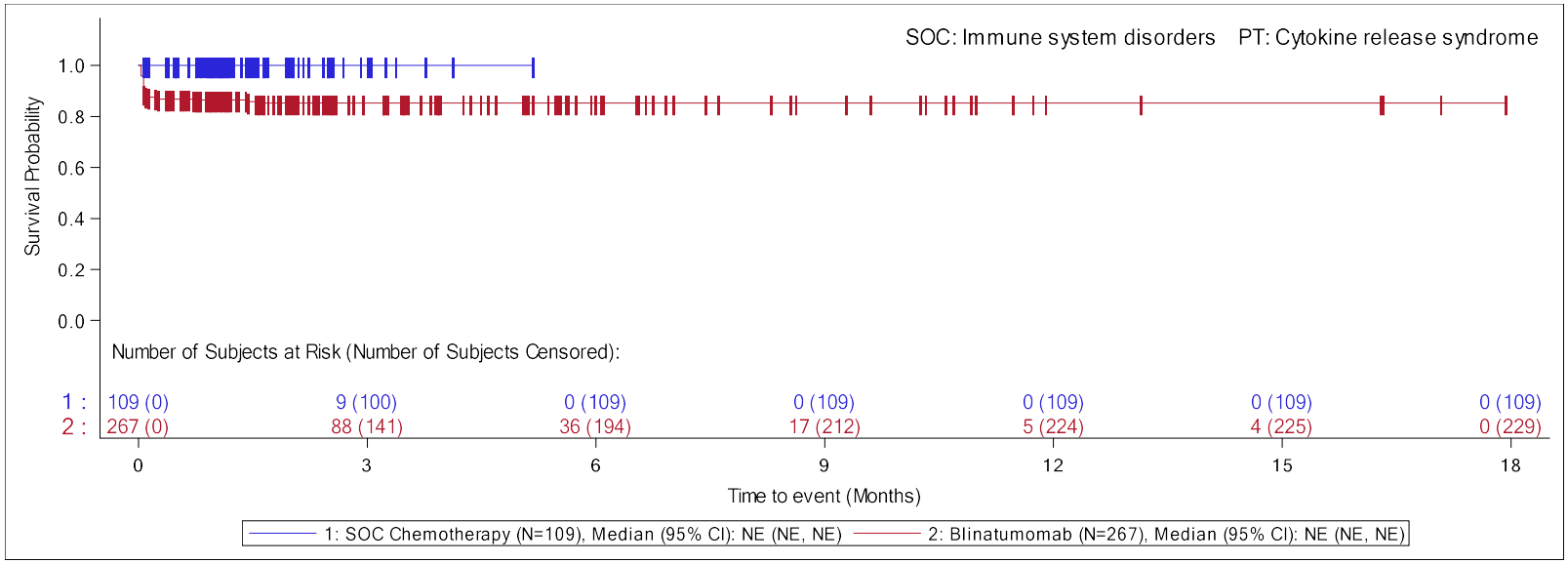

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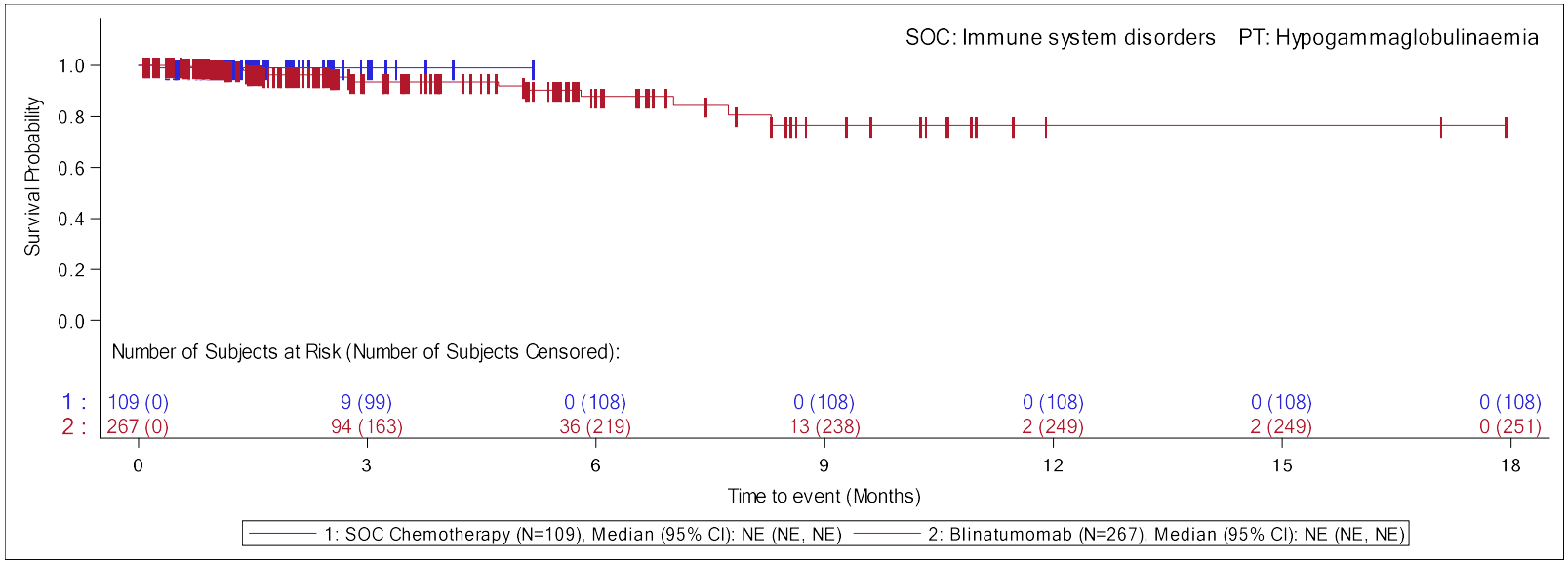

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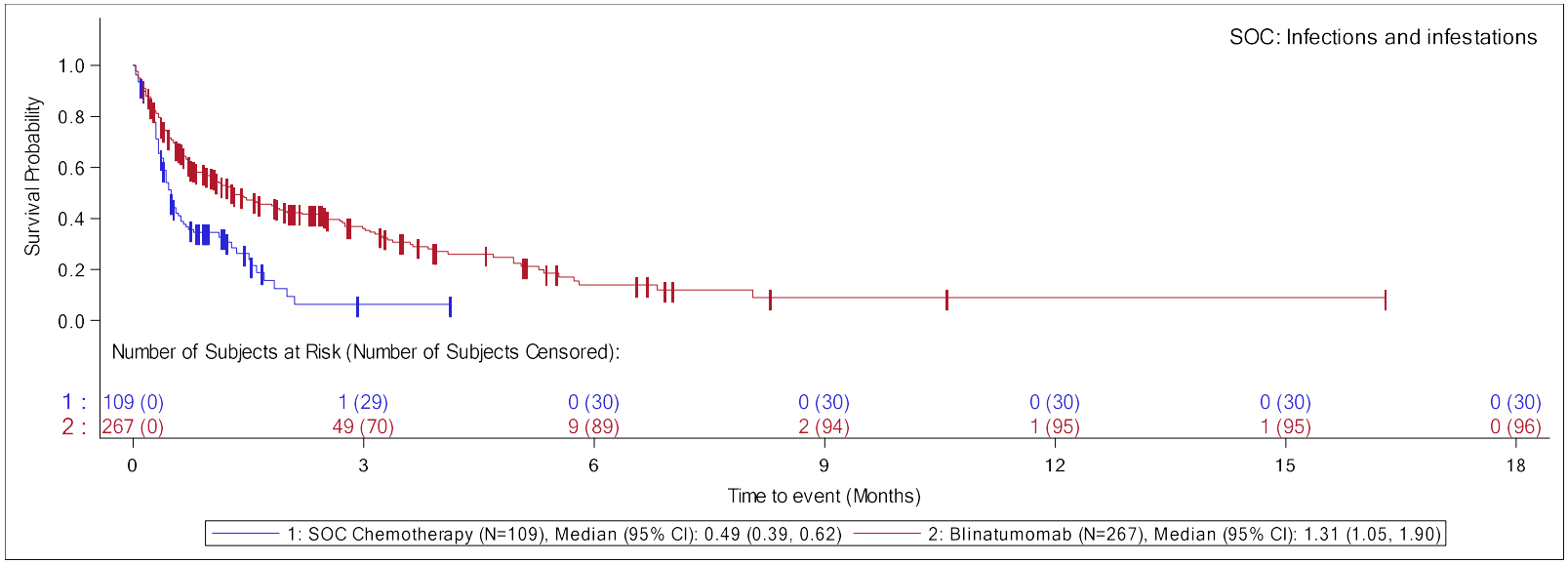

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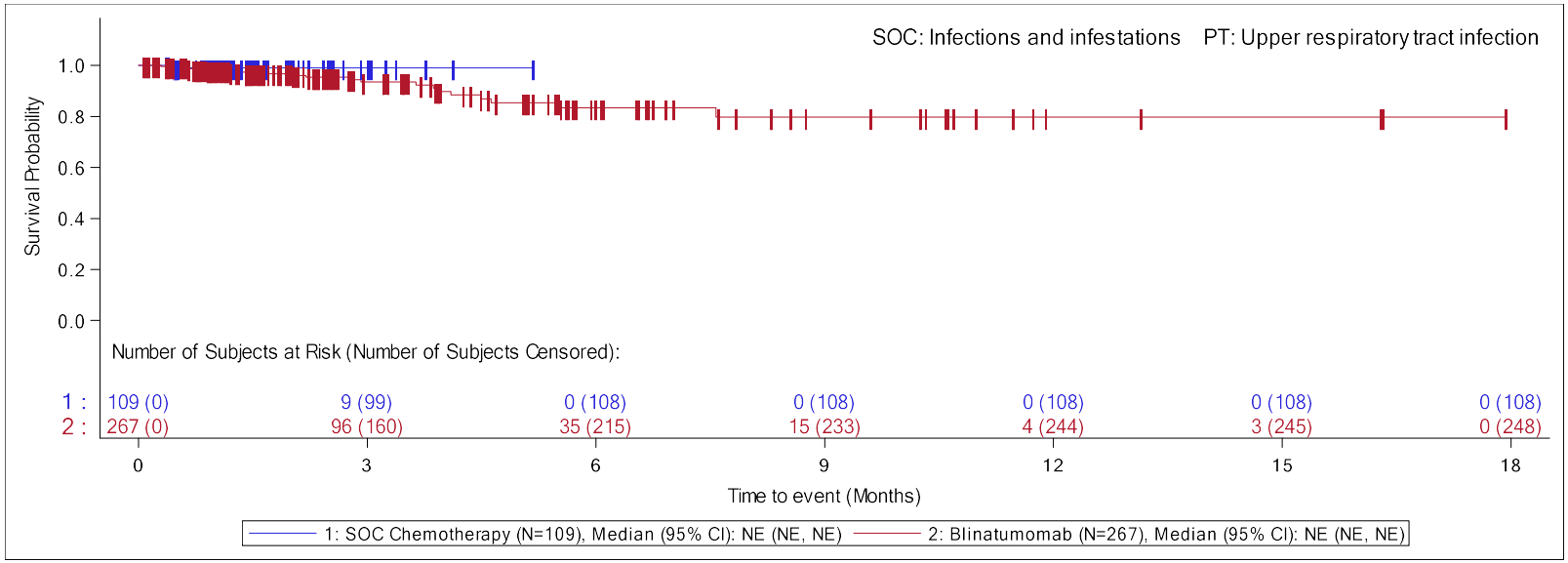

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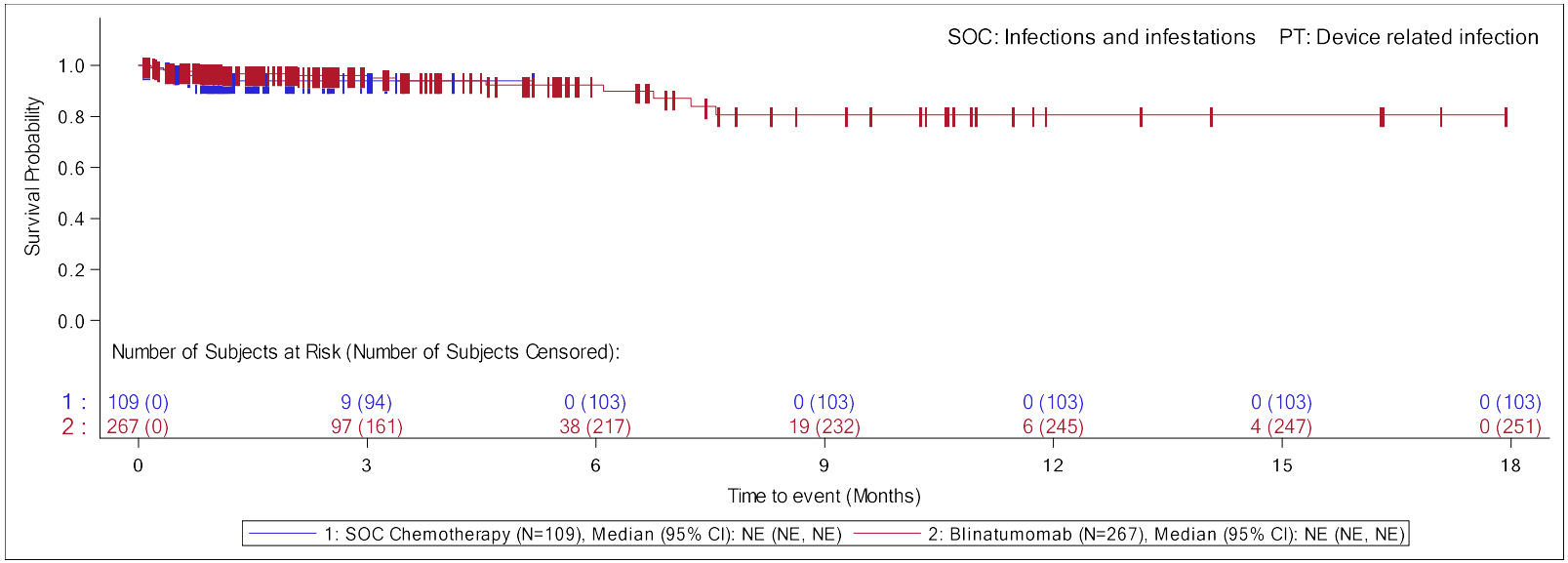

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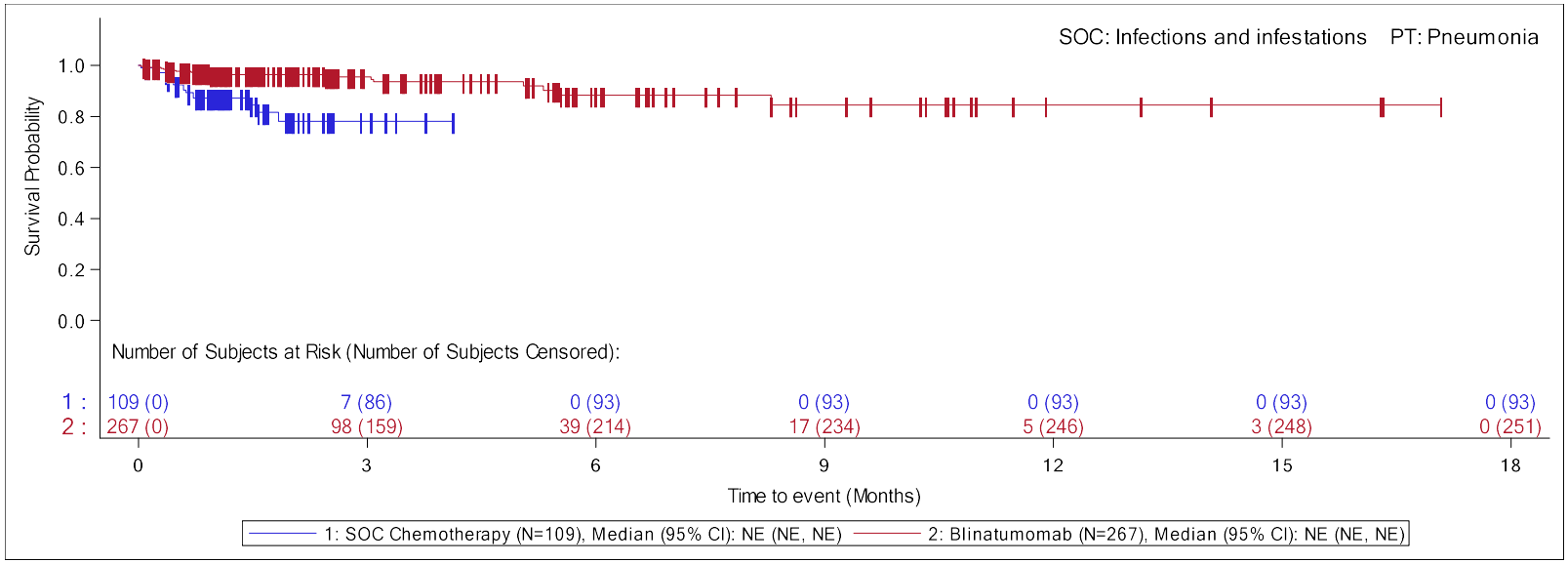

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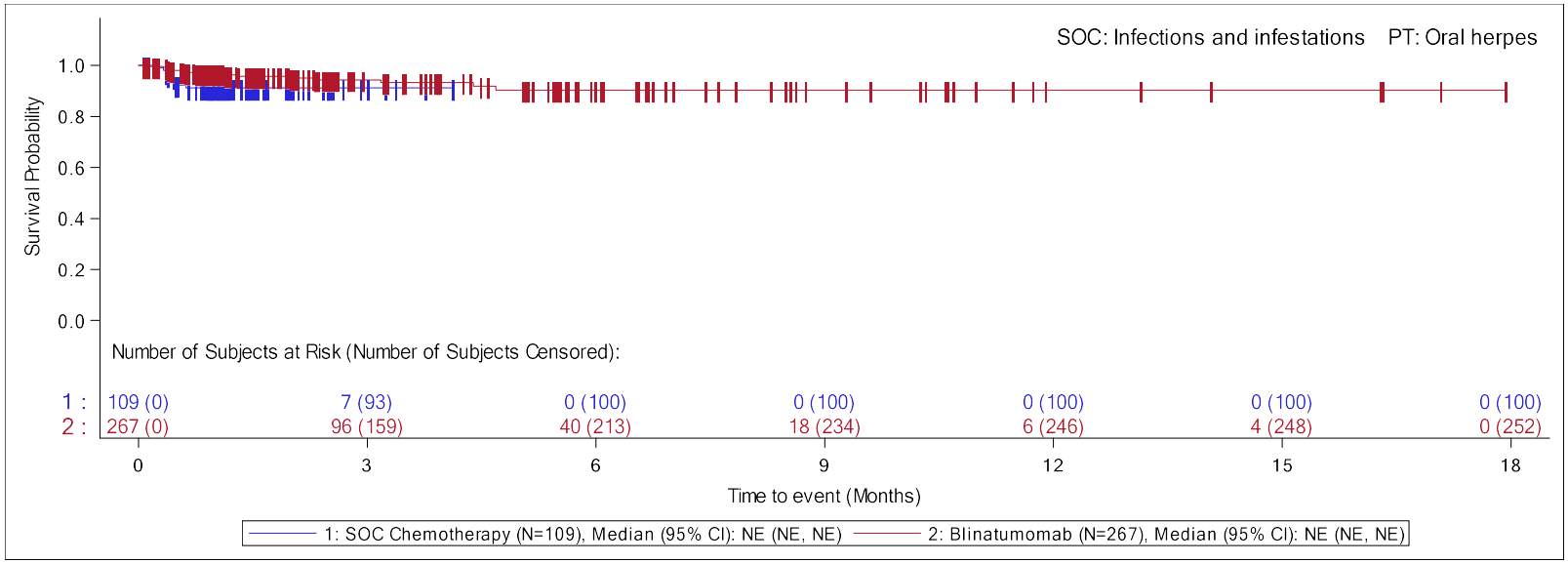

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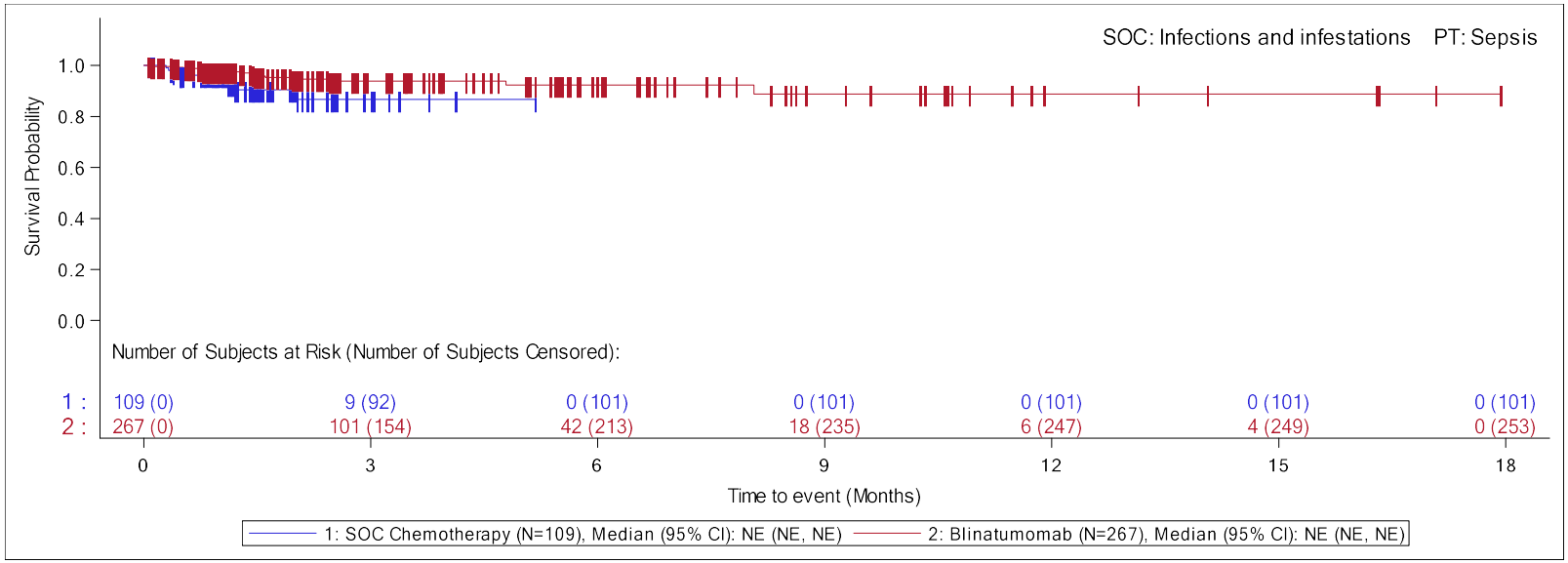

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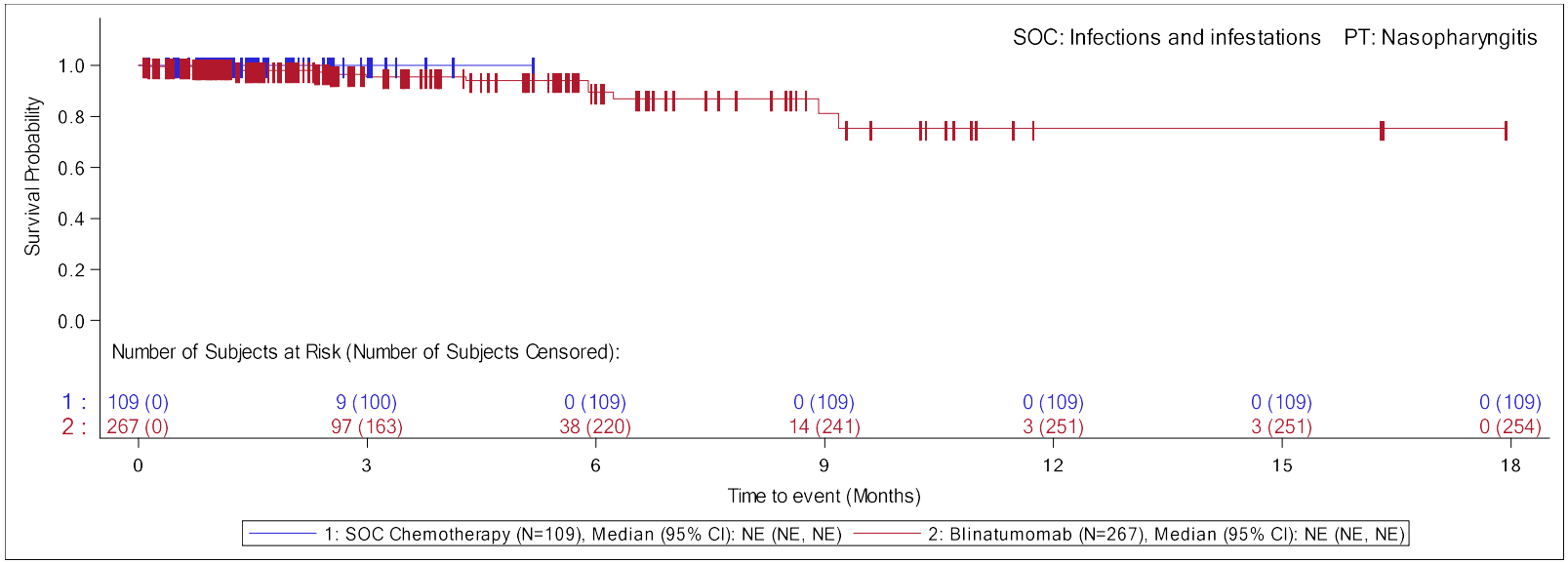

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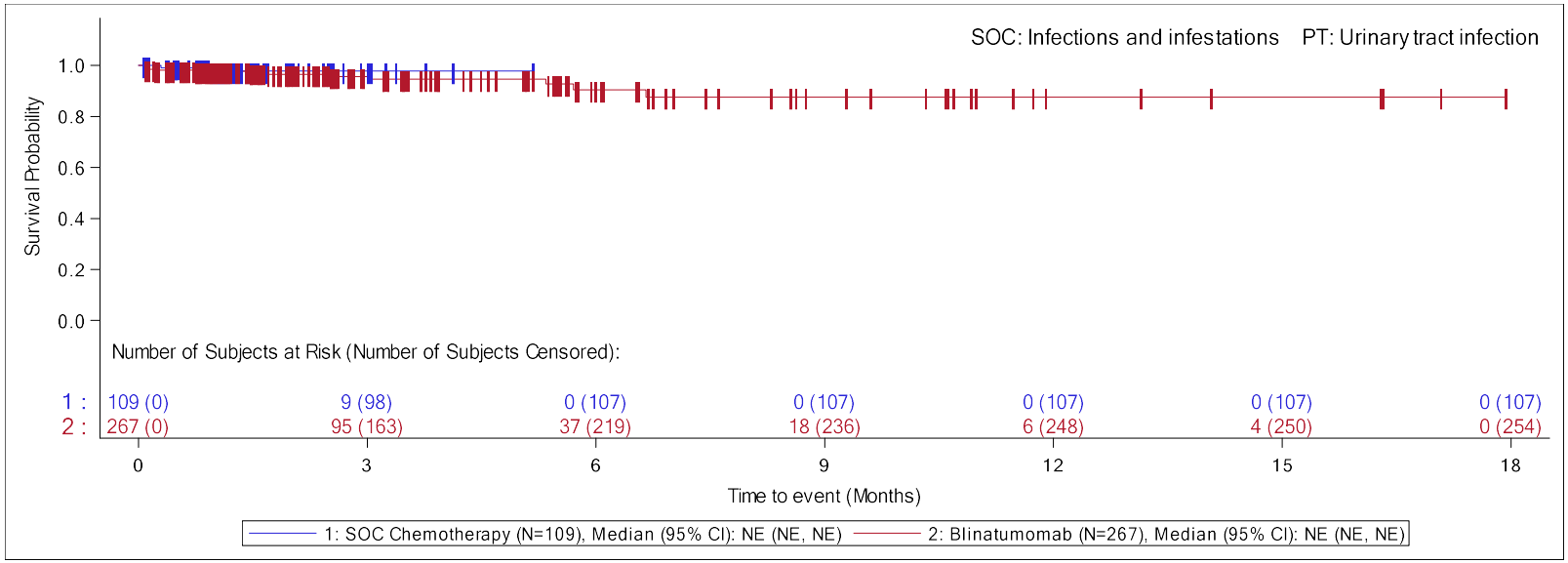

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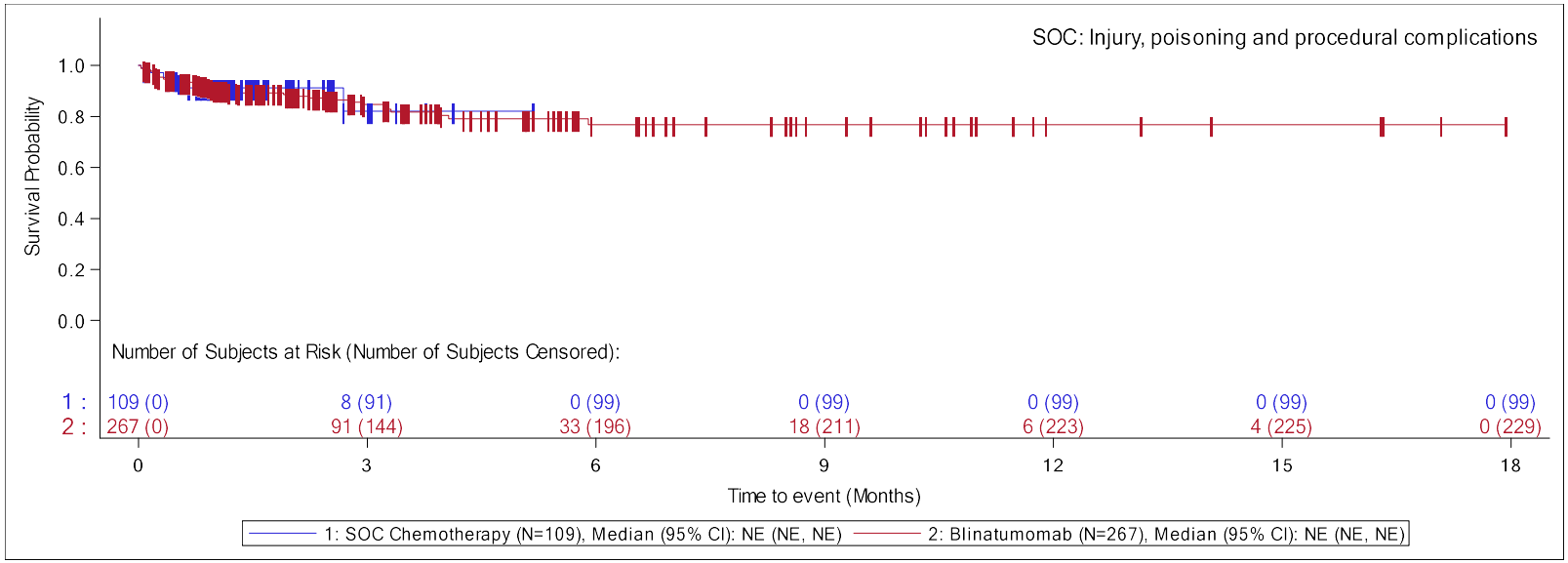

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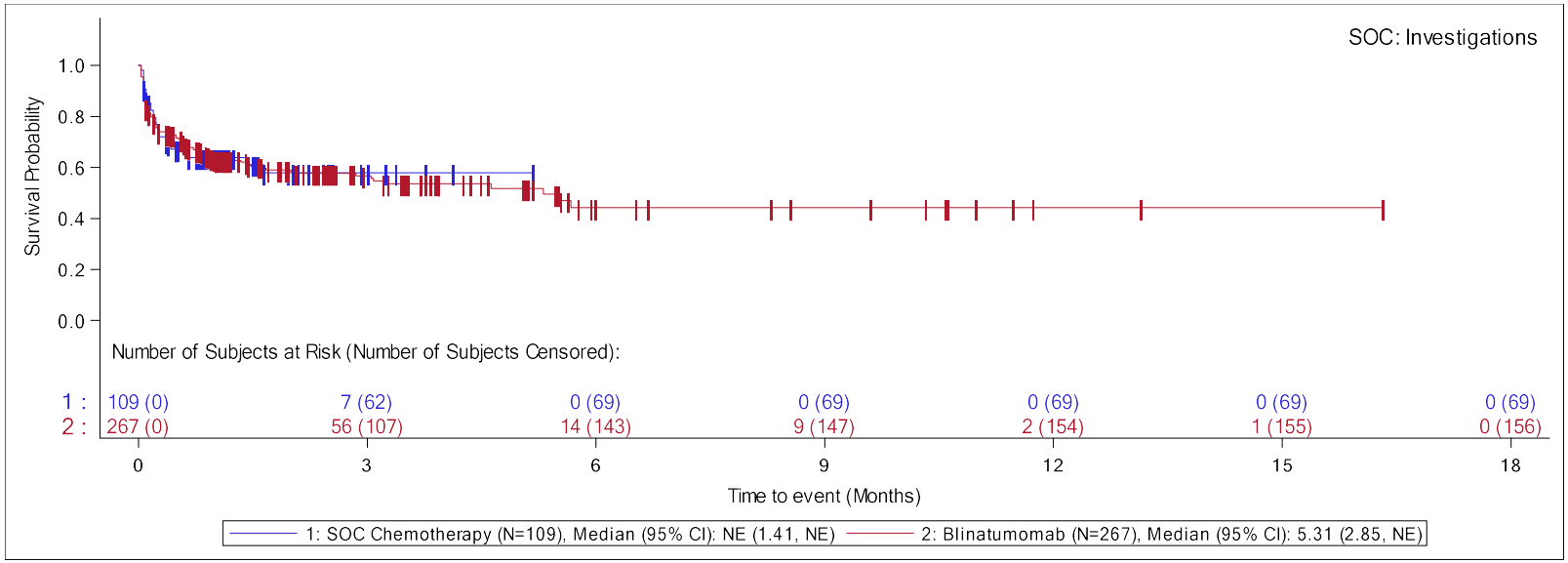

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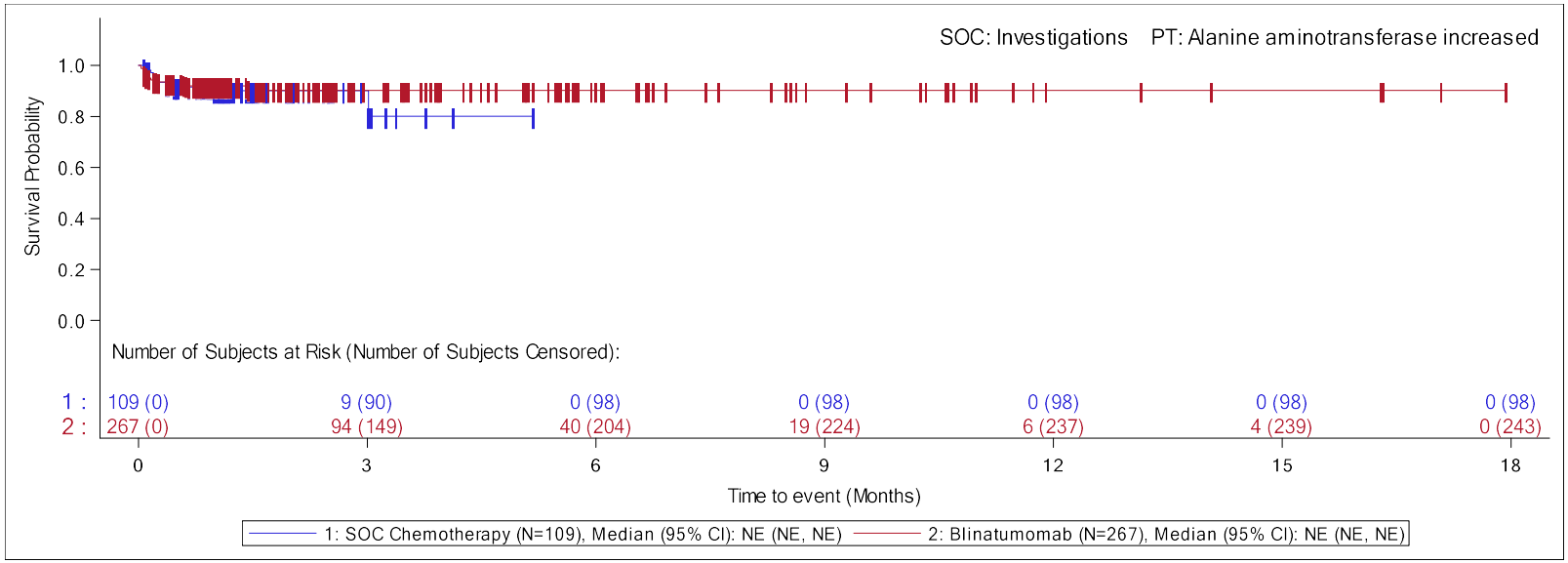

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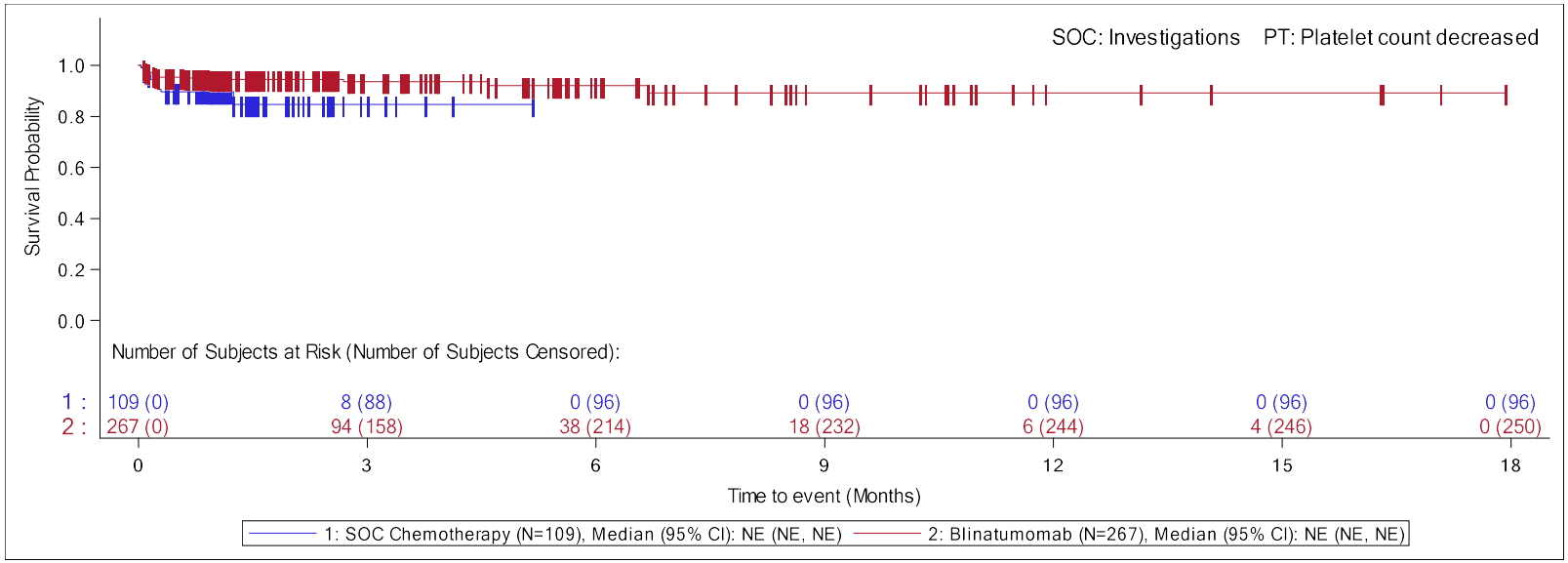

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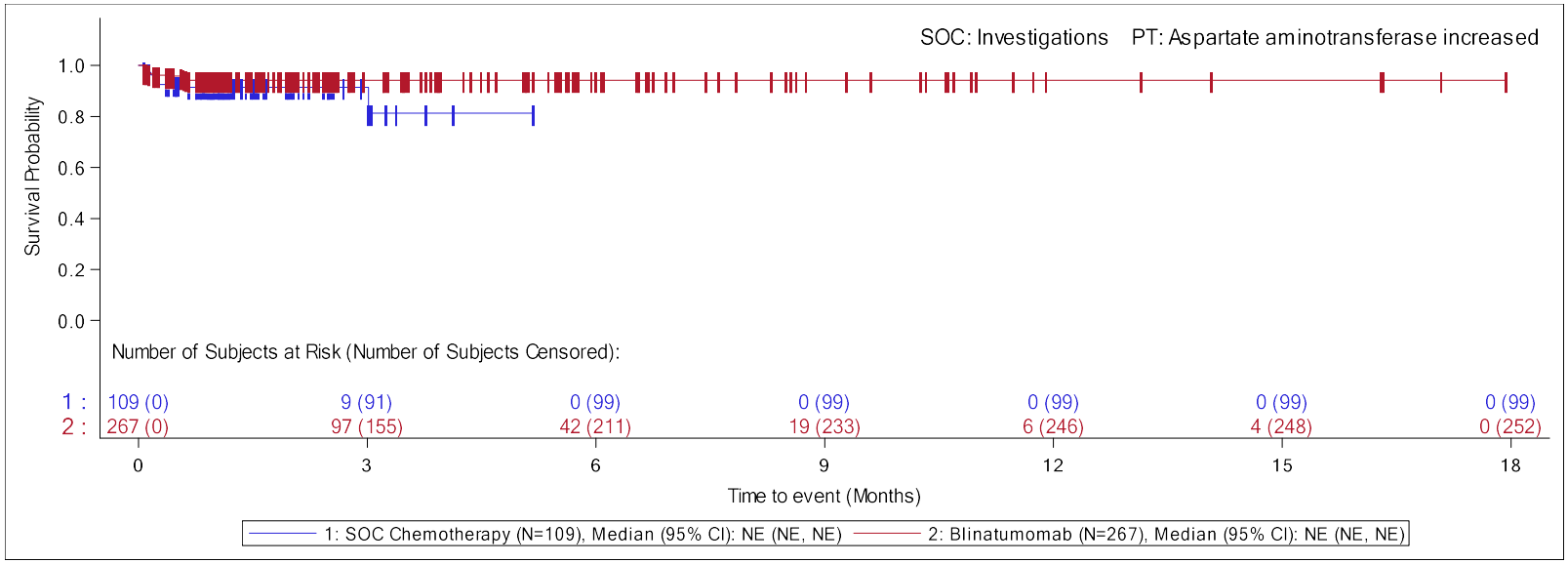

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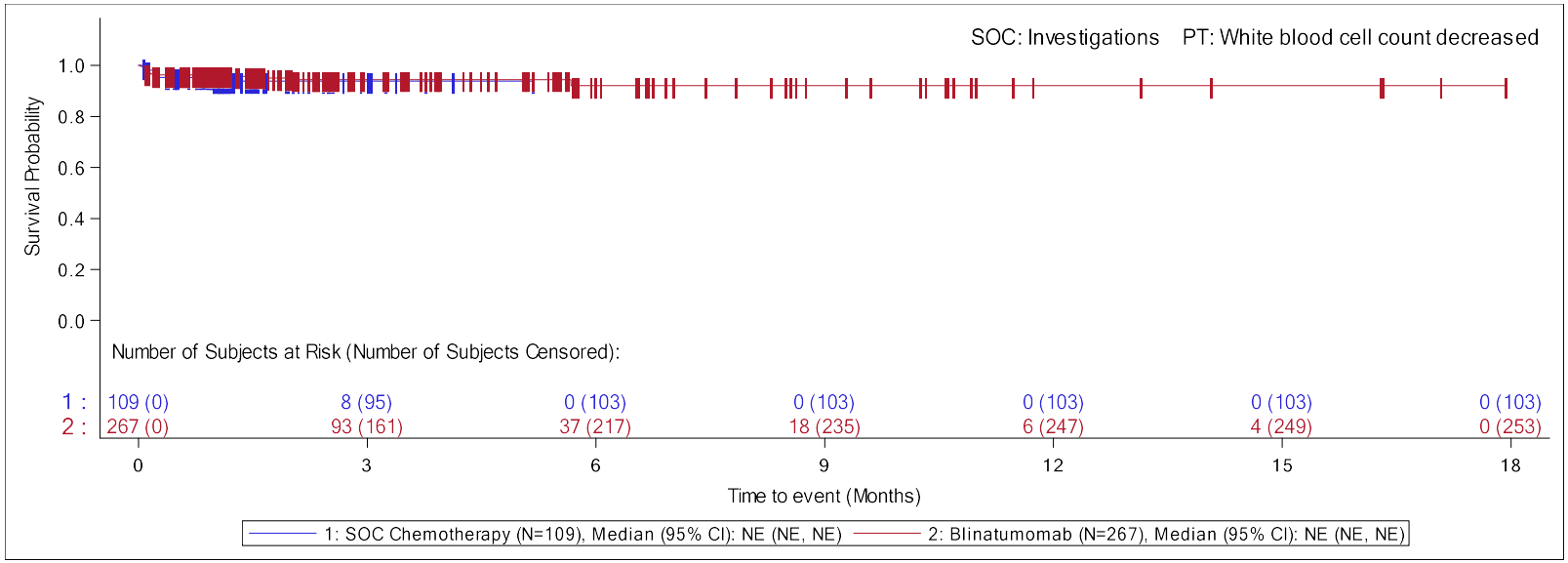

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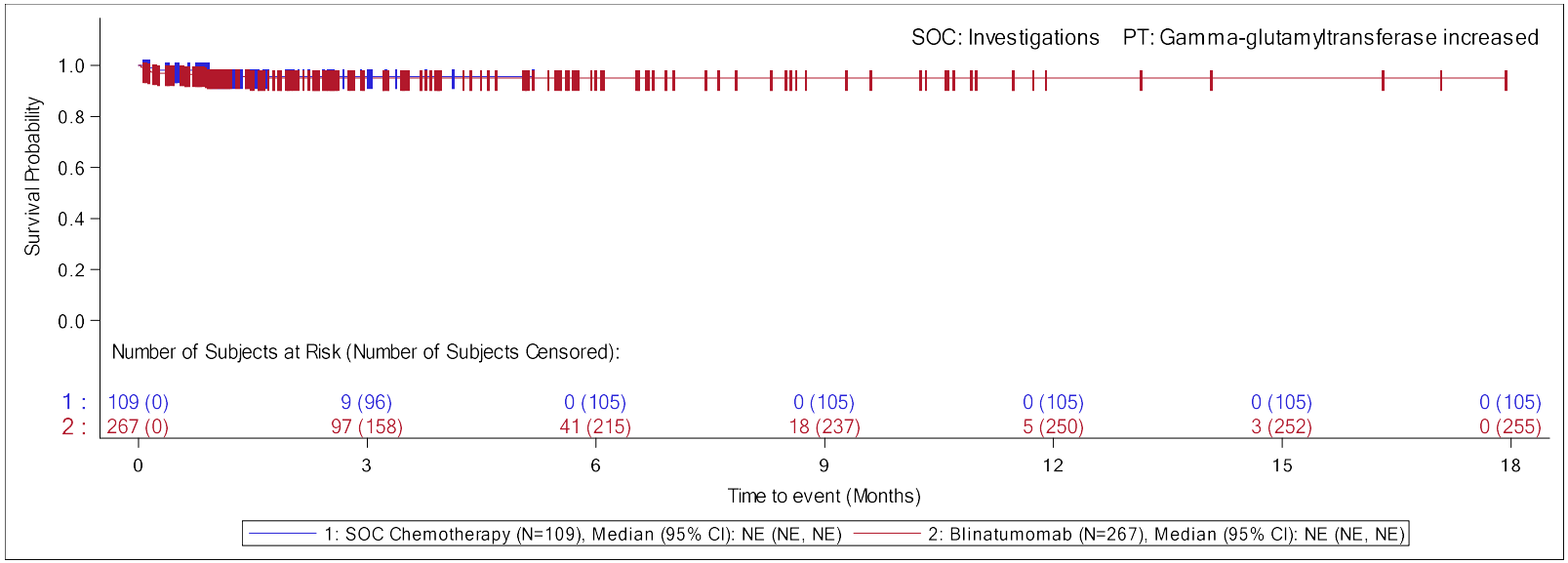

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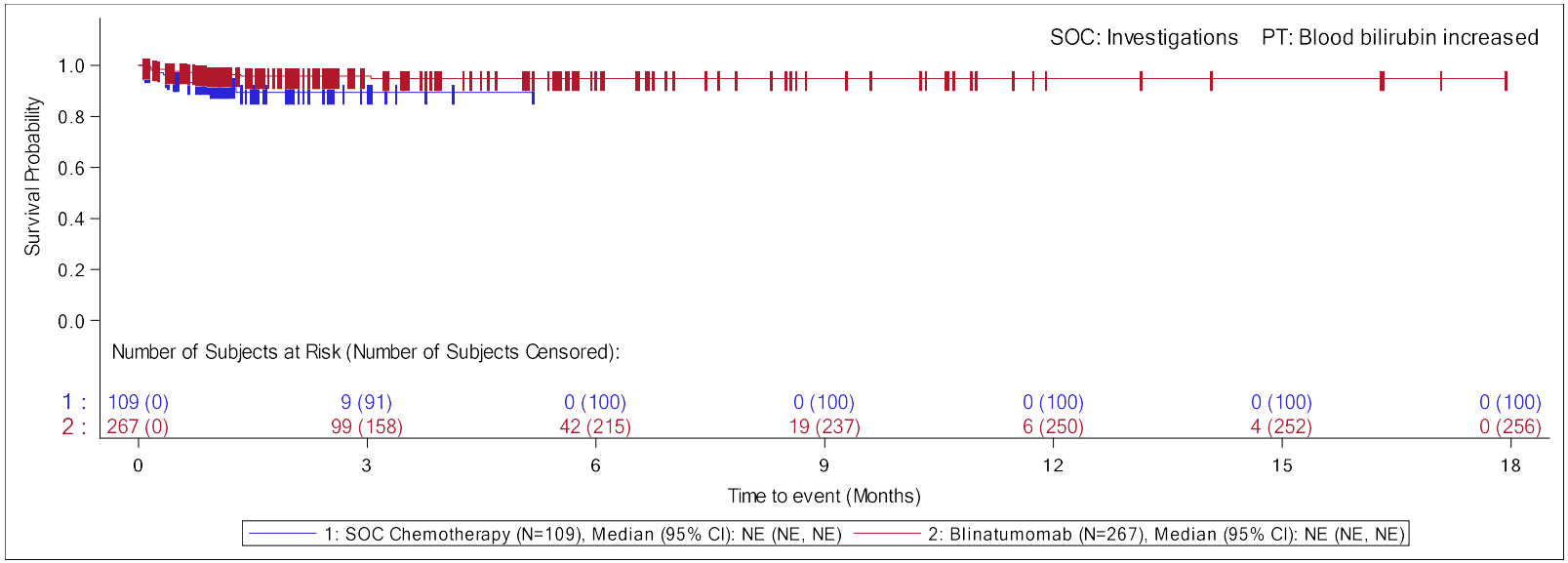

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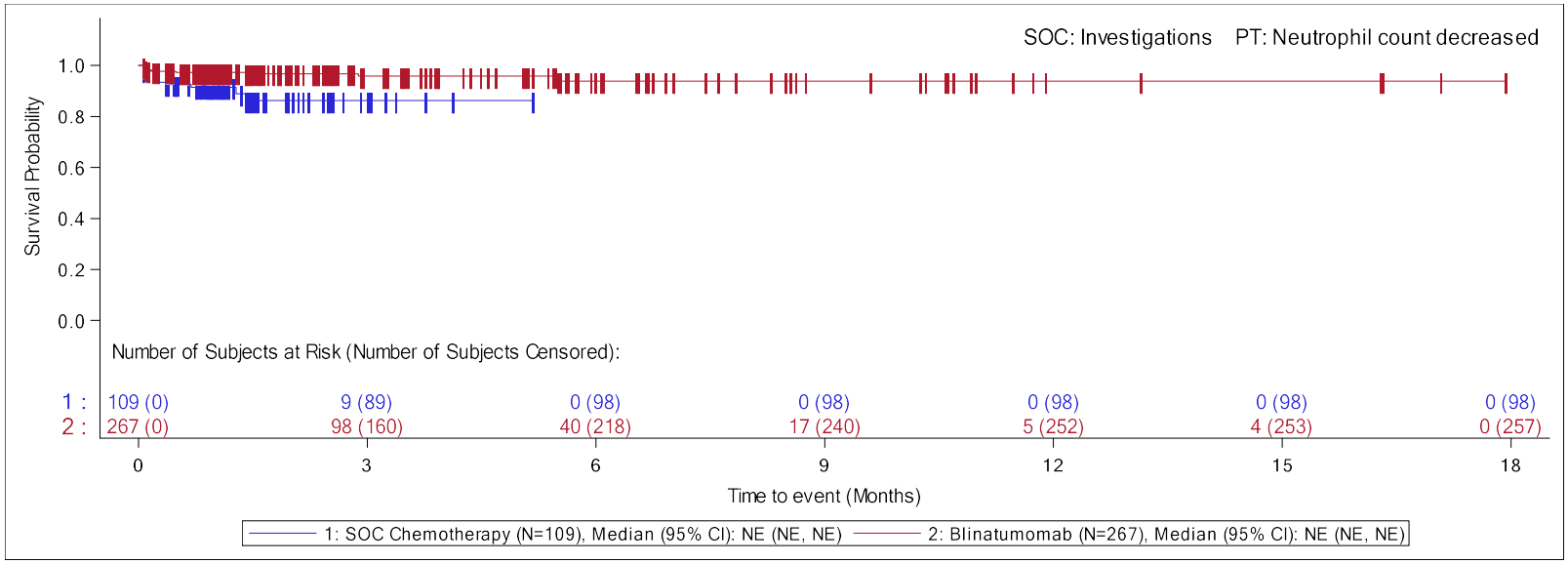

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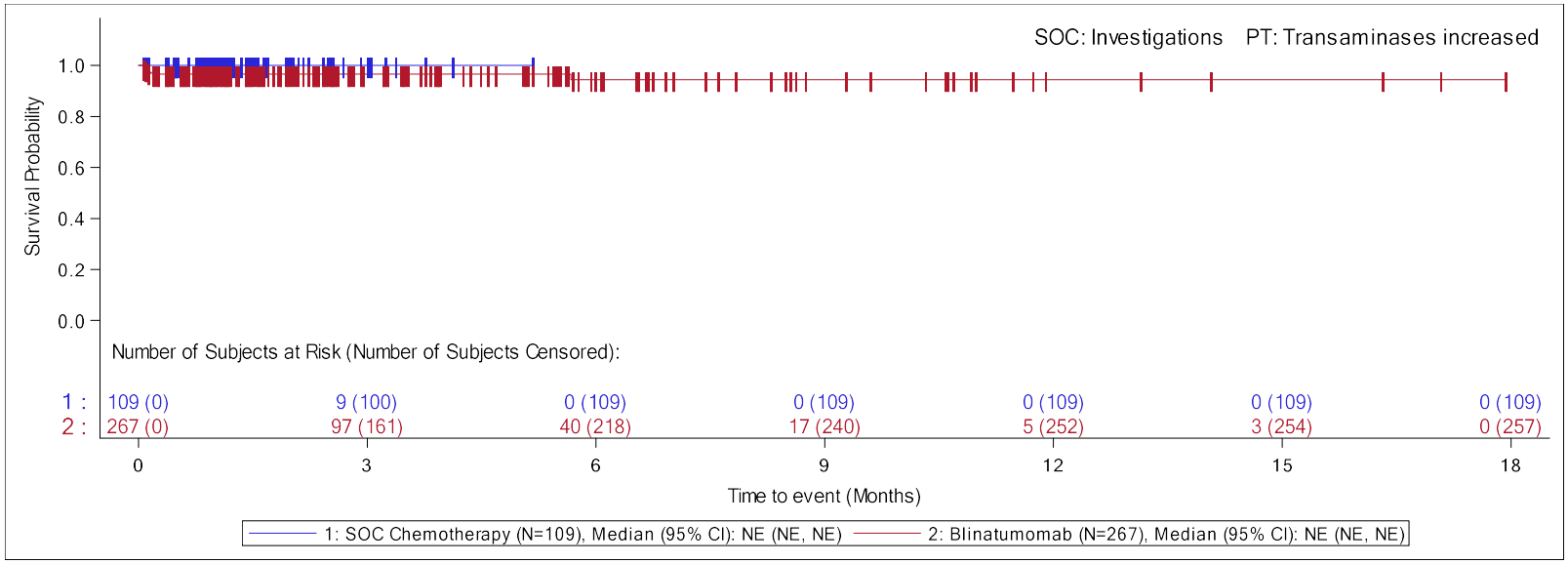

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Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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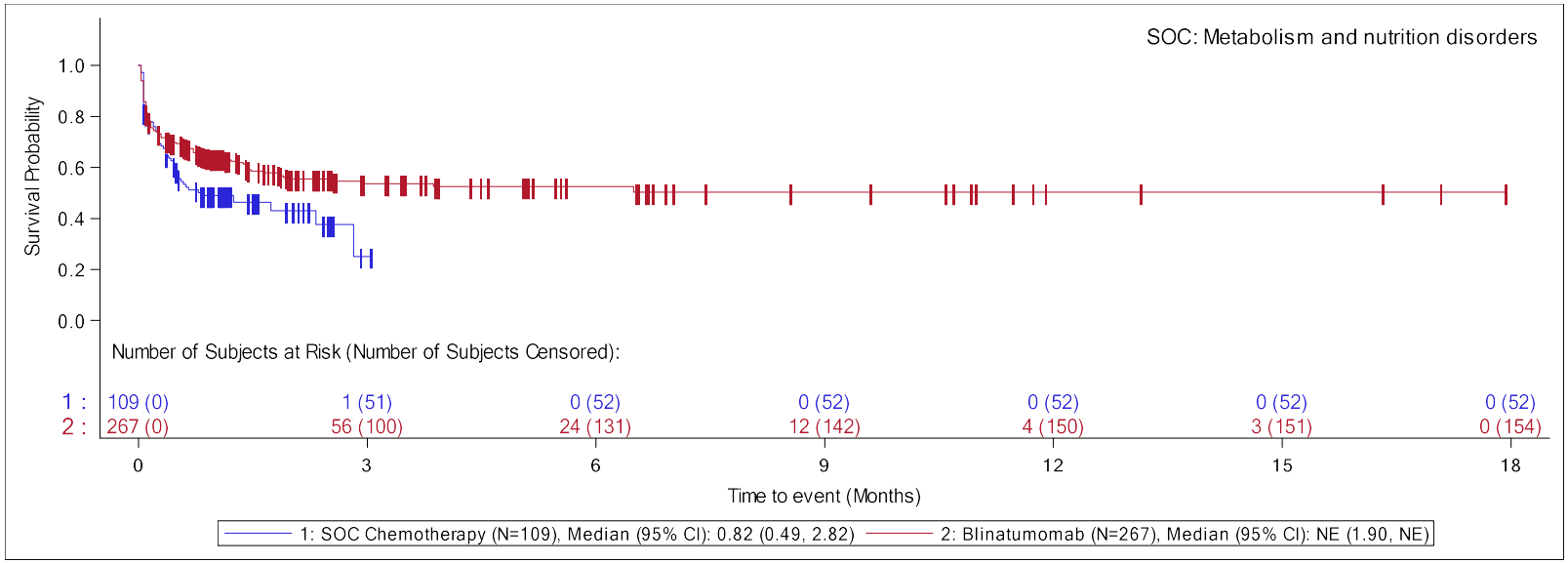
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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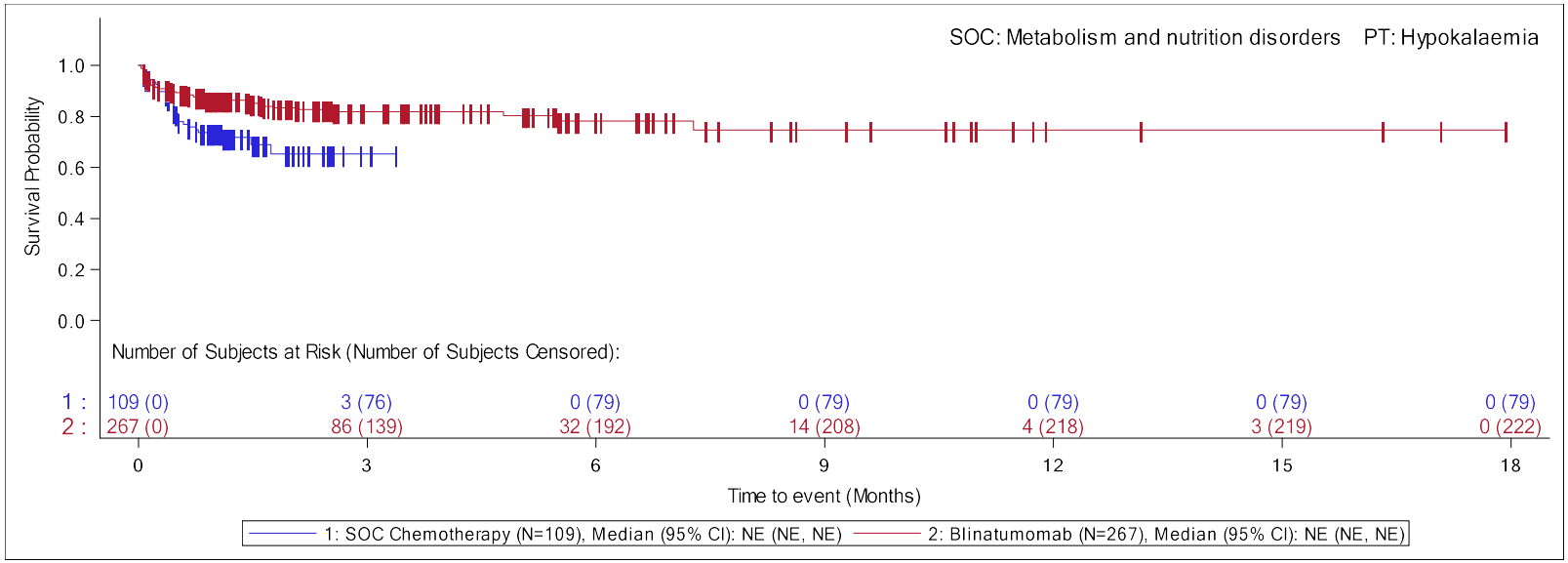

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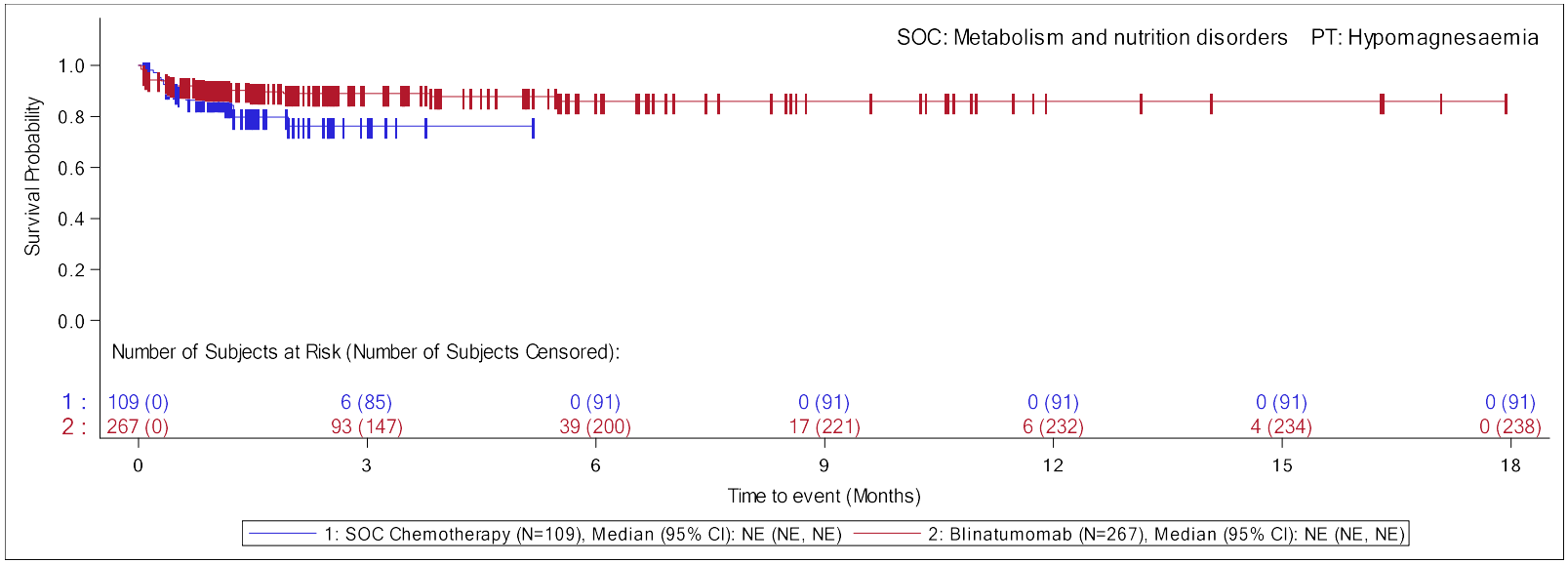

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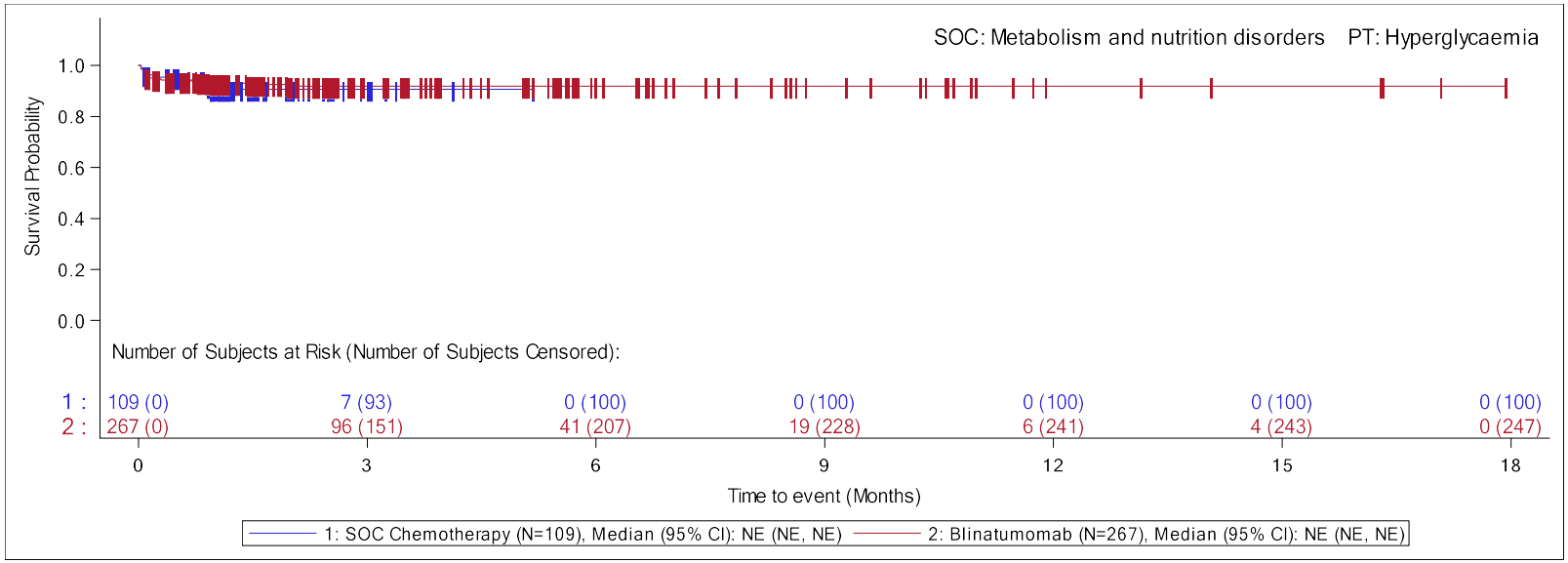

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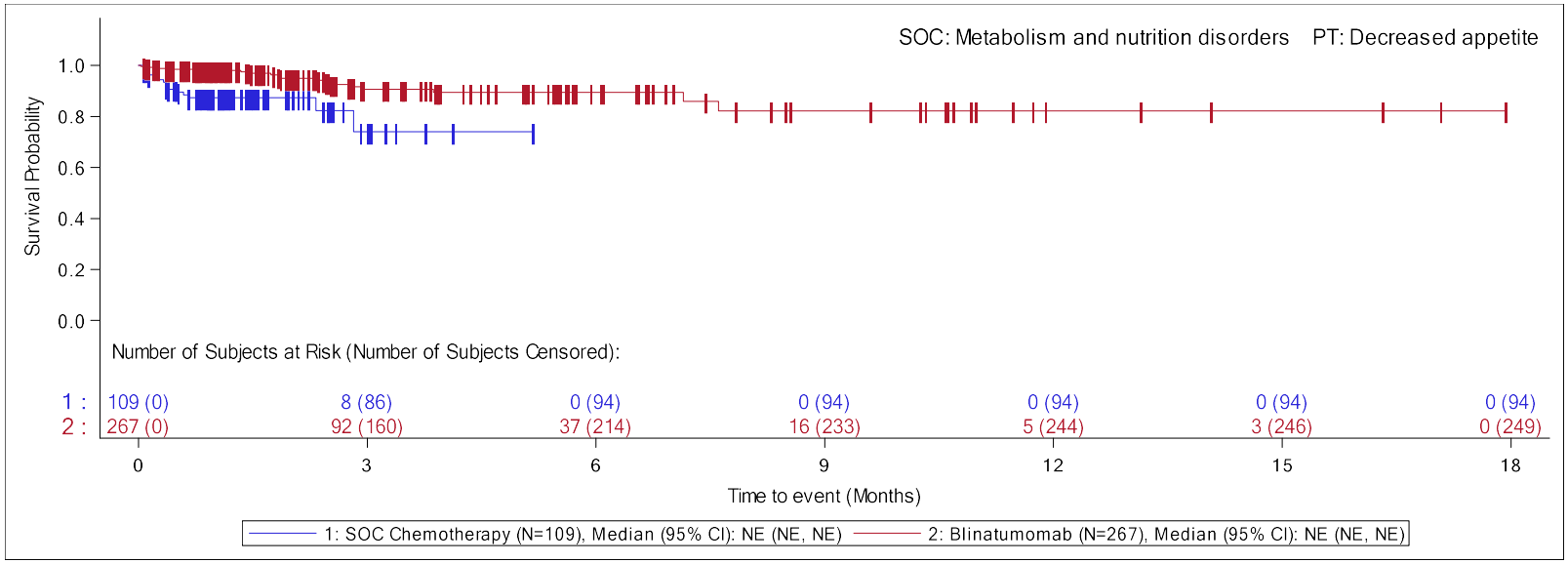

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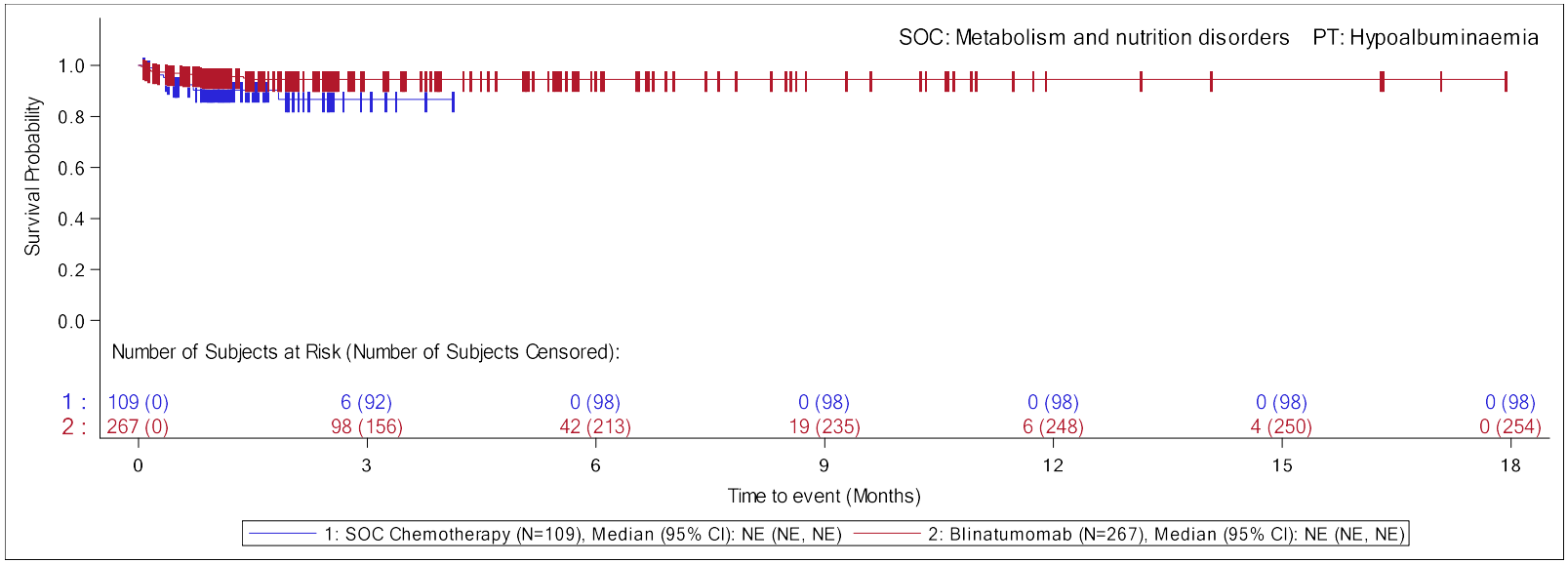

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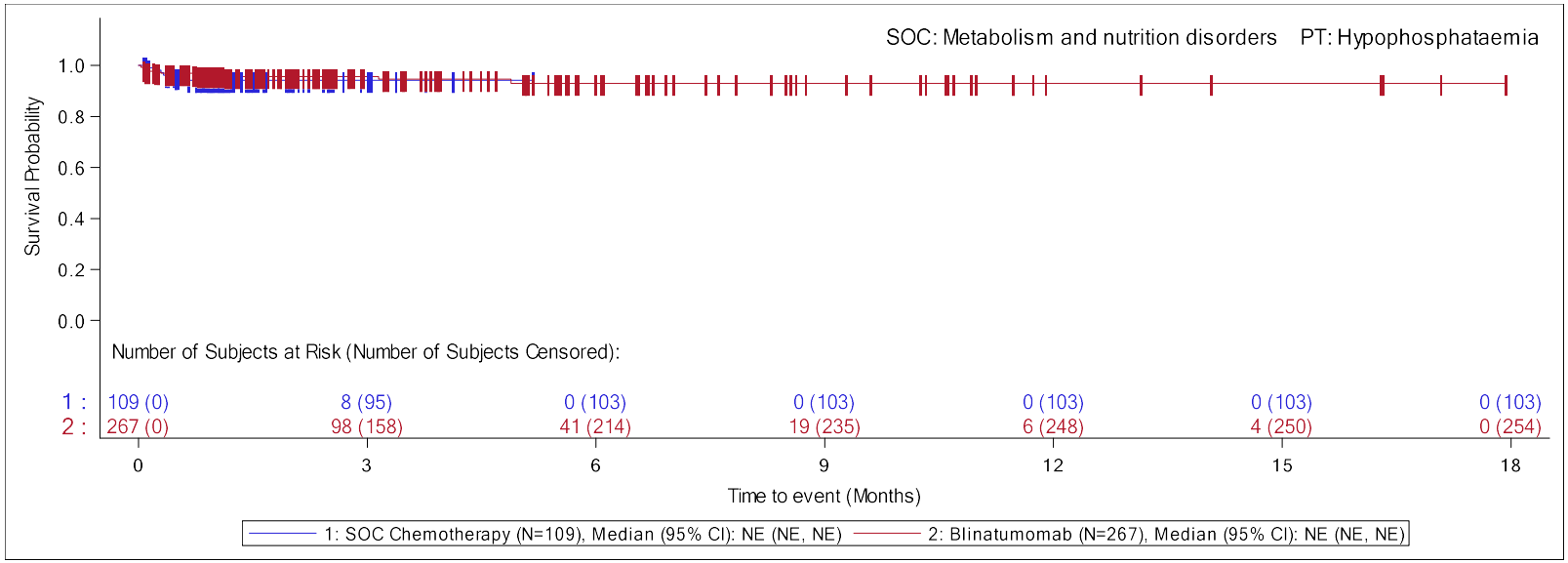

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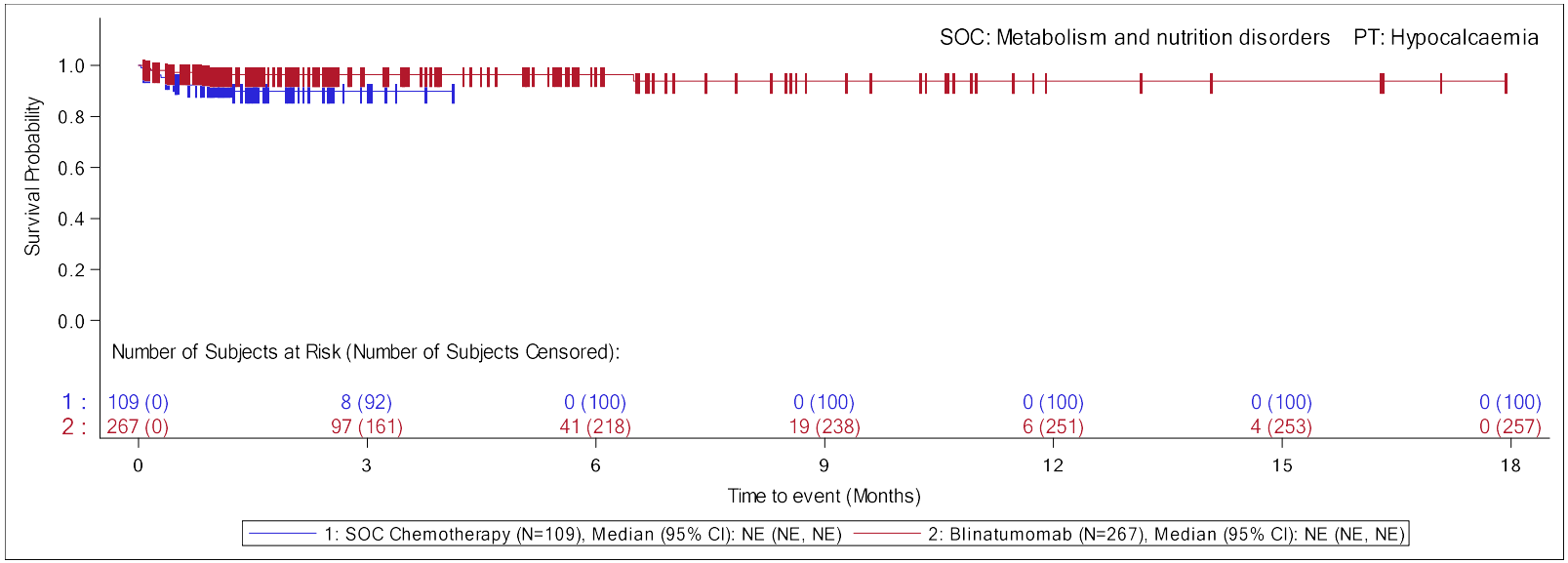

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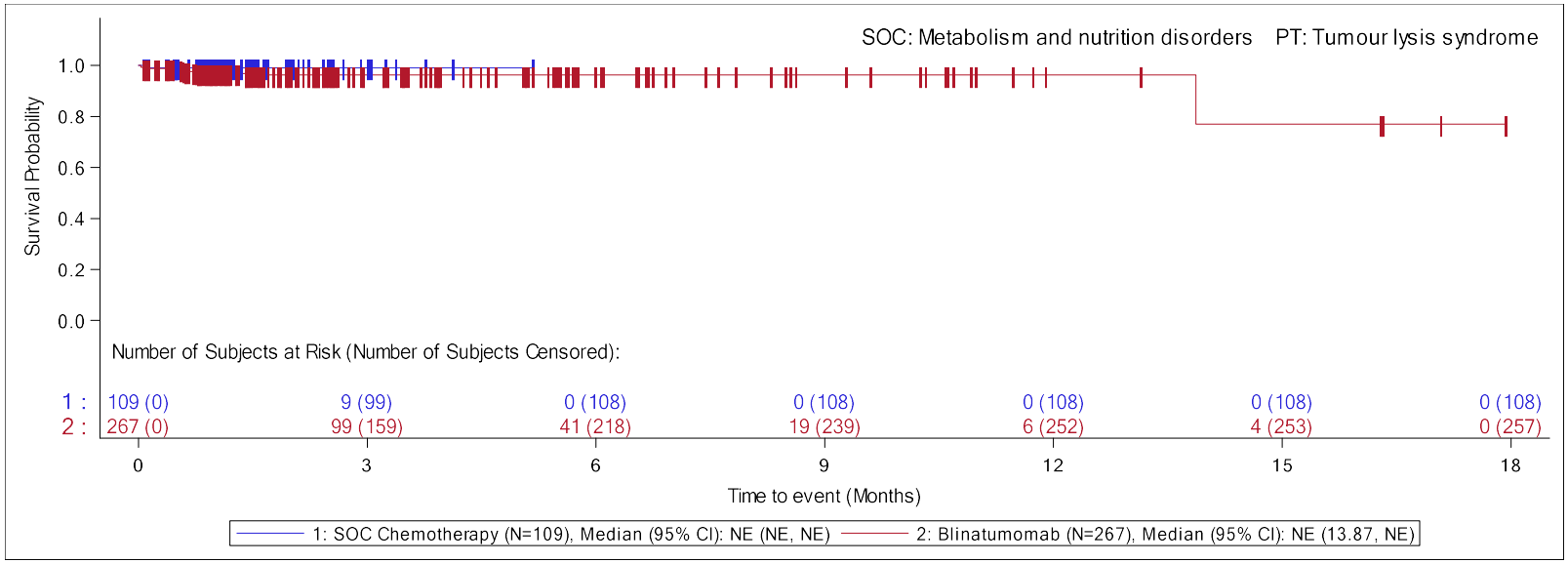

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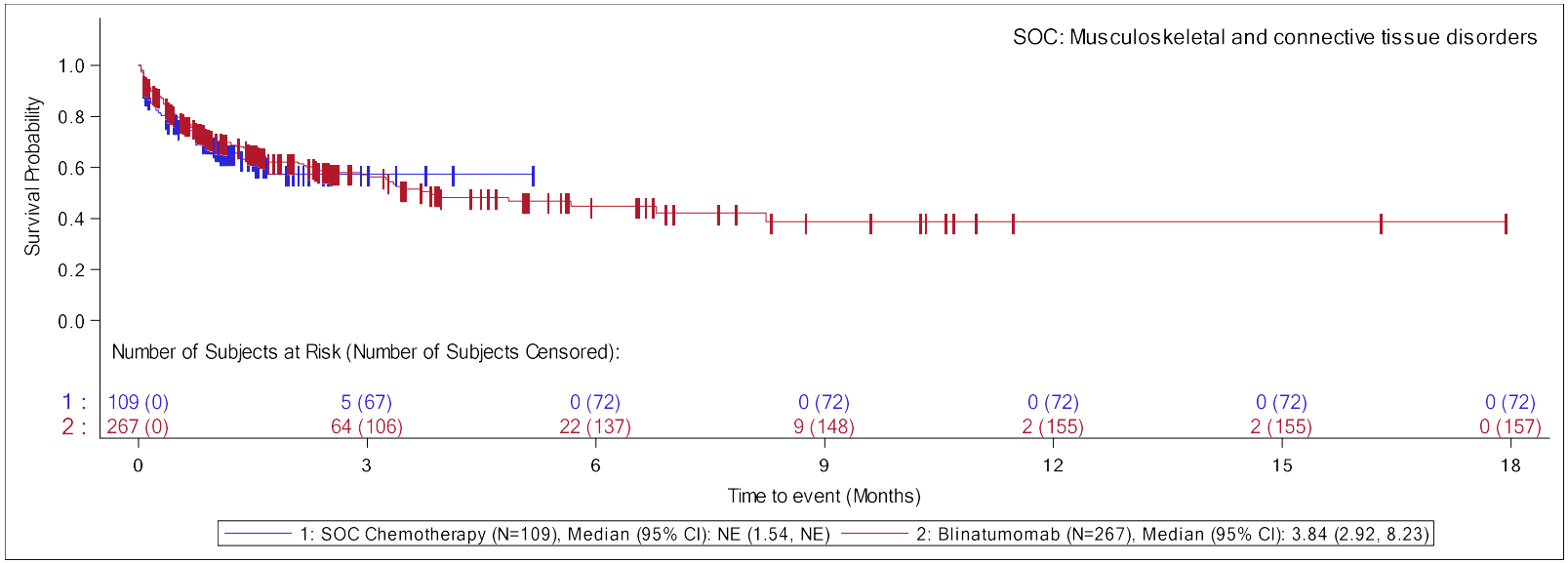

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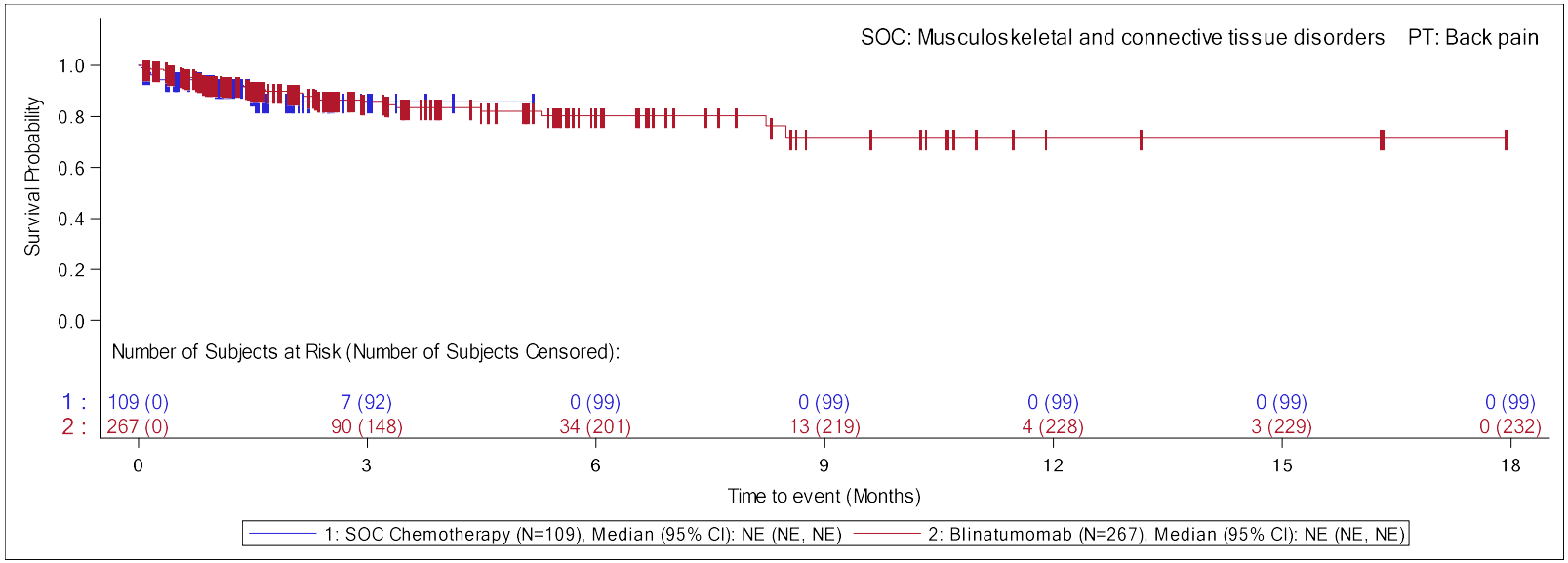

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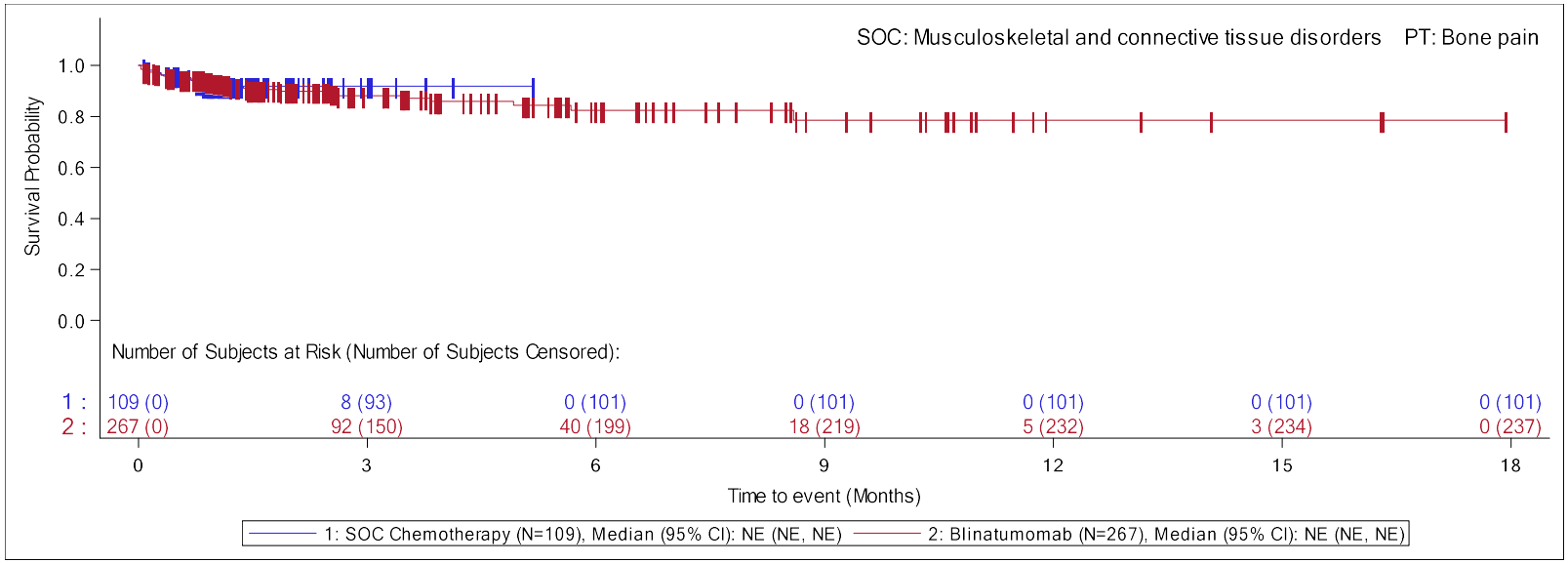

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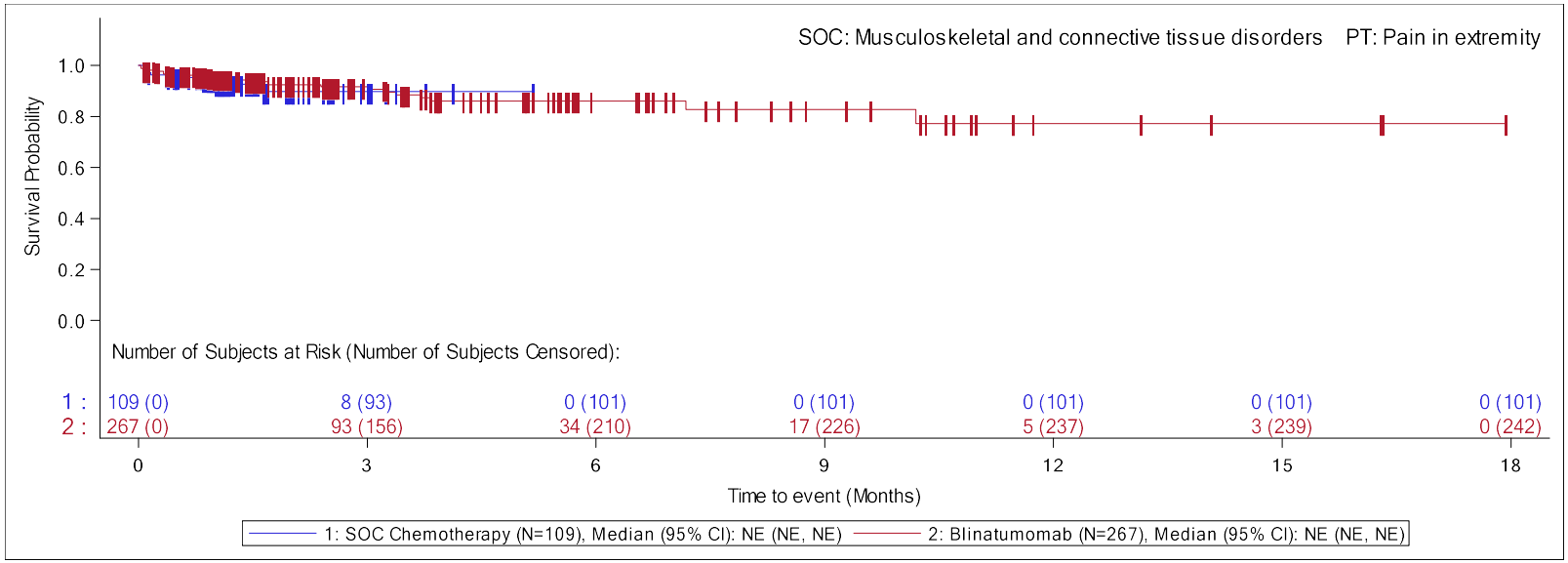

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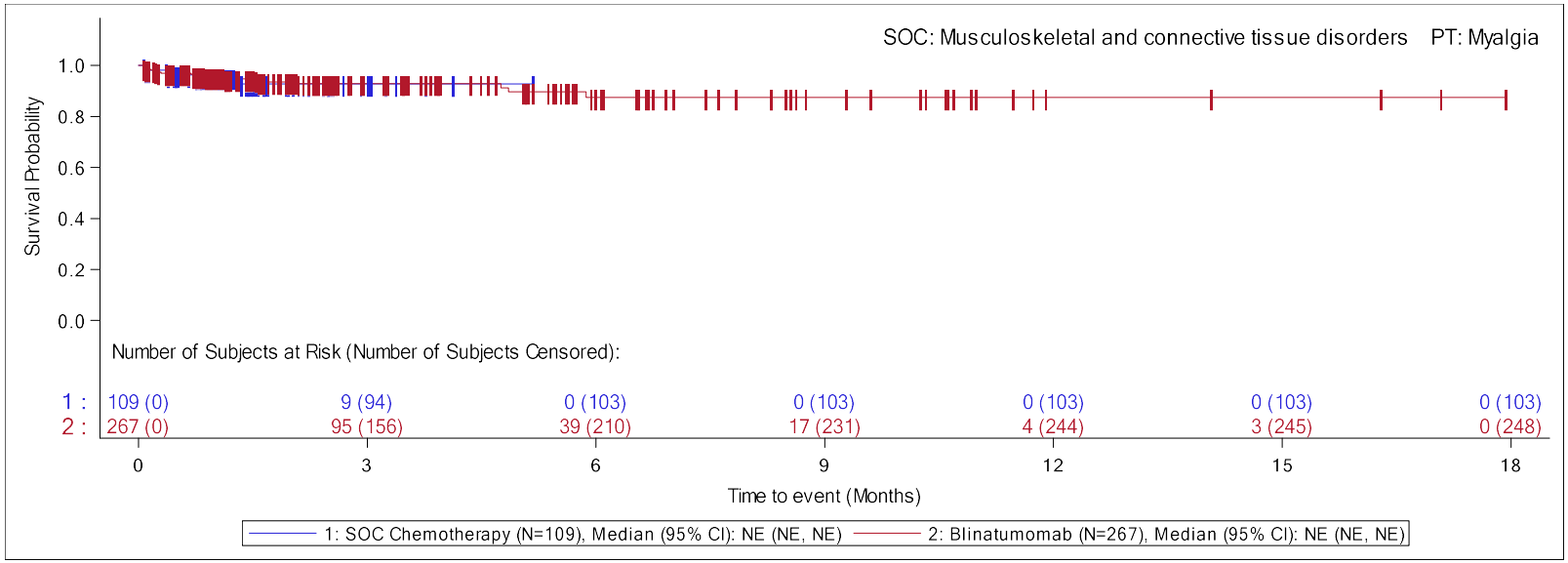

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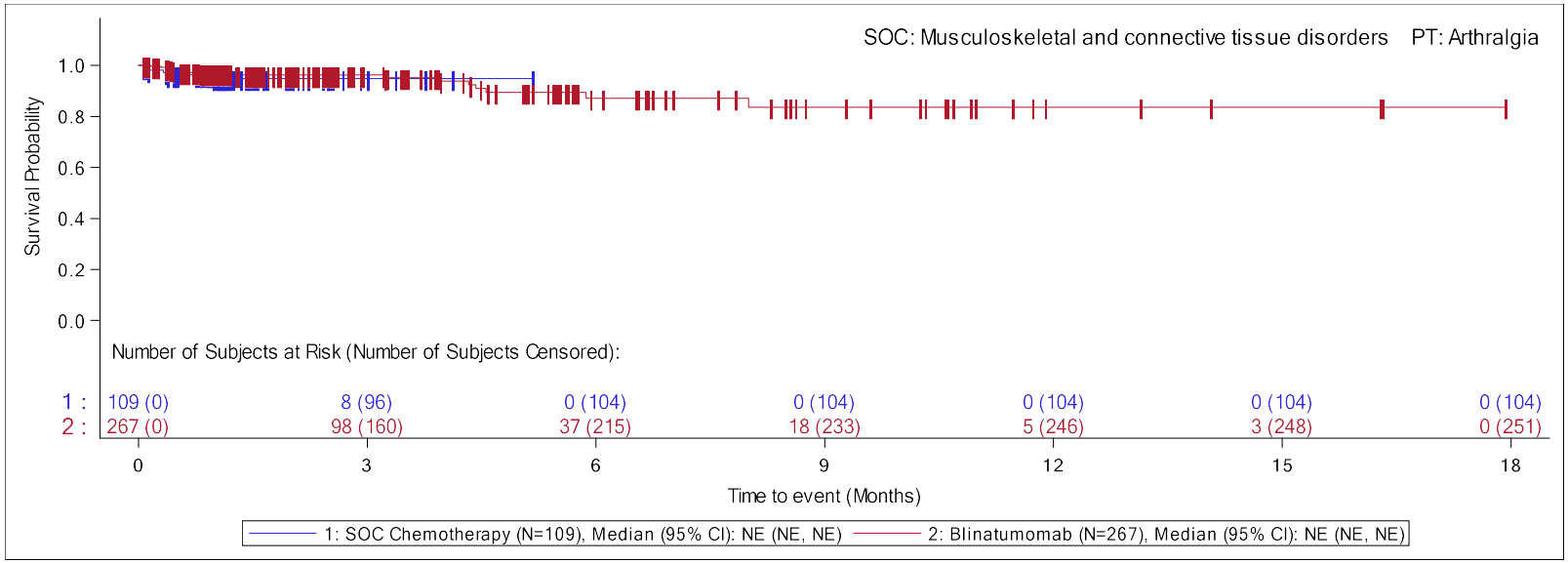

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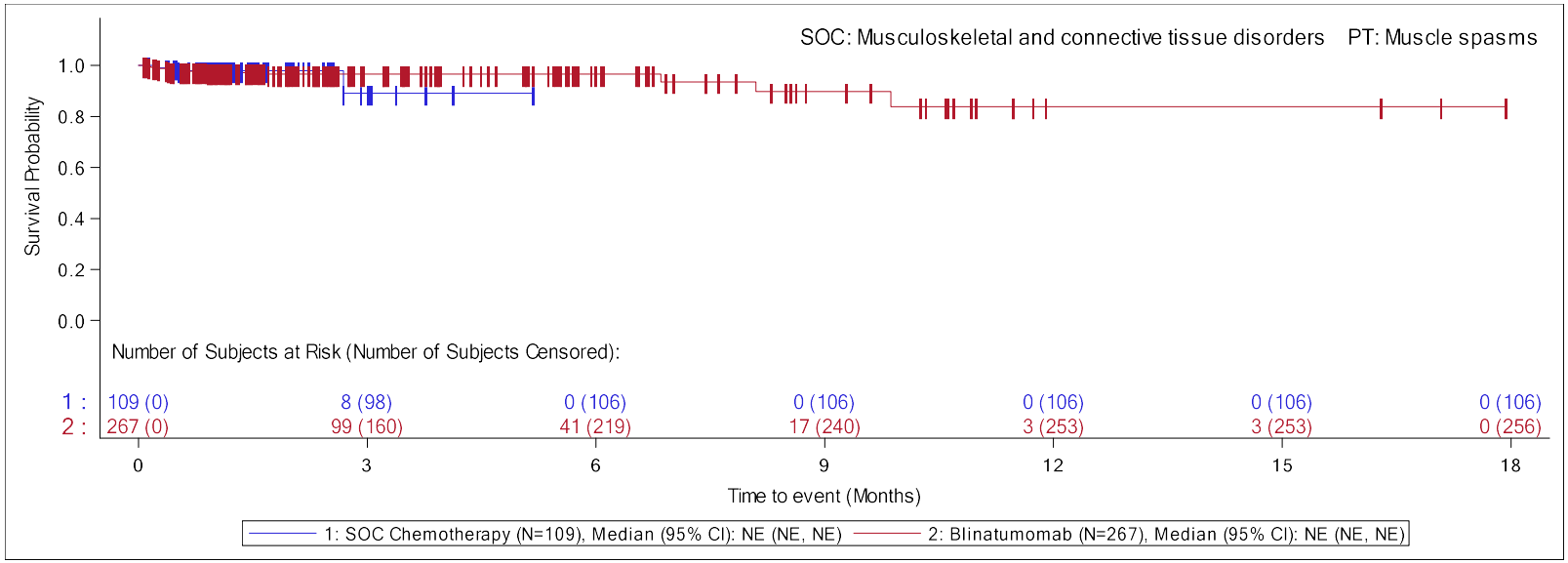

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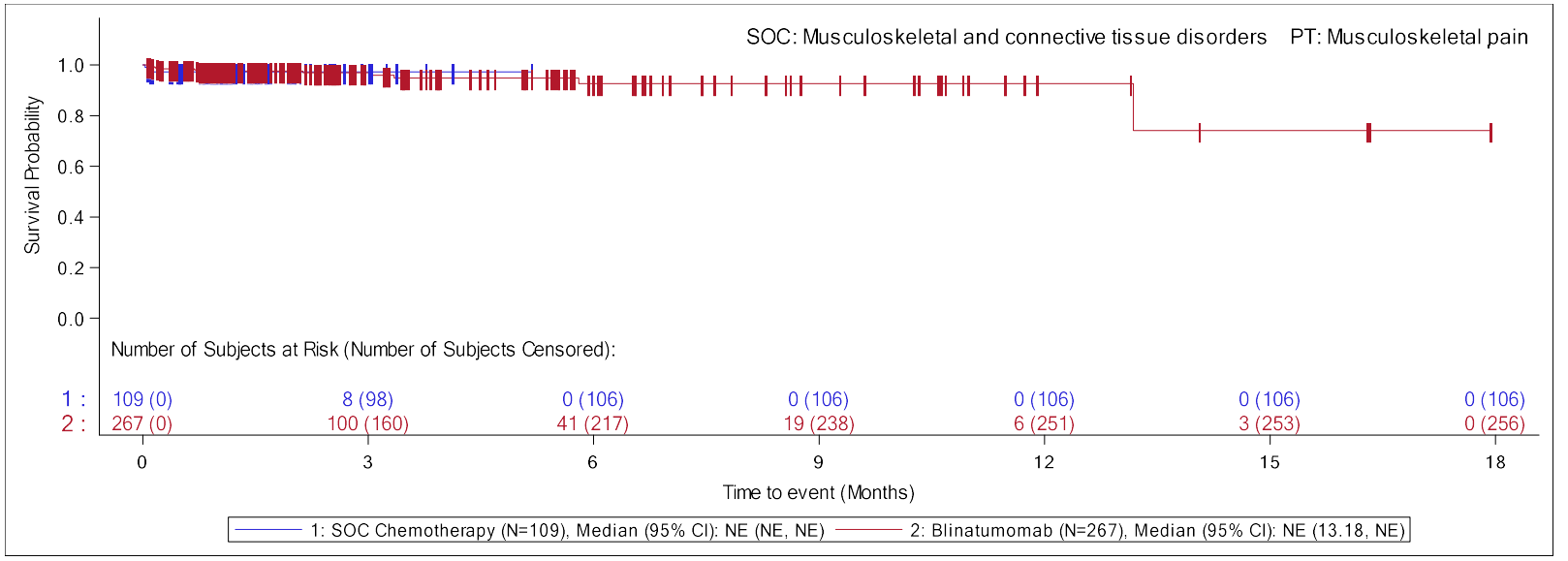

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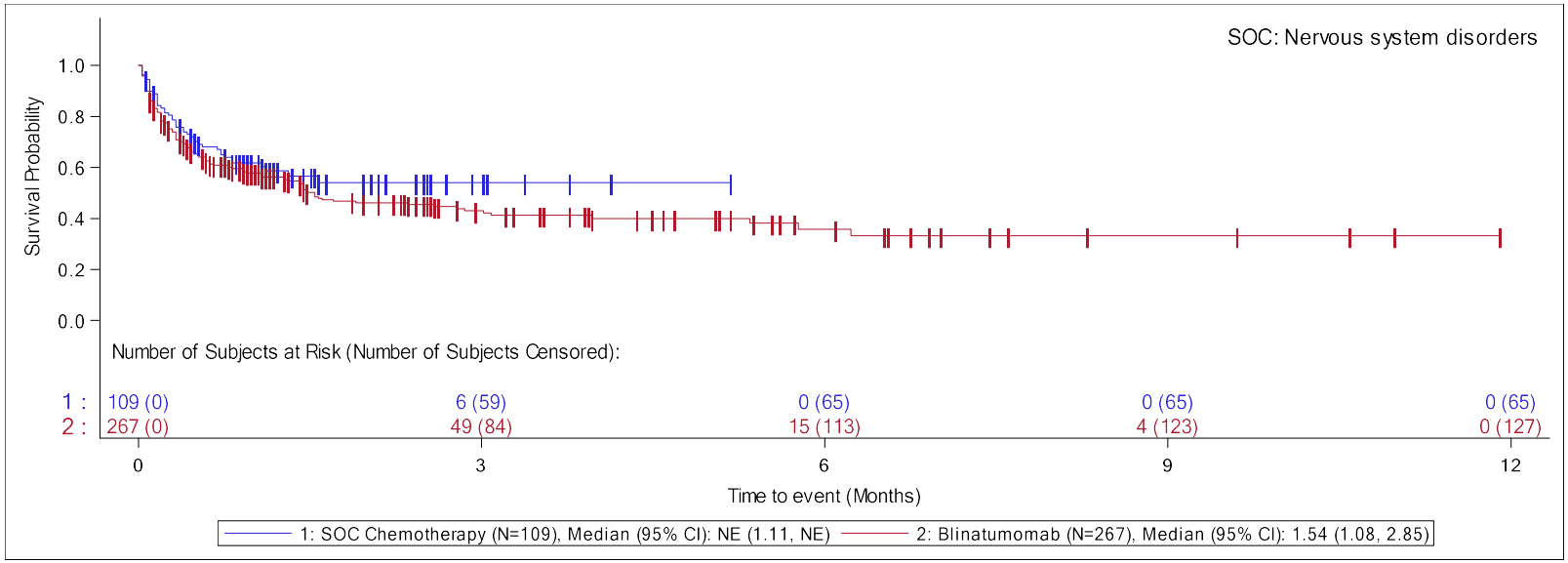

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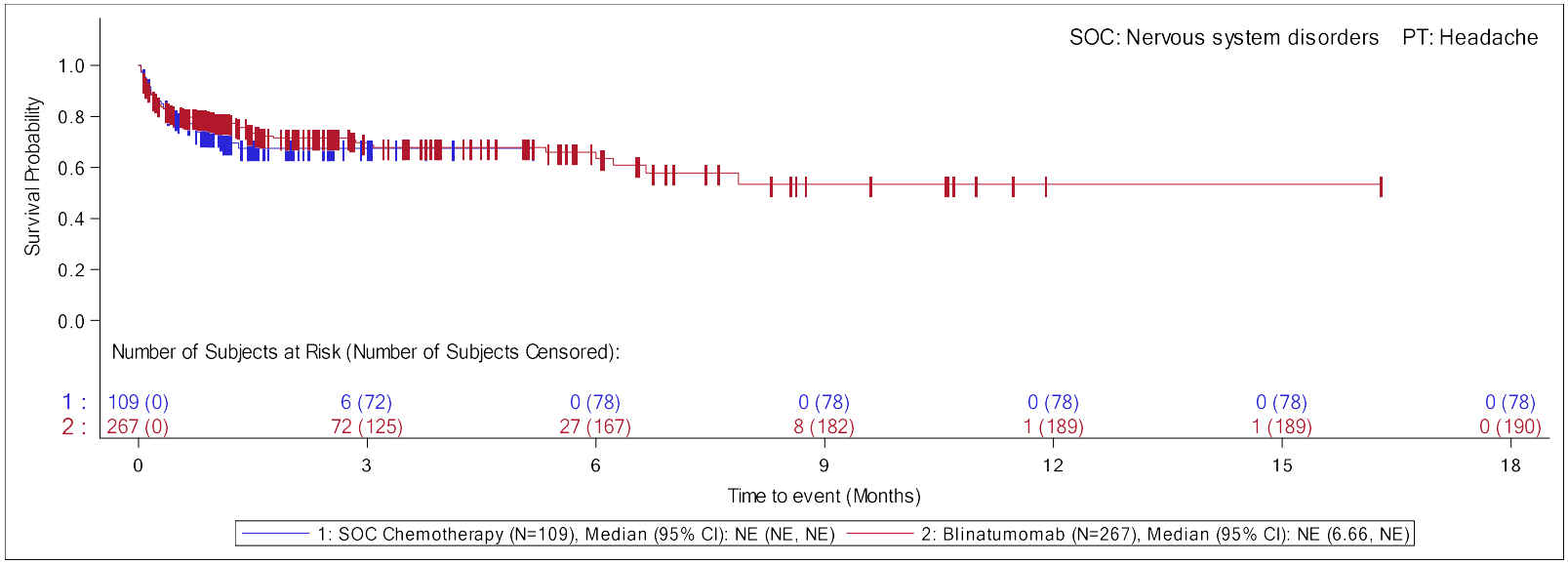

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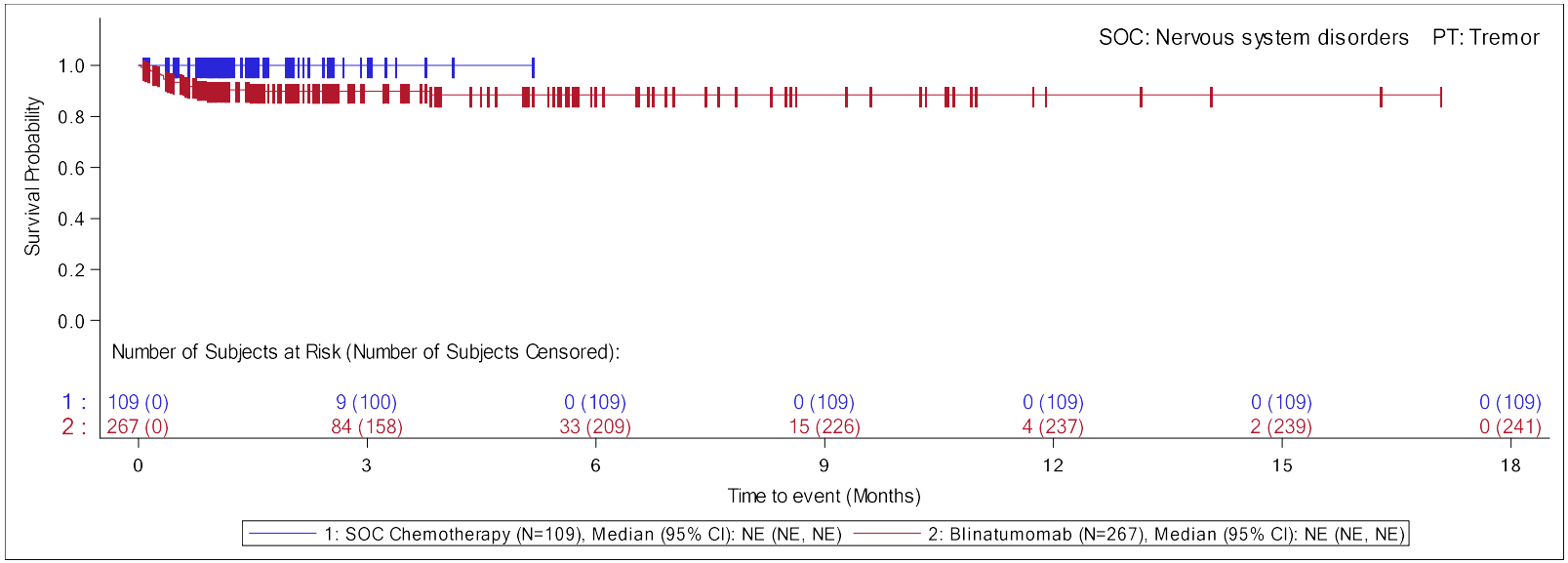

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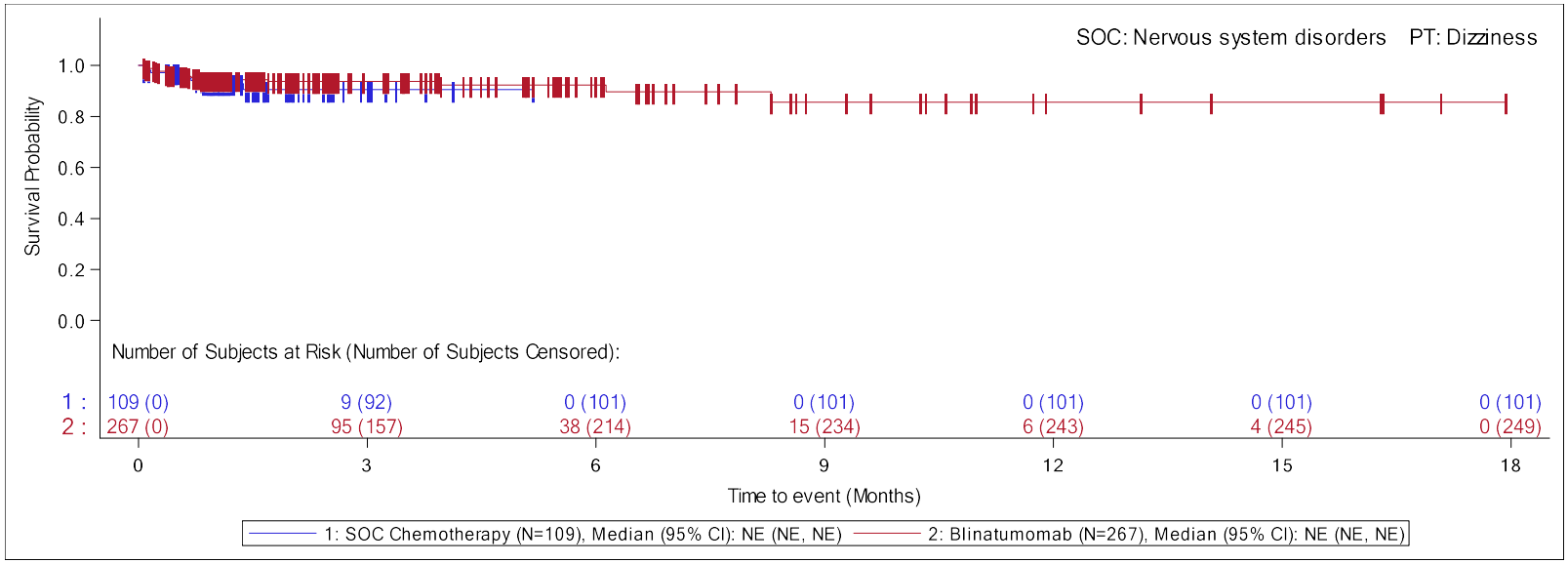

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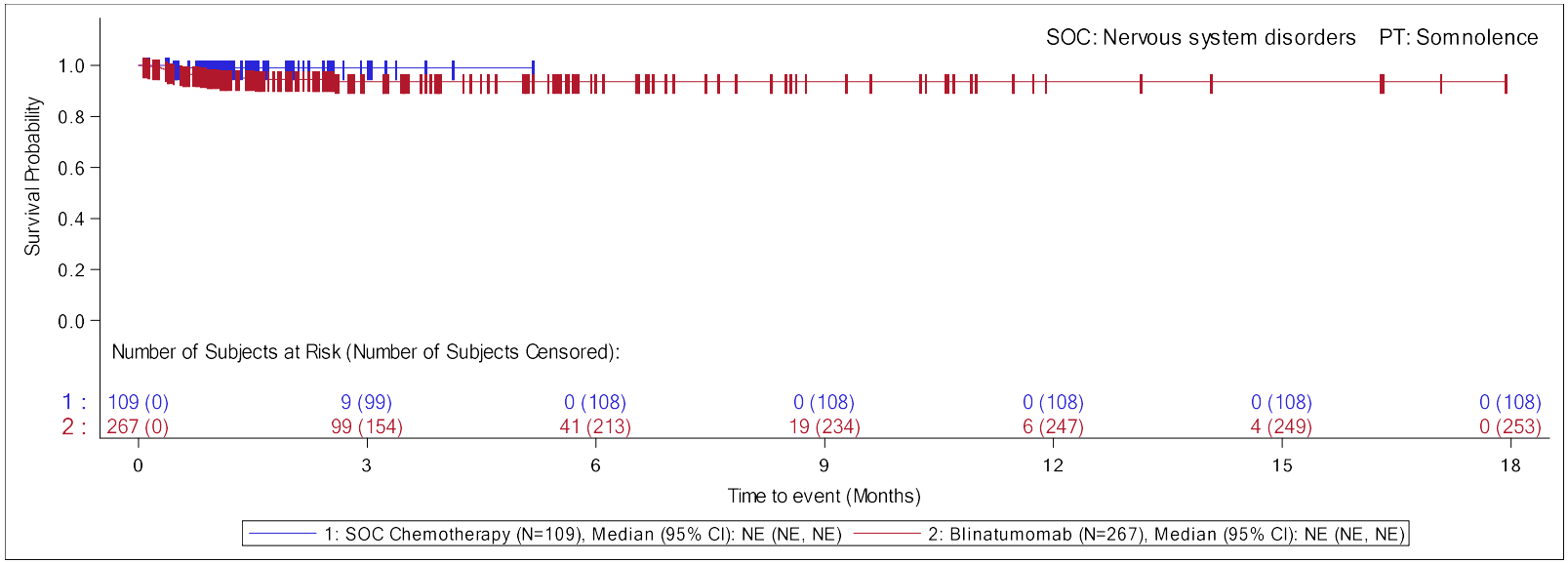

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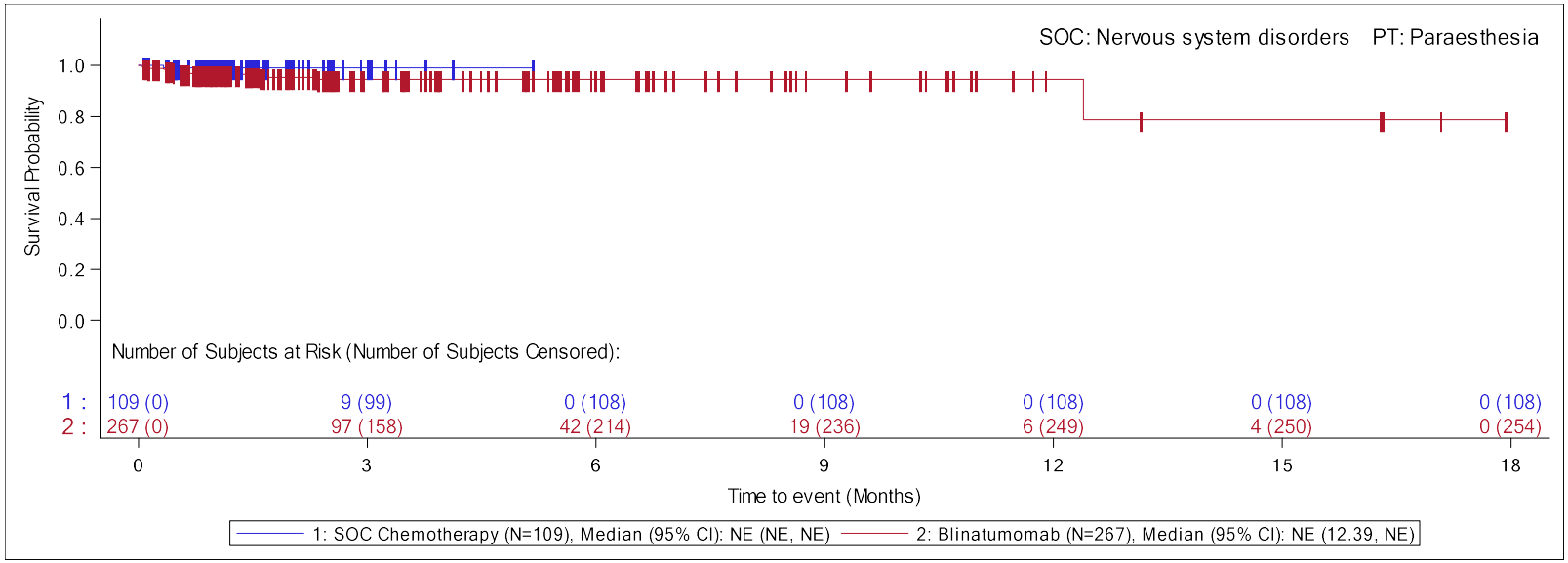

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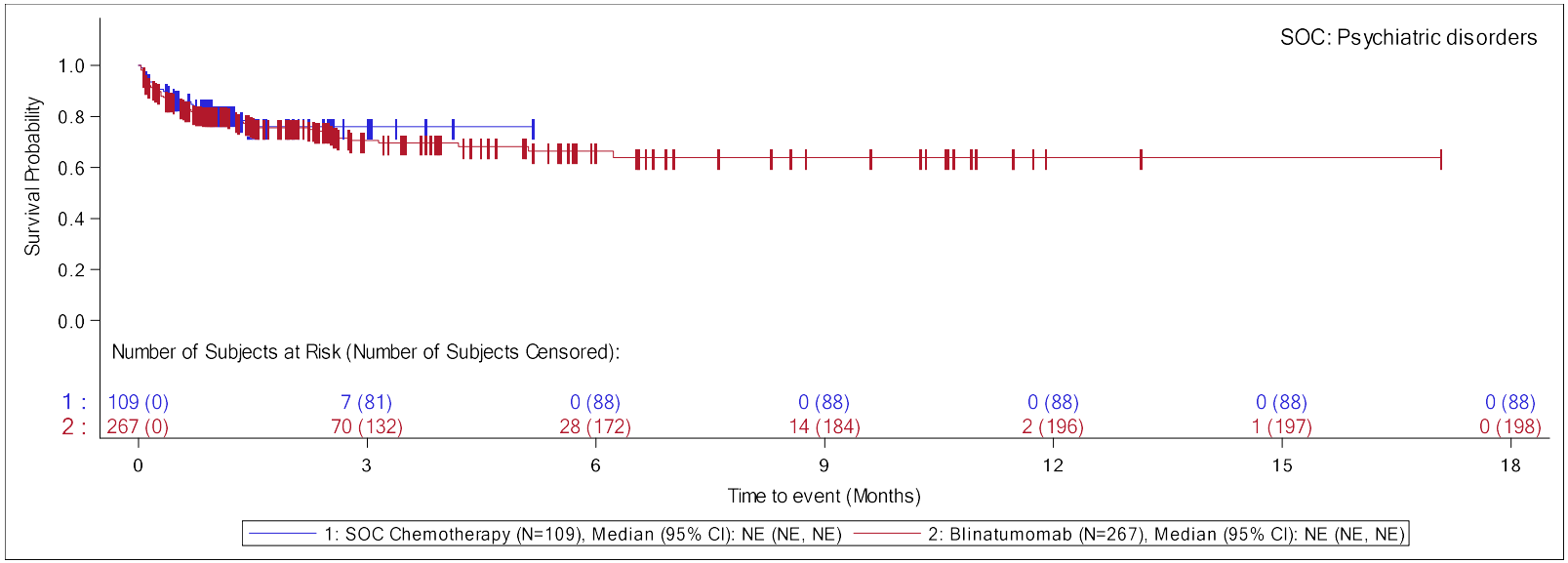
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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Data cut-off date: 04JAN2016

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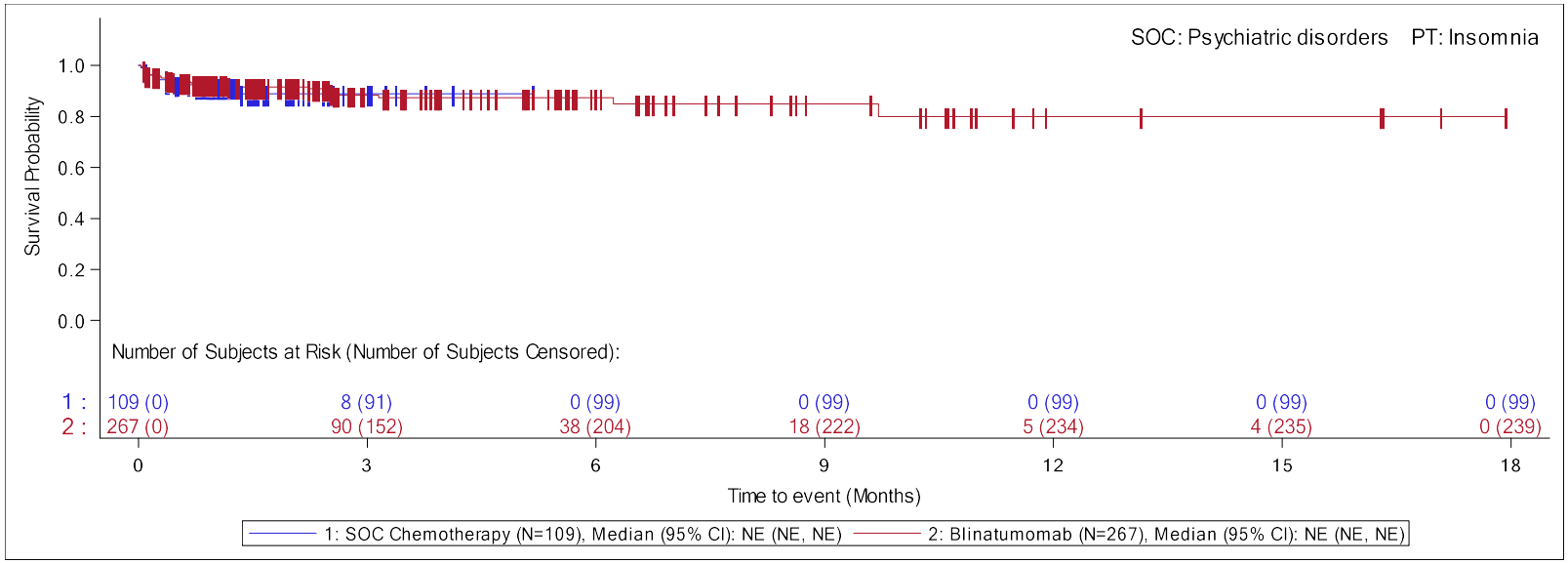

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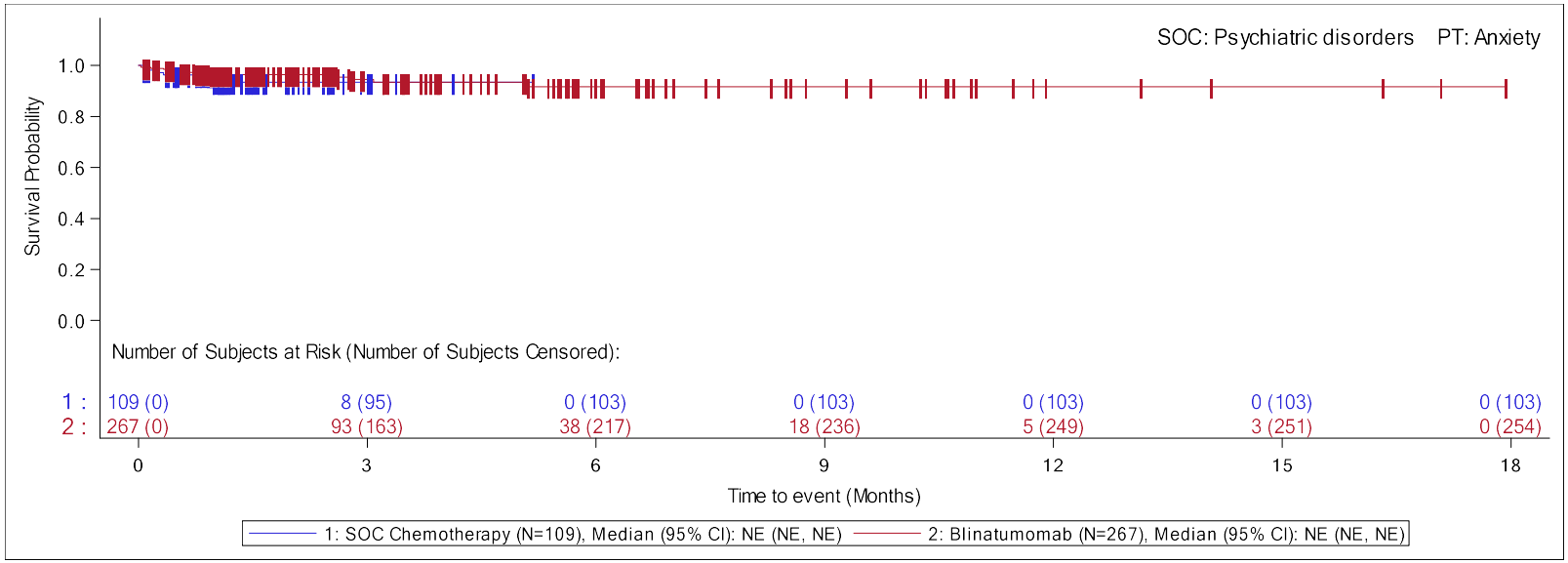

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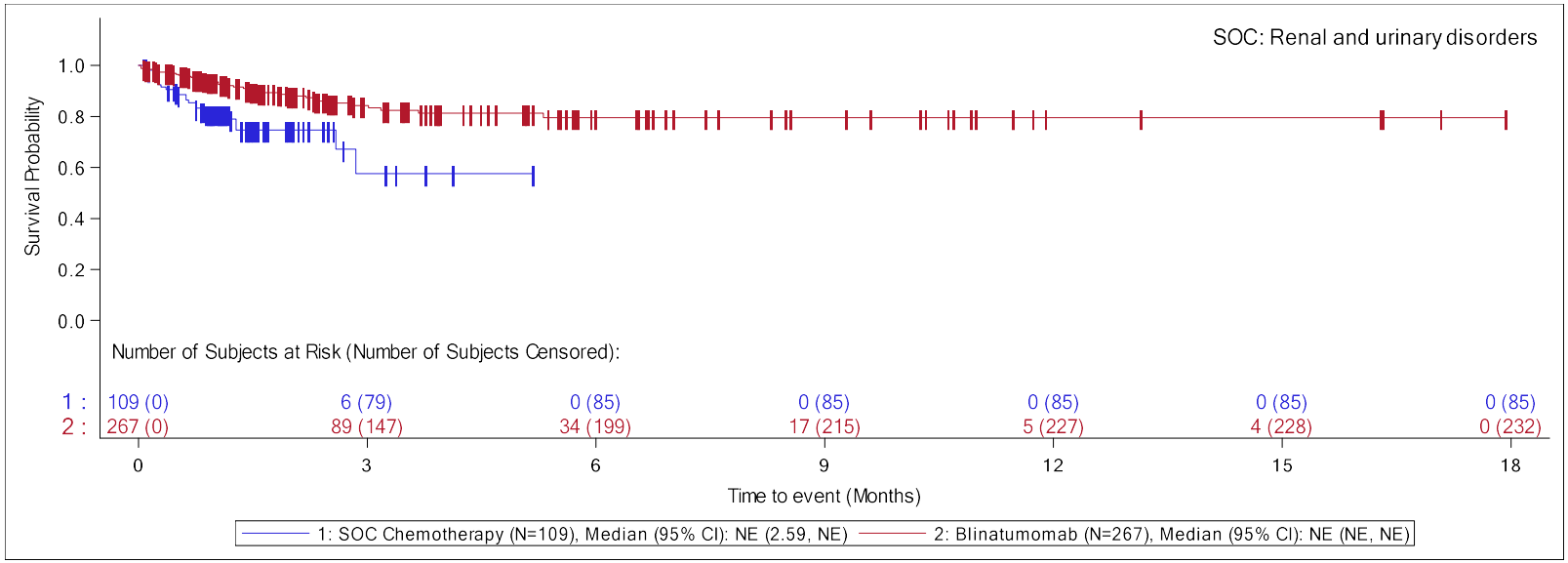

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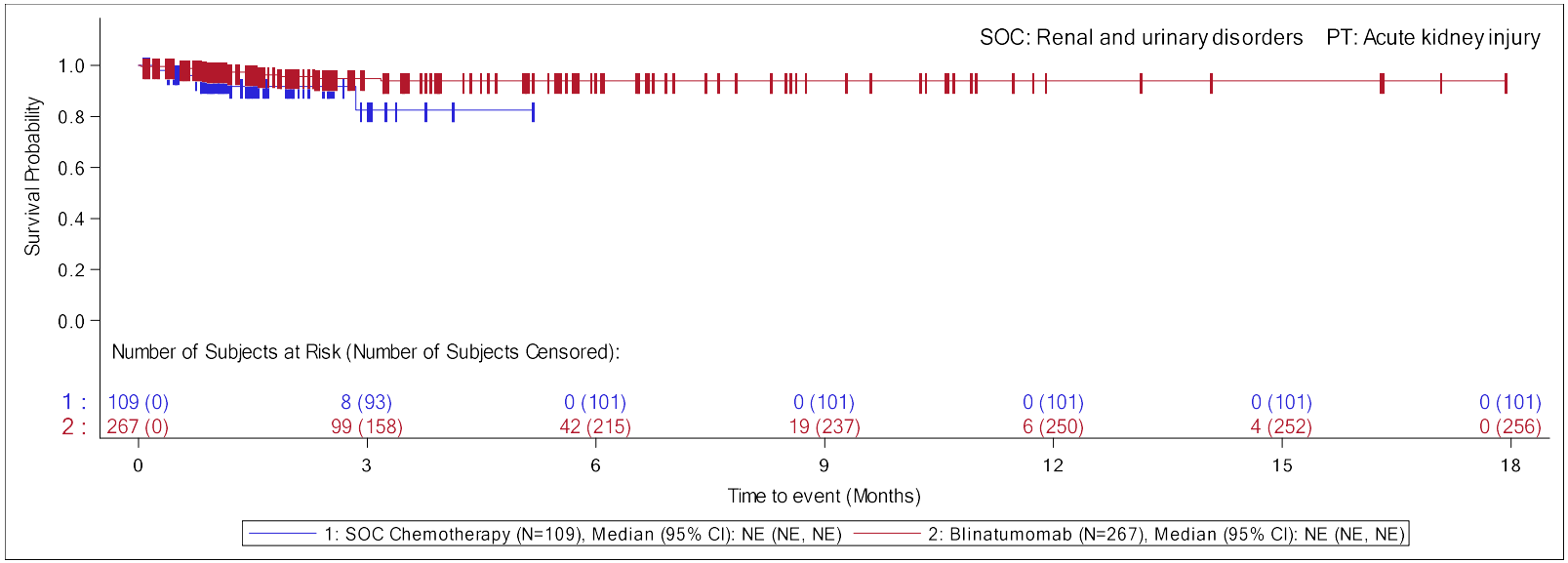

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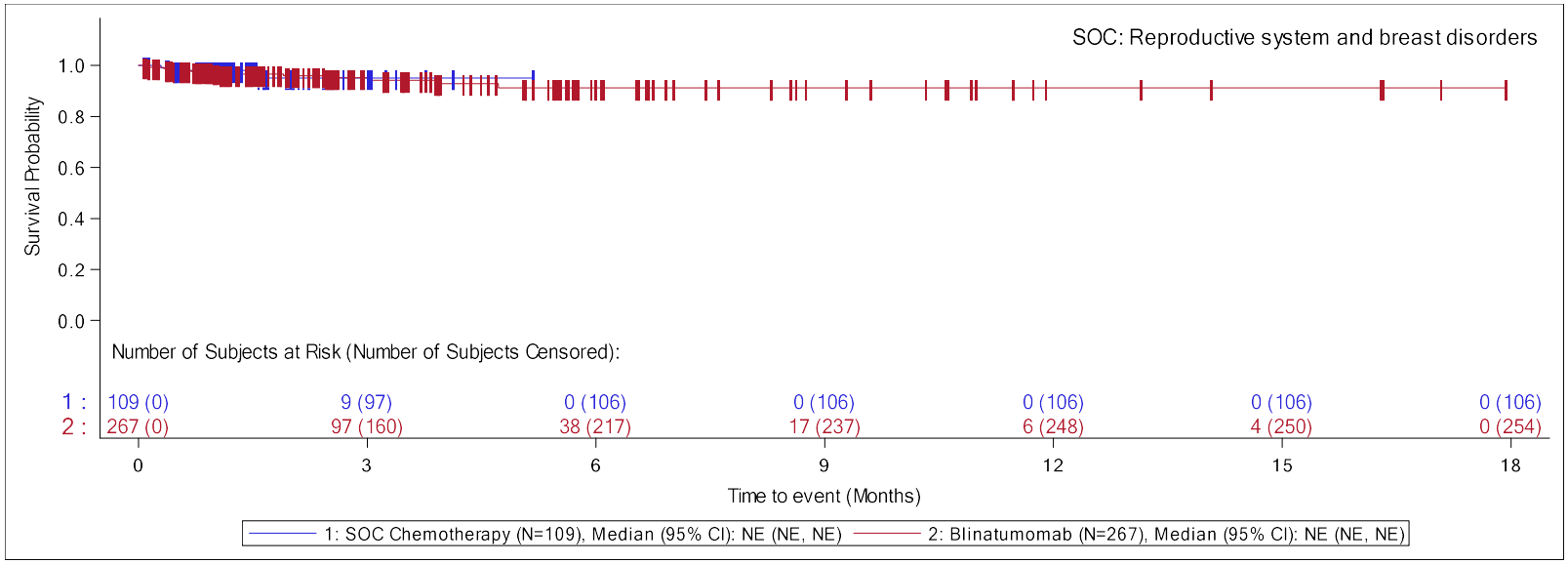

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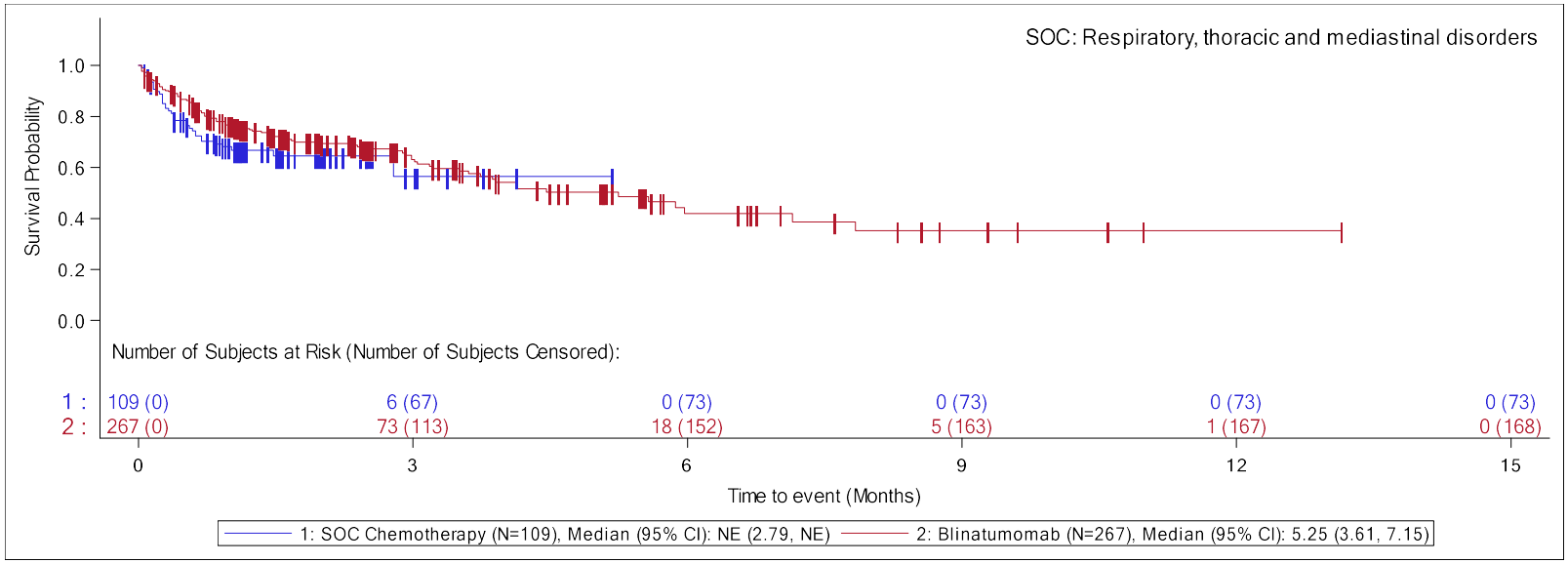

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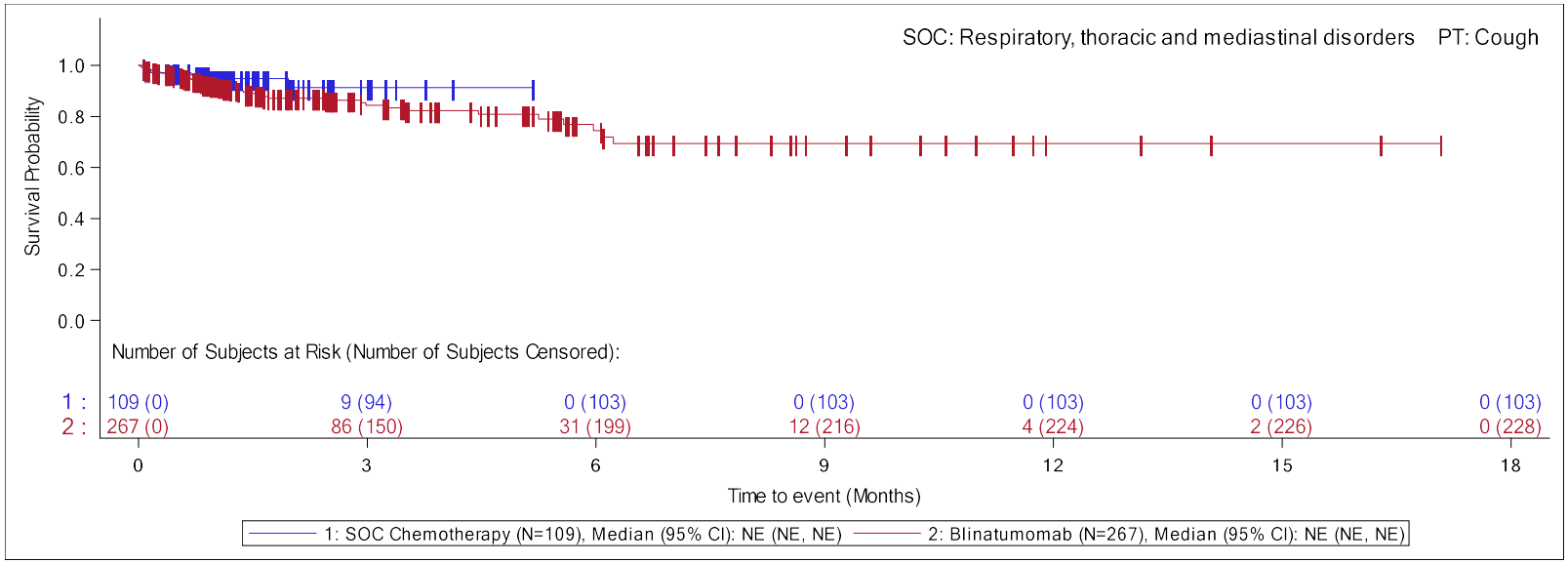

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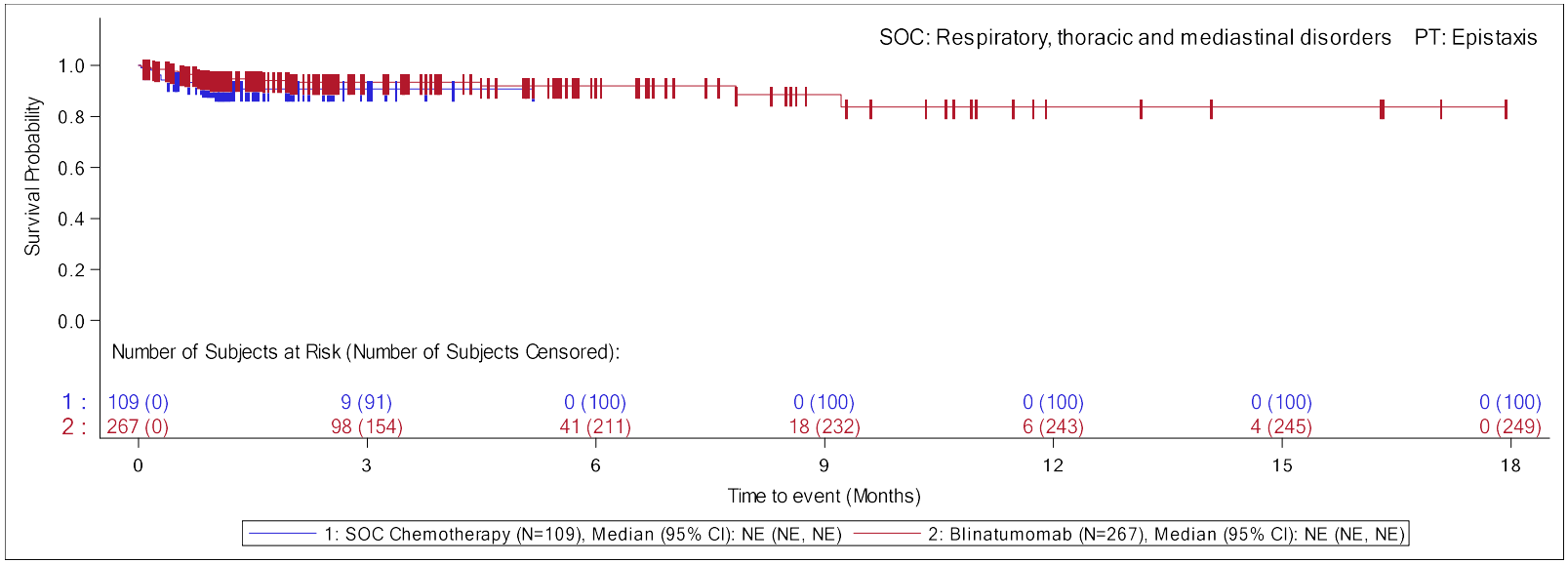

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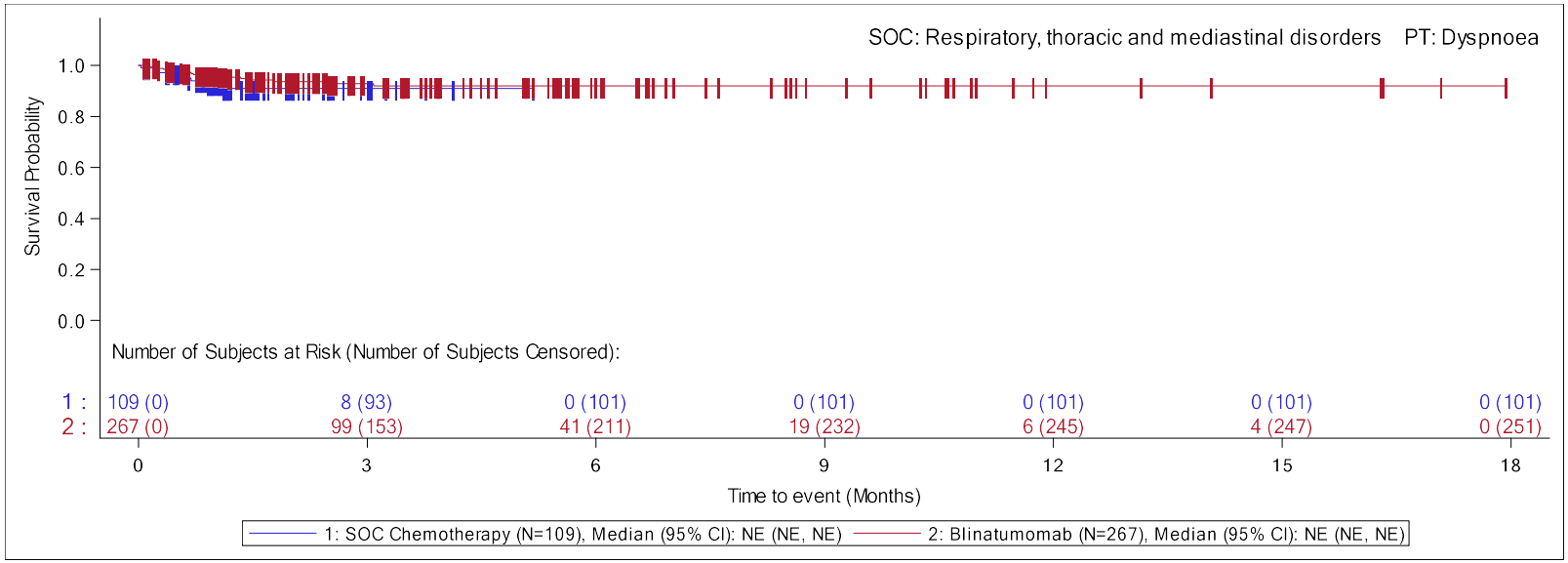

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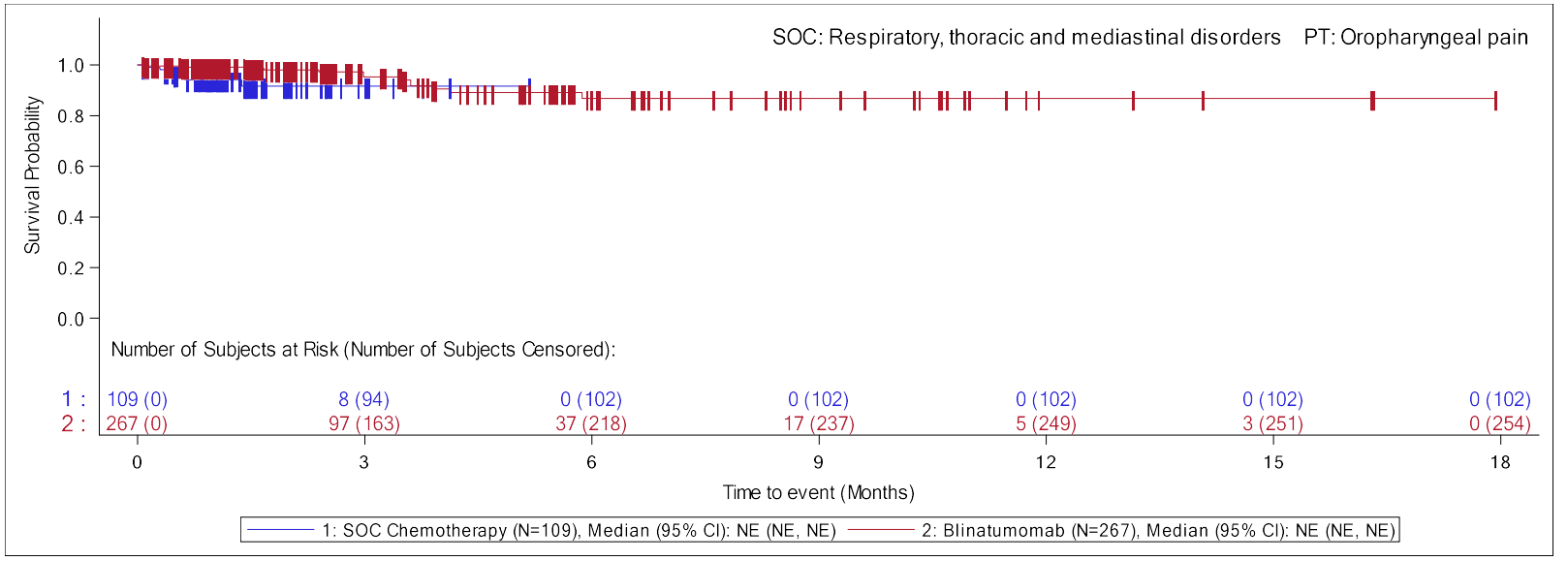

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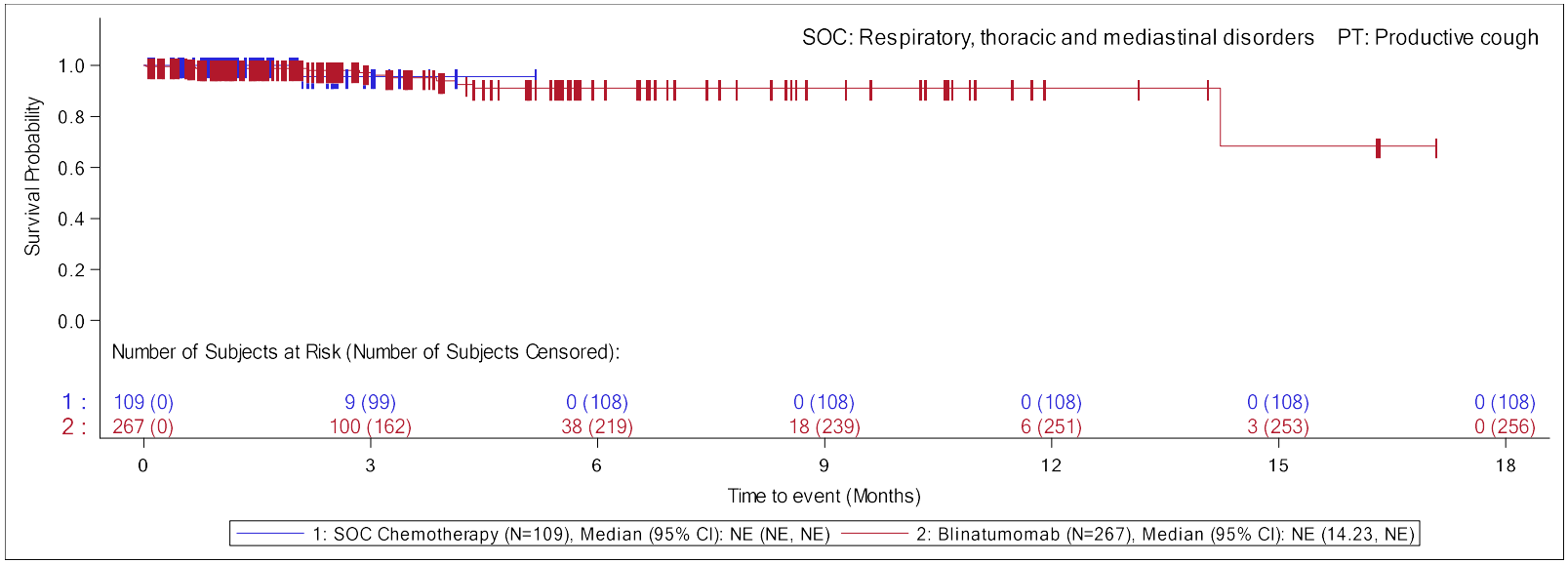

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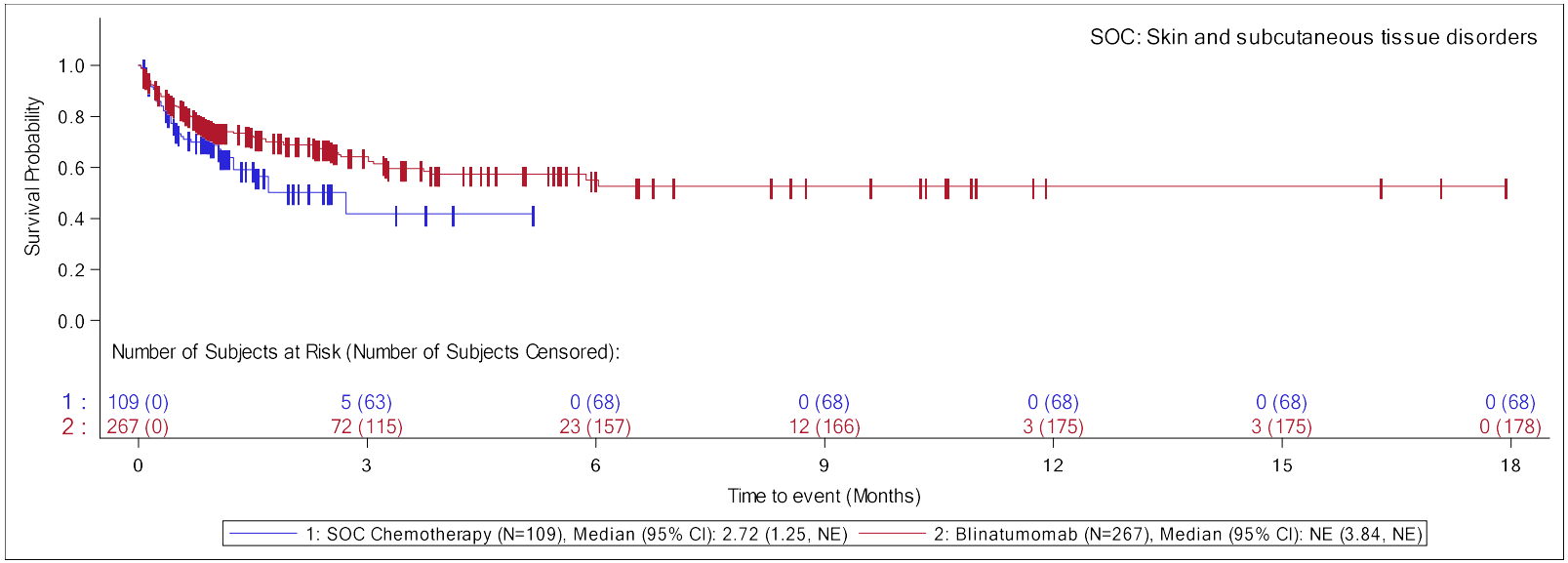

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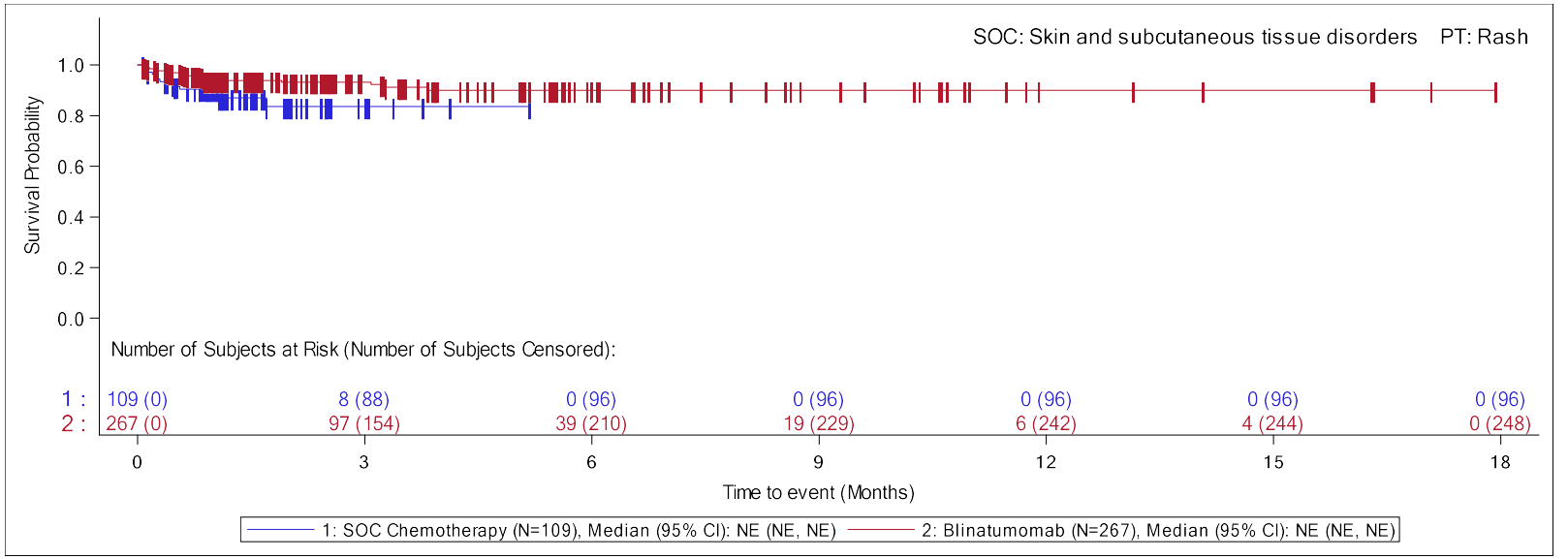

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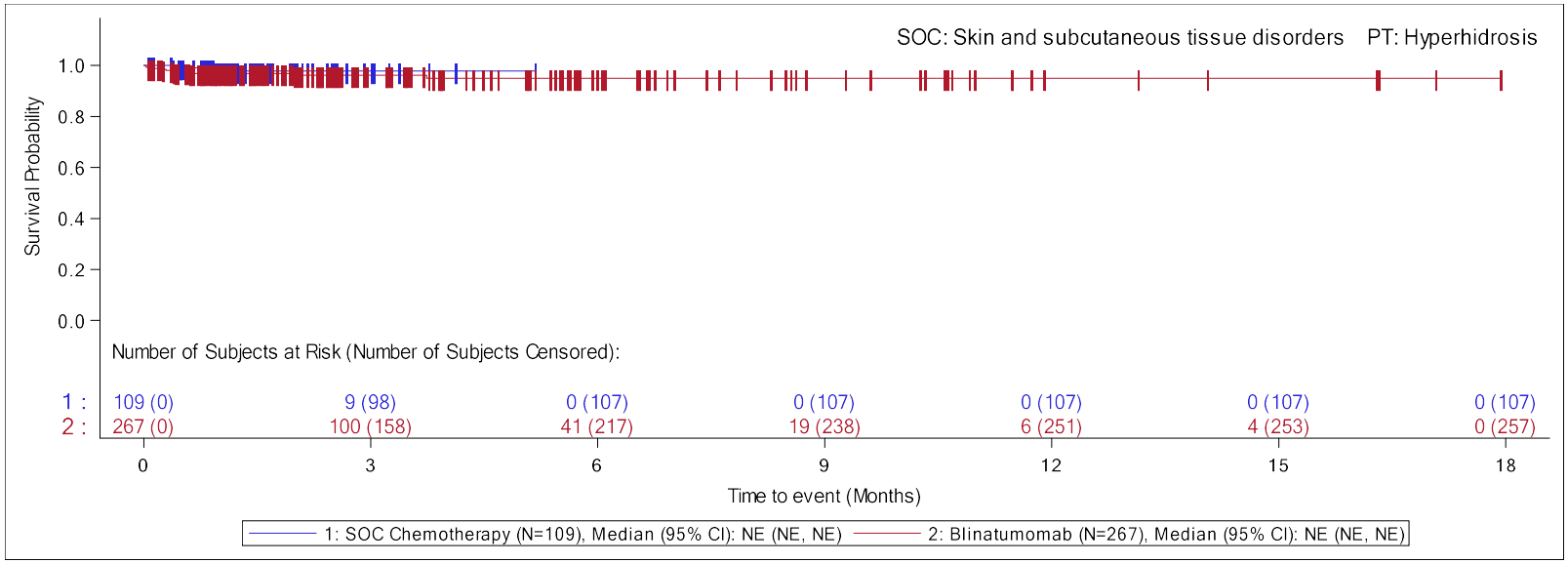

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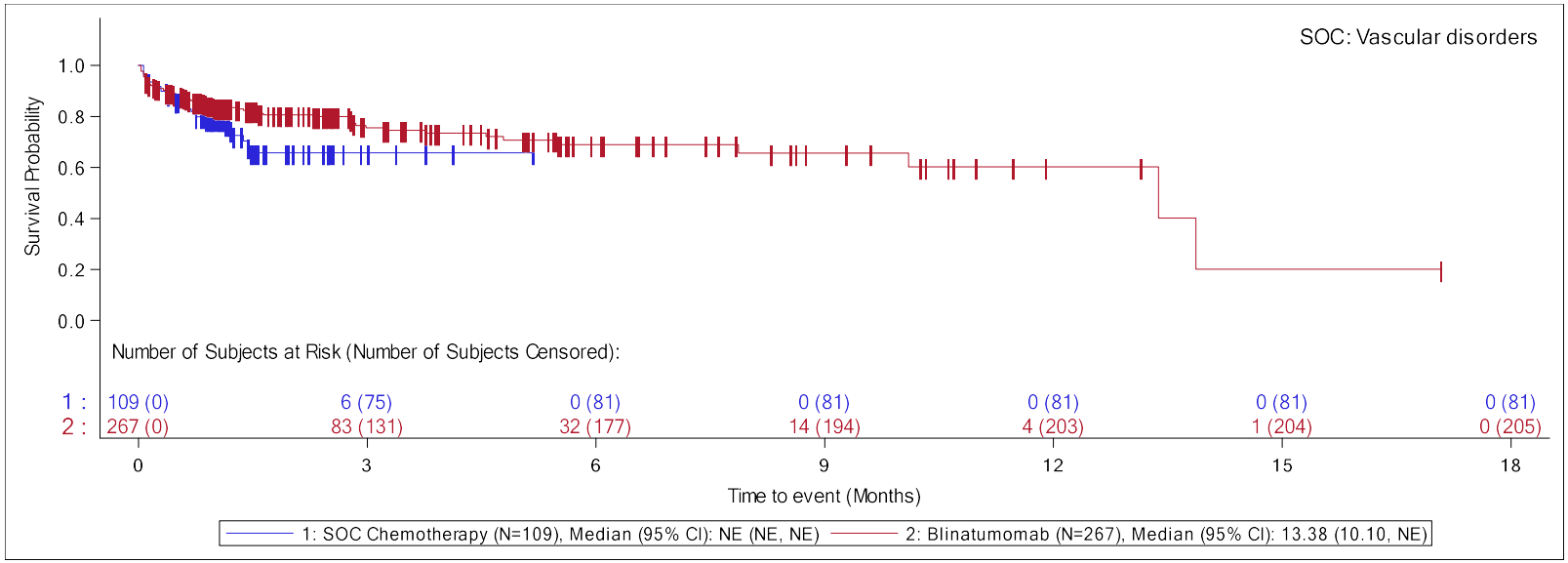

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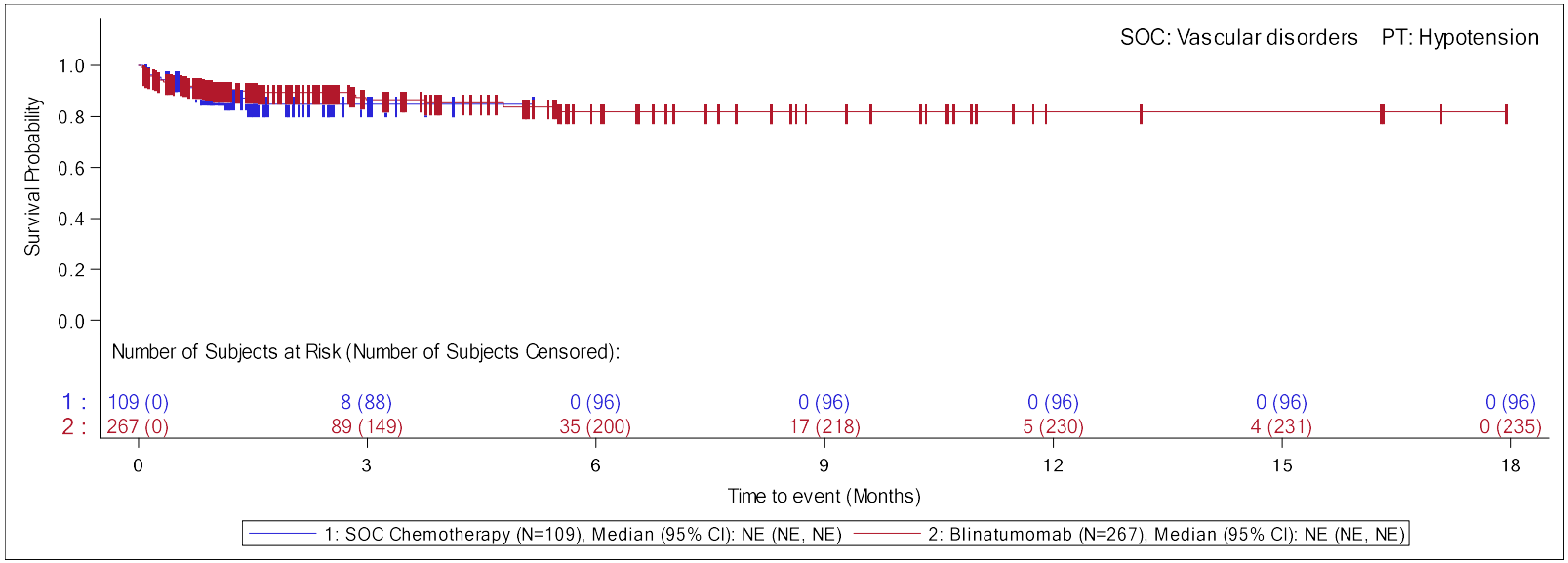

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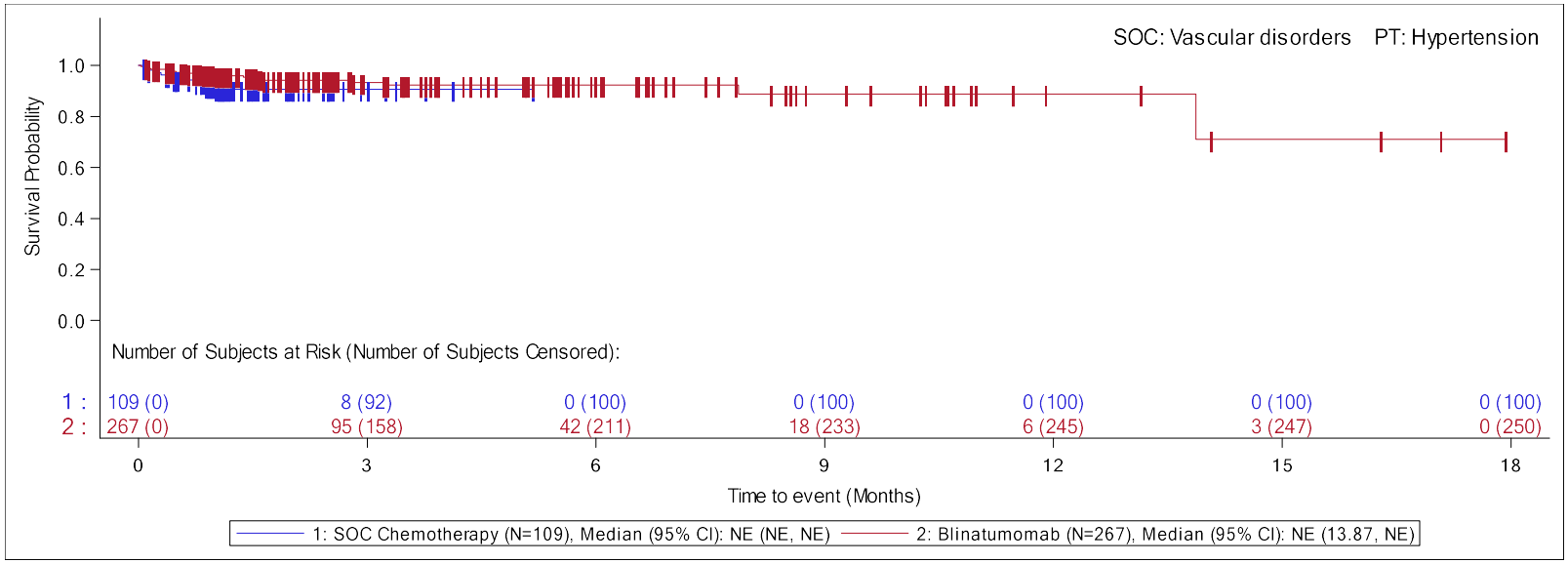

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Anhang 4-G2.9.6: Sicherheit: SUE nach SOC, PT

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	17 (15.6)	36 (13.5)	
Unstratified log-rank test			
Normal score[b]			-5.69
p-value			0.0505
Stratified log-rank test[c]			
Normal score[b]			-5.92
p-value			0.0398

Page 1 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:50) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	1.97, NE	NE, NE	
Min, Max	0.1, 2.8	0.1, 6.7	
Unstratified hazard ratio[e]			0.55
(95% CI)			(0.31, 1.01)
p-value			0.0534
Stratified hazard ratio[c,e]			0.54
(95% CI)			(0.29, 0.98)
p-value			0.0433

Page 2 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	23 (8.6)	
Unstratified log-rank test			
Normal score[b]			-4.55
p-value			0.0541
Stratified log-rank test[c]			
Normal score[b]			-4.45
p-value			0.0599

Page 3 of 24

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	2.82, NE	NE, NE	
Min, Max	0.2, 2.8	0.1, 6.7	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.24, 1.03)
p-value			0.0587
Stratified hazard ratio[c,e]			0.50
(95% CI)			(0.24, 1.04)
p-value			0.0650

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:50) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	27 (10.1)	
Unstratified log-rank test			
Normal score[b]			3.77
p-value			0.0698
Stratified log-rank test[c]			
Normal score[b]			3.66
p-value			0.0735

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.7, 1.0	0.1, 10.0	
Unstratified hazard ratio[e]			3.52
(95% CI)			(0.83, 15.05)
p-value			0.0891
Stratified hazard ratio[c,e]			3.49
(95% CI)			(0.81, 14.96)
p-value			0.0928

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			2.25
p-value			0.1499
Stratified log-rank test[c]			
Normal score[b]			2.27
p-value			0.1460

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	1.0, 1.0	0.1, 10.0	
Unstratified hazard ratio[e]			4.00
(95% CI)			(0.52, 30.82)
p-value			0.1828
Stratified hazard ratio[c,e]			4.06
(95% CI)			(0.53, 31.30)
p-value			0.1792

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			2.65
p-value			0.0567
Stratified log-rank test[c]			
Normal score[b]			2.57
p-value			0.0625

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 3.3	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	33 (30.3)	75 (28.1)	
Unstratified log-rank test			
Normal score[b]			-12.05
p-value			0.0023
Stratified log-rank test[c]			
Normal score[b]			-11.91
p-value			0.0025

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	7.44	
95% CI (median)	(2.03, NE)	(5.80, NE)	
Q1, Q3	0.92, NE	2.56, NE	
Min, Max	0.0, 2.1	0.0, 10.0	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.33, 0.80)
p-value			0.0028
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.33, 0.80)
p-value			0.0030

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sepsis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-2.98
p-value			0.0883
Stratified log-rank test[c]			
Normal score[b]			-2.85
p-value			0.1055

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.1, 8.1	
Unstratified hazard ratio[e]			0.44
(95% CI)			(0.17, 1.16)
p-value			0.0965
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.17, 1.21)
p-value			0.1148

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pneumonia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			0.33
p-value			0.8009
Stratified log-rank test[c]			
Normal score[b]			0.26
p-value			0.8398

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.6	0.0, 8.3	
Unstratified hazard ratio[e]			1.22
(95% CI)			(0.25, 5.96)
p-value			0.8016
Stratified hazard ratio[c,e]			1.18
(95% CI)			(0.24, 5.77)
p-value			0.8400

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Injury, poisoning and procedural complications			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			3.36
p-value			0.0573
Stratified log-rank test[c]			
Normal score[b]			3.49
p-value			0.0506

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:50) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.5, 0.5	0.0, 2.5	
Unstratified hazard ratio[e]			5.69
(95% CI)			(0.75, 43.23)
p-value			0.0926
Stratified hazard ratio[c,e]			5.93
(95% CI)			(0.78, 45.01)
p-value			0.0854

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			1.19
p-value			0.4330
Stratified log-rank test[c]			
Normal score[b]			1.18
p-value			0.4353

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
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[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.4, 0.7	0.0, 2.1	
Unstratified hazard ratio[e]			1.82
(95% CI)			(0.40, 8.36)
p-value			0.4401
Stratified hazard ratio[c,e]			1.82
(95% CI)			(0.40, 8.37)
p-value			0.4419

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			1.21
p-value			0.5395
Stratified log-rank test[c]			
Normal score[b]			1.05
p-value			0.5894

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 5.9	
Unstratified hazard ratio[e]			1.41
(95% CI)			(0.47, 4.20)
p-value			0.5422
Stratified hazard ratio[c,e]			1.35
(95% CI)			(0.45, 4.04)
p-value			0.5909

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			0.56
p-value			0.7602
Stratified log-rank test[c]			
Normal score[b]			0.20
p-value			0.9078

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.7	0.1, 3.7	
Unstratified hazard ratio[e]			1.19
(95% CI)			(0.39, 3.64)
p-value			0.7608
Stratified hazard ratio[c,e]			1.06
(95% CI)			(0.35, 3.28)
p-value			0.9128

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
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[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
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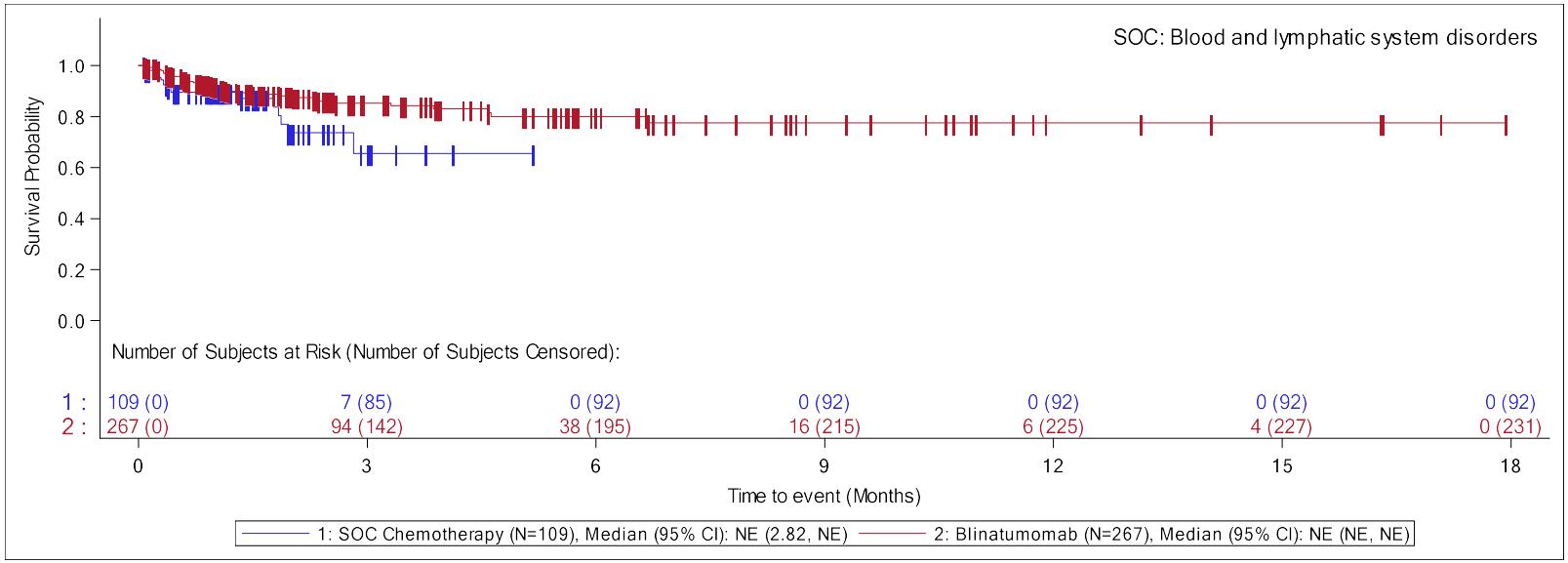
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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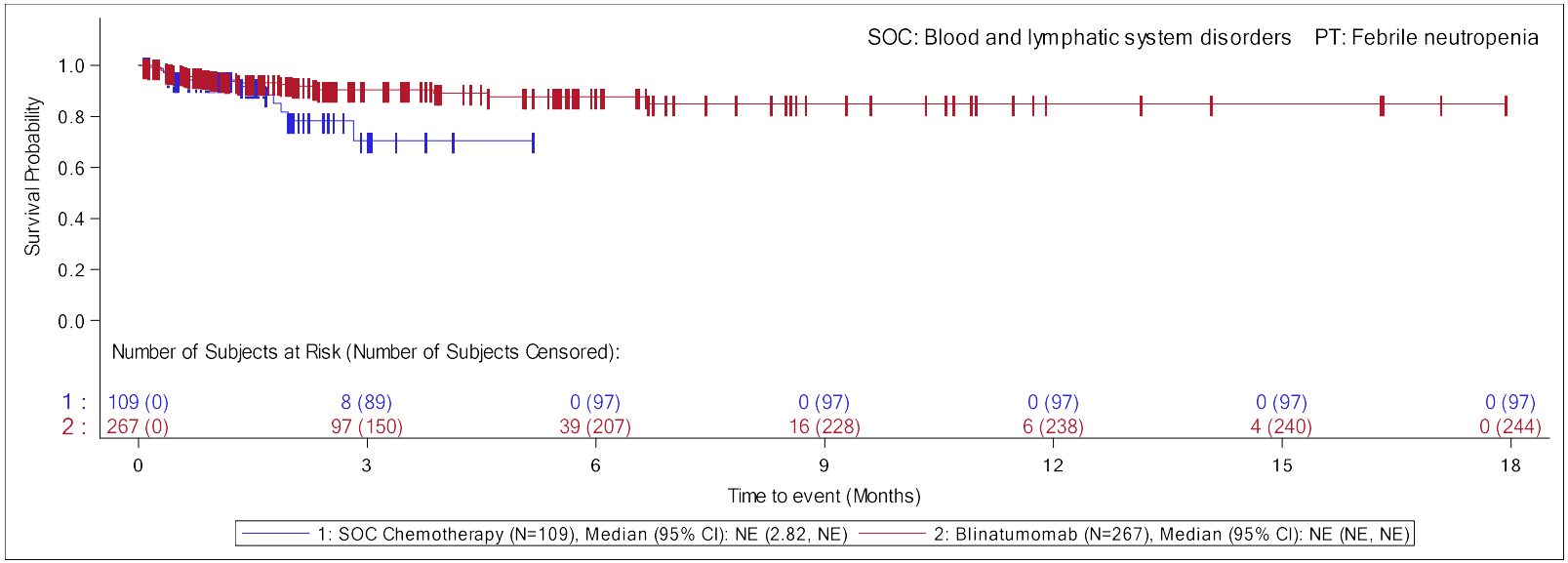

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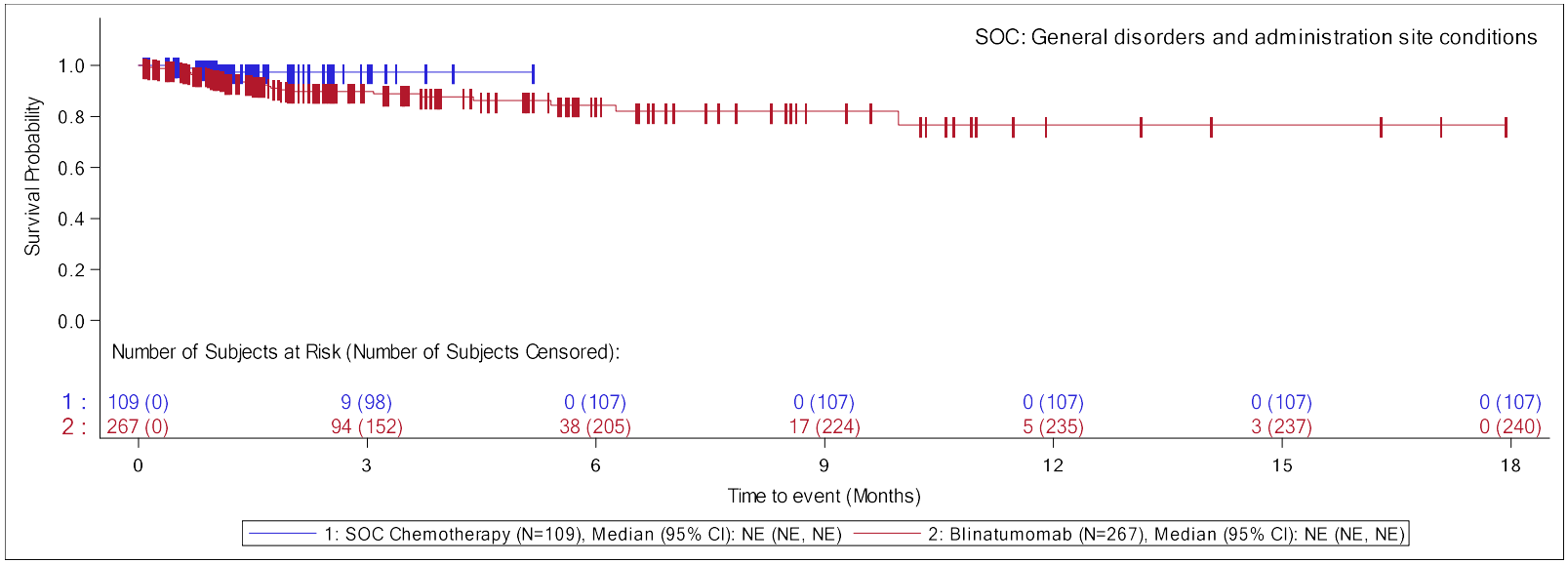

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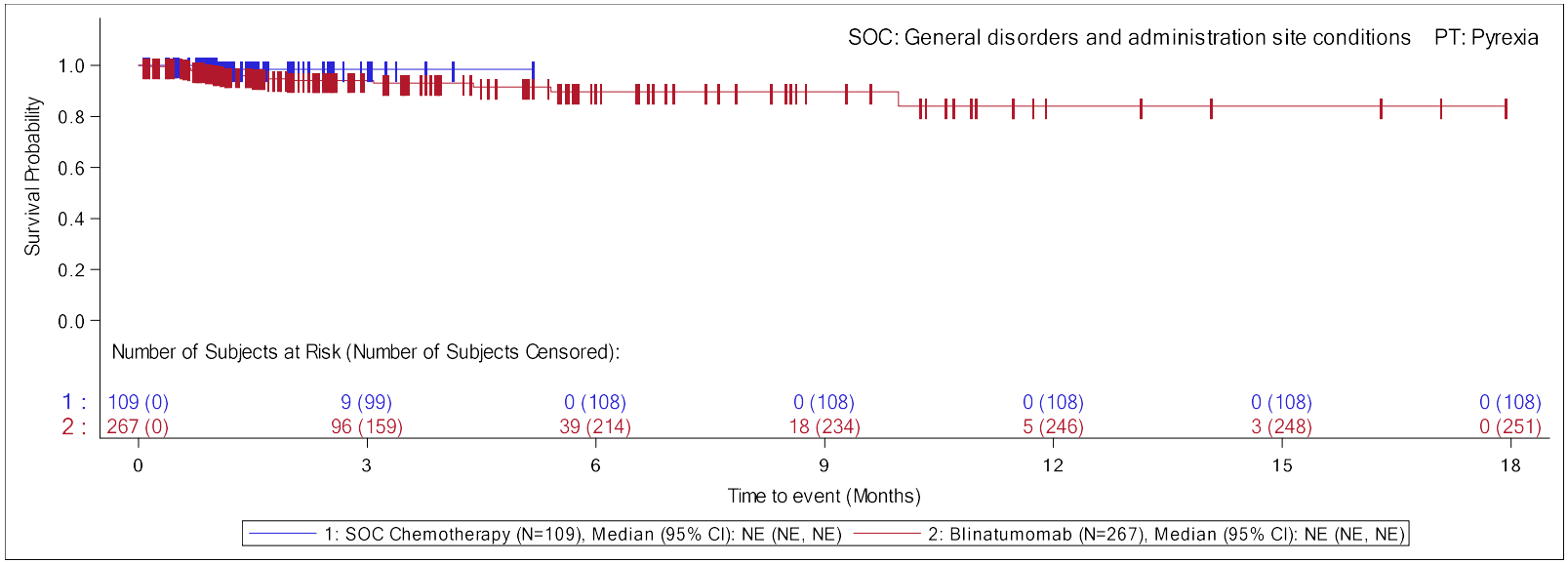

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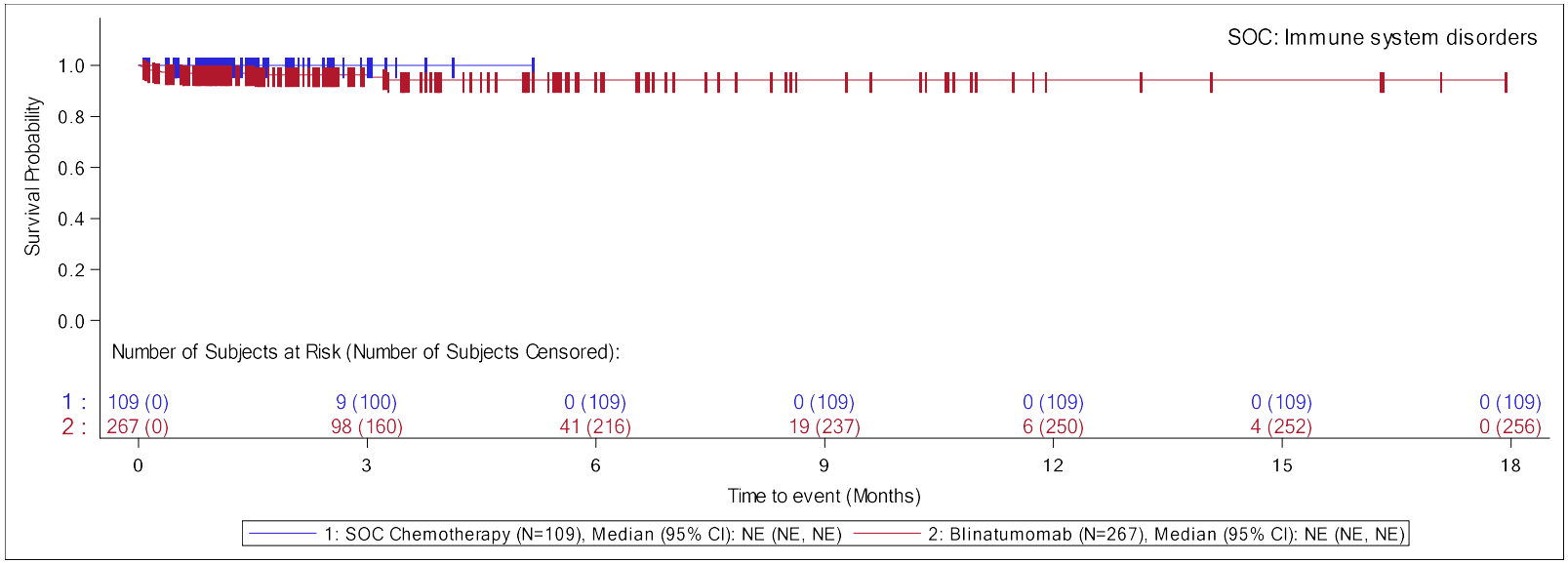

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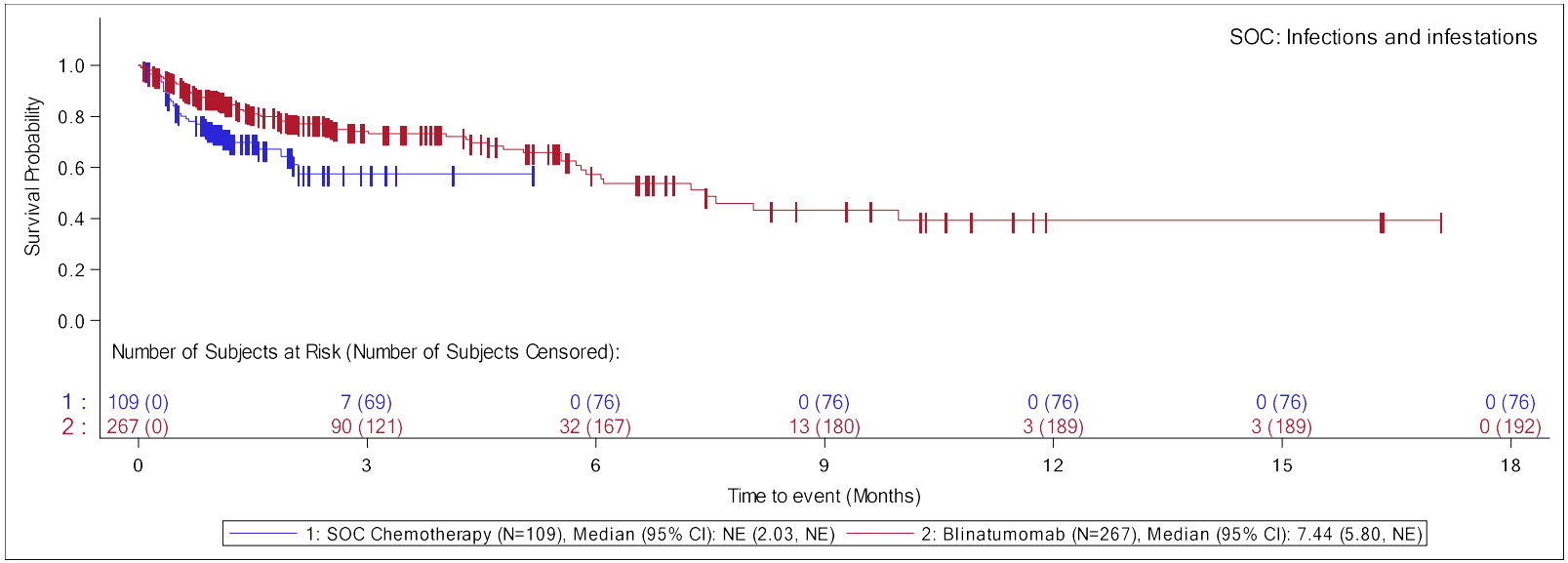

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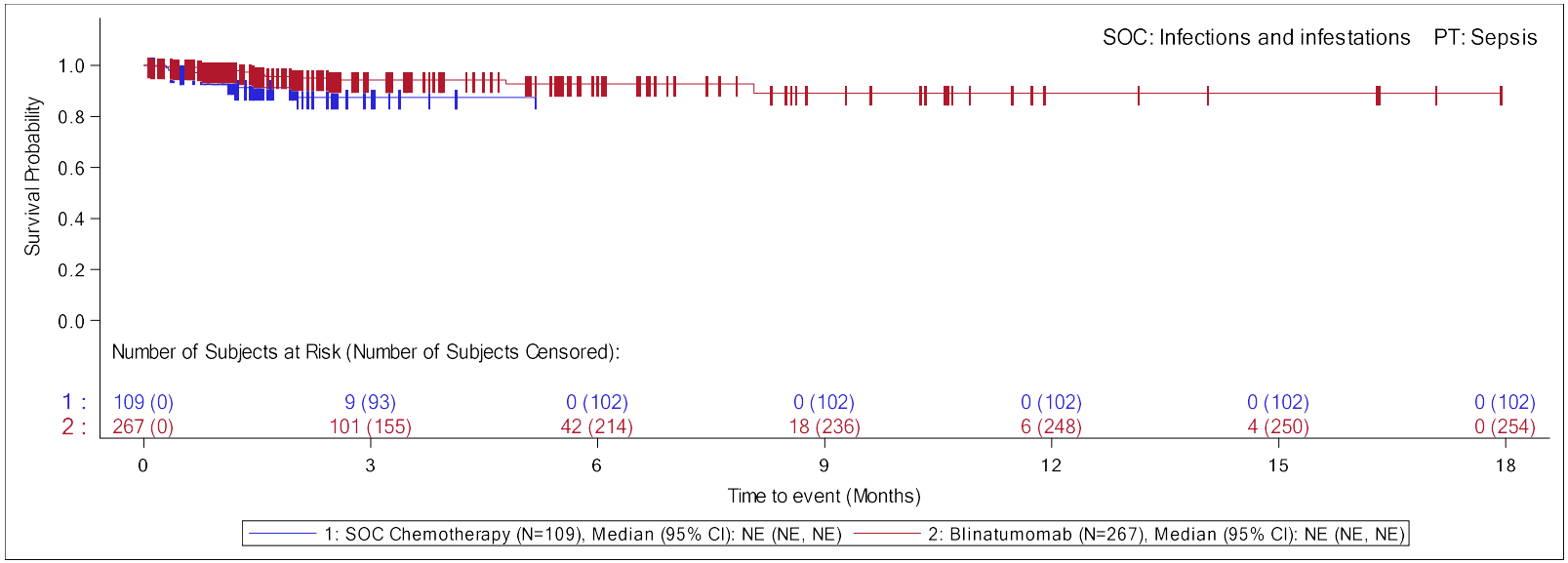

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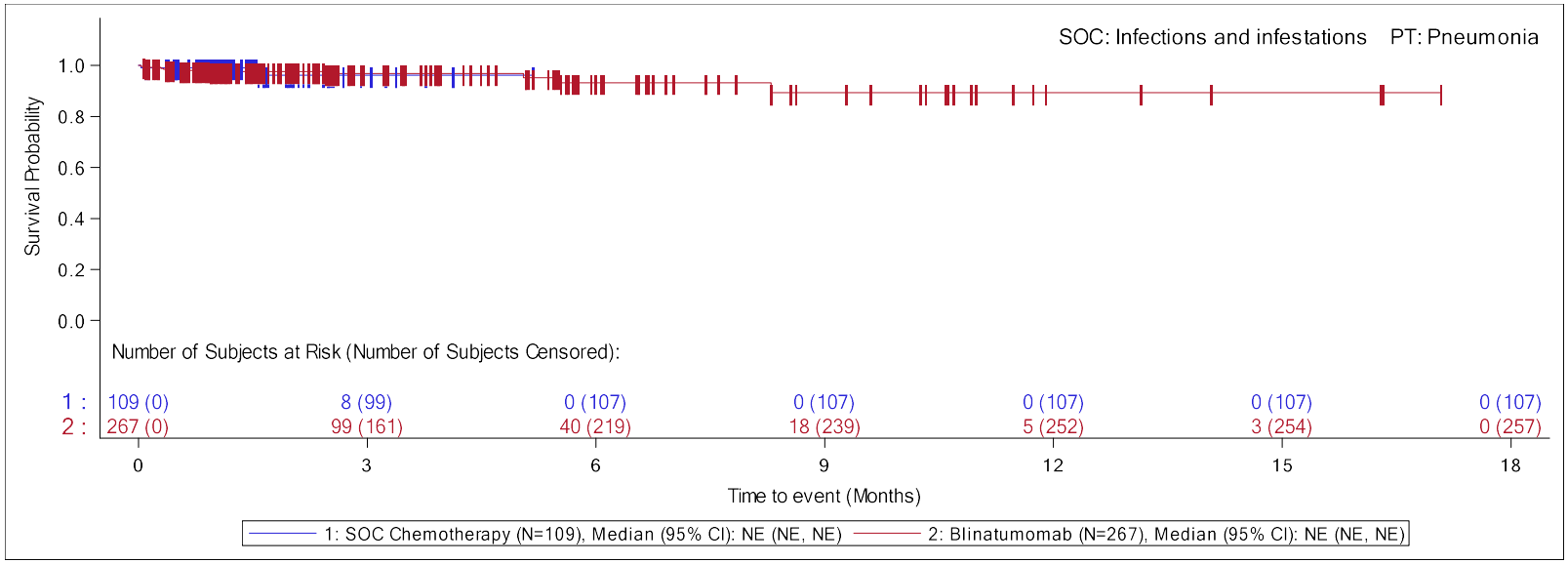

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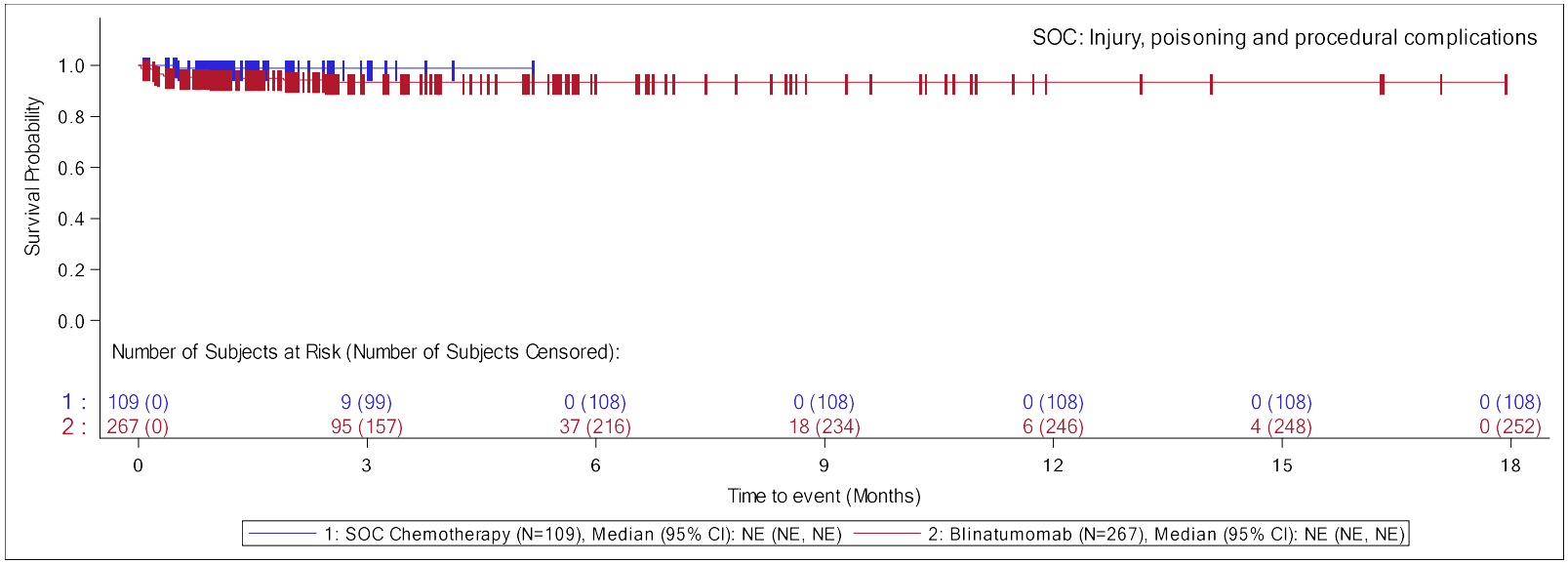

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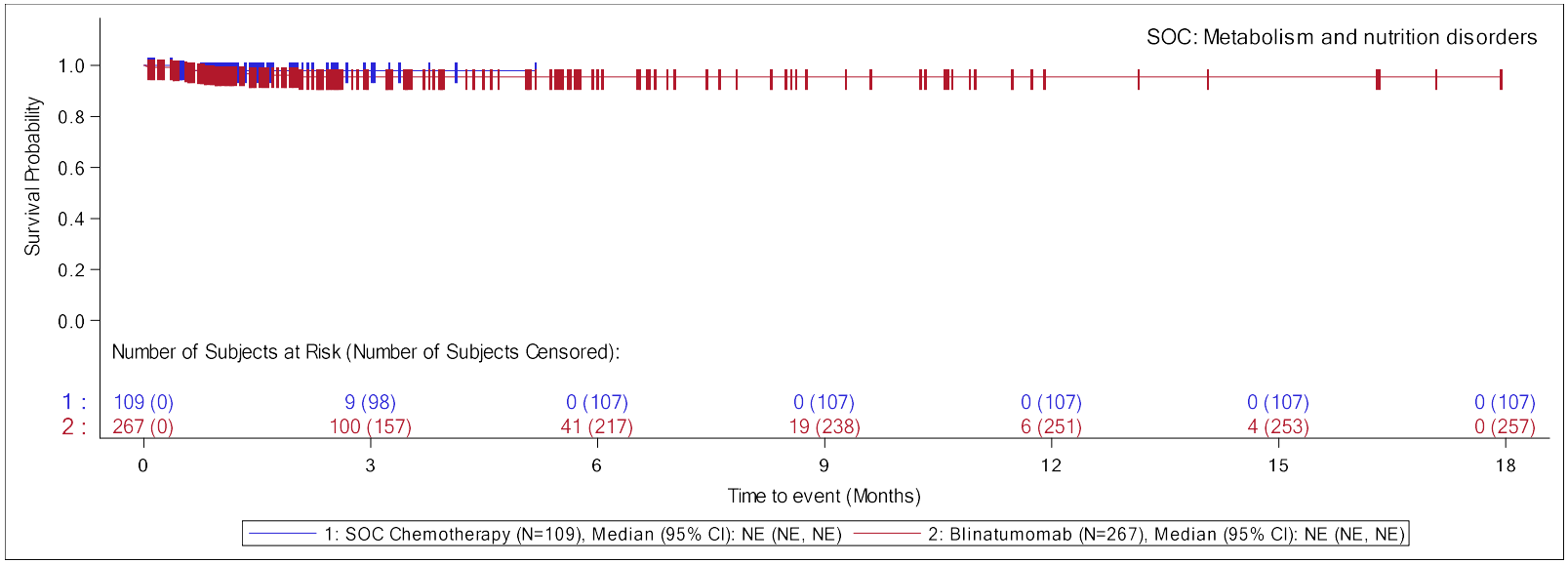

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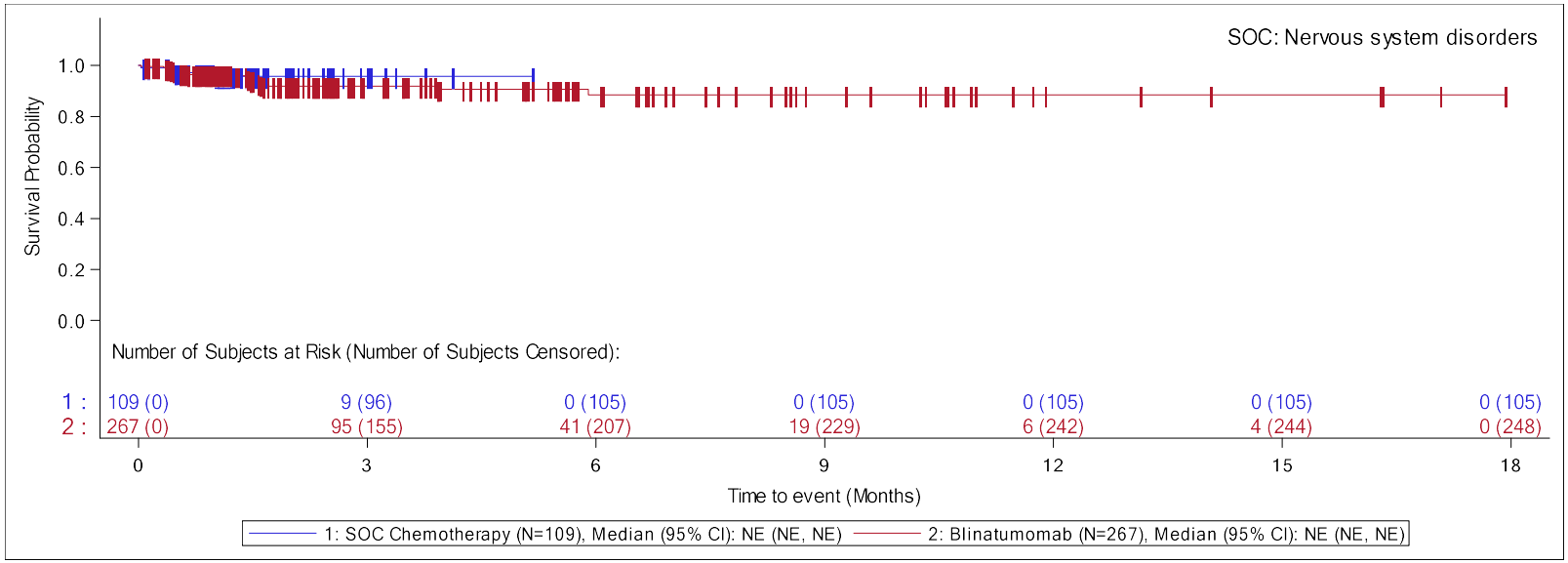

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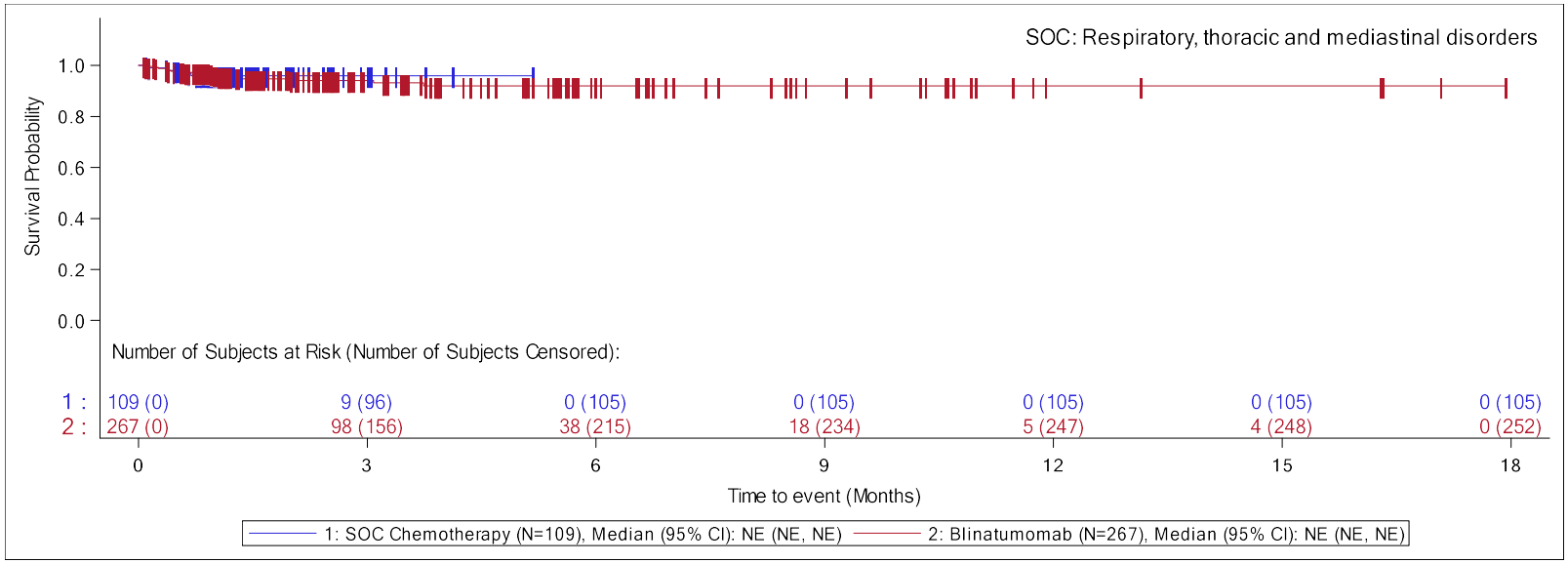
Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-ser-teae-soc-pt-saf.sas
Output: f14-06-001-013-km-ser-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_ser_aette_socpref

Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-ser-teae-soc-pt-saf.sas
Output: f14-06-001-013-km-ser-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_ser_aette_socpref

Anhang 4-G2.9.7: Sicherheit: Schwere UE nach SOC, PT

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	75 (68.8)	154 (57.7)	
Unstratified log-rank test			
Normal score[b]			-22.72
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			-21.52
p-value			0.0004

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.30	1.31	
95% CI (median)	(0.26, 0.36)	(0.75, 2.20)	
Q1, Q3	0.16, NE	0.20, 6.85	
Min, Max	0.0, 1.9	0.0, 8.3	
Unstratified hazard ratio[e]			0.59
(95% CI)			(0.45, 0.78)
p-value			0.0003
Stratified hazard ratio[c,e]			0.60
(95% CI)			(0.45, 0.80)
p-value			0.0005

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	38 (34.9)	57 (21.3)	
Unstratified log-rank test			
Normal score[b]			-14.50
p-value			0.0004
Stratified log-rank test[c]			
Normal score[b]			-14.23
p-value			0.0006

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.77, NE)	(NE, NE)	
Q1, Q3	0.43, NE	4.59, NE	
Min, Max	0.0, 2.8	0.0, 6.7	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.32, 0.73)
p-value			0.0006
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.32, 0.74)
p-value			0.0008

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Anaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	38 (34.9)	53 (19.9)	
Unstratified log-rank test			
Normal score[b]			-13.95
p-value			0.0008
Stratified log-rank test[c]			
Normal score[b]			-13.82
p-value			0.0009

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.93, NE)	(11.90, NE)	
Q1, Q3	0.39, NE	11.90, NE	
Min, Max	0.0, 1.9	0.0, 11.9	
Unstratified hazard ratio[e]			0.49
(95% CI)			(0.32, 0.75)
p-value			0.0010
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.32, 0.75)
p-value			0.0011

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	29 (26.6)	47 (17.6)	
Unstratified log-rank test			
Normal score[b]			-12.79
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			-13.22
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.36, NE	4.62, NE	
Min, Max	0.1, 2.3	0.0, 8.3	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.25, 0.66)
p-value			0.0003
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.23, 0.63)
p-value			0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Thrombocytopenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	30 (27.5)	39 (14.6)	
Unstratified log-rank test			
Normal score[b]			-11.58
p-value			0.0014
Stratified log-rank test[c]			
Normal score[b]			-11.01
p-value			0.0027

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.36, NE	NE, NE	
Min, Max	0.0, 2.0	0.0, 6.9	
Unstratified hazard ratio[e]			0.46
(95% CI)			(0.29, 0.75)
p-value			0.0018
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.30, 0.79)
p-value			0.0032

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Cardiac disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			-0.30
p-value			0.8542
Stratified log-rank test[c]			
Normal score[b]			-0.57
p-value			0.7218

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.3	0.0, 8.7	
Unstratified hazard ratio[e]			0.90
(95% CI)			(0.28, 2.87)
p-value			0.8543
Stratified hazard ratio[c,e]			0.81
(95% CI)			(0.25, 2.62)
p-value			0.7223

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			-8.08
p-value			0.0004
Stratified log-rank test[c]			
Normal score[b]			-8.05
p-value			0.0004

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(11.80, NE)	
Q1, Q3	NE, NE	11.80, NE	
Min, Max	0.0, 1.9	0.1, 11.8	
Unstratified hazard ratio[e]			0.28
(95% CI)			(0.13, 0.59)
p-value			0.0008
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.13, 0.59)
p-value			0.0008

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	46 (17.2)	
Unstratified log-rank test			
Normal score[b]			-0.94
p-value			0.7755
Stratified log-rank test[c]			
Normal score[b]			-0.99
p-value			0.7628

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	8.07, NE	
Min, Max	0.0, 2.0	0.0, 8.5	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.51, 1.65)
p-value			0.7800
Stratified hazard ratio[c,e]			0.92
(95% CI)			(0.51, 1.64)
p-value			0.7656

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			0.87
p-value			0.6717
Stratified log-rank test[c]			
Normal score[b]			0.82
p-value			0.6912

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.5	0.0, 8.1	
Unstratified hazard ratio[e]			1.24
(95% CI)			(0.46, 3.39)
p-value			0.6695
Stratified hazard ratio[c,e]			1.22
(95% CI)			(0.45, 3.33)
p-value			0.6921

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Hepatobiliary disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-1.18
p-value			0.5307
Stratified log-rank test[c]			
Normal score[b]			-1.06
p-value			0.5748

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.0, 3.0	
Unstratified hazard ratio[e]			0.73
(95% CI)			(0.28, 1.94)
p-value			0.5313
Stratified hazard ratio[c,e]			0.76
(95% CI)			(0.29, 2.01)
p-value			0.5766

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			3.81
p-value			0.0232
Stratified log-rank test[c]			
Normal score[b]			3.74
p-value			0.0251

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 7.0	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	57 (52.3)	91 (34.1)	
Unstratified log-rank test			
Normal score[b]			-29.03
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-29.19
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.11	6.10	
95% CI (median)	(0.62, 2.03)	(5.54, NE)	
Q1, Q3	0.39, NE	1.57, NE	
Min, Max	0.0, 2.1	0.0, 8.1	
Unstratified hazard ratio[e]			0.33
(95% CI)			(0.23, 0.48)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.22, 0.46)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sepsis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-3.18
p-value			0.0629
Stratified log-rank test[c]			
Normal score[b]			-3.02
p-value			0.0814

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.1, 8.1	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.16, 1.08)
p-value			0.0709
Stratified hazard ratio[c,e]			0.43
(95% CI)			(0.16, 1.14)
p-value			0.0905

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 04JAN2016

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Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Device related infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-1.87
p-value			0.2152
Stratified log-rank test[c]			
Normal score[b]			-1.75
p-value			0.2512

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.7	0.2, 7.6	
Unstratified hazard ratio[e]			0.49
(95% CI)			(0.15, 1.55)
p-value			0.2246
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.16, 1.63)
p-value			0.2591

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pneumonia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-5.64
p-value			0.0042
Stratified log-rank test[c]			
Normal score[b]			-5.67
p-value			0.0039

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.6	0.0, 8.3	
Unstratified hazard ratio[e]			0.30
(95% CI)			(0.12, 0.72)
p-value			0.0069
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.12, 0.71)
p-value			0.0066

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Bacteraemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	2 (0.7)	
Unstratified log-rank test			
Normal score[b]			-3.97
p-value			0.0011
Stratified log-rank test[c]			
Normal score[b]			-3.98
p-value			0.0011

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 2.1	0.1, 1.3	
Unstratified hazard ratio[e]			0.11
(95% CI)			(0.02, 0.54)
p-value			0.0069
Stratified hazard ratio[c,e]			0.11
(95% CI)			(0.02, 0.54)
p-value			0.0067

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Investigations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	28 (25.7)	60 (22.5)	
Unstratified log-rank test			
Normal score[b]			-5.33
p-value			0.1830
Stratified log-rank test[c]			
Normal score[b]			-4.81
p-value			0.2314

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.98, NE	4.59, NE	
Min, Max	0.0, 1.6	0.0, 7.1	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.47, 1.16)
p-value			0.1890
Stratified hazard ratio[c,e]			0.76
(95% CI)			(0.48, 1.21)
p-value			0.2474

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Alanine aminotransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-2.62
p-value			0.2211
Stratified log-rank test[c]			
Normal score[b]			-2.63
p-value			0.2184

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 3.0	0.0, 3.0	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.26, 1.38)
p-value			0.2259
Stratified hazard ratio[c,e]			0.60
(95% CI)			(0.26, 1.38)
p-value			0.2257

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: White blood cell count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			-1.25
p-value			0.5014
Stratified log-rank test[c]			
Normal score[b]			-1.22
p-value			0.5091

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.1, 2.0	
Unstratified hazard ratio[e]			0.72
(95% CI)			(0.27, 1.92)
p-value			0.5078
Stratified hazard ratio[c,e]			0.72
(95% CI)			(0.27, 1.94)
p-value			0.5173

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Platelet count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-6.75
p-value			0.0015
Stratified log-rank test[c]			
Normal score[b]			-6.56
p-value			0.0022

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.3	0.0, 4.6	
Unstratified hazard ratio[e]			0.29
(95% CI)			(0.13, 0.65)
p-value			0.0029
Stratified hazard ratio[c,e]			0.30
(95% CI)			(0.13, 0.68)
p-value			0.0039

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutrophil count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-5.89
p-value			0.0023
Stratified log-rank test[c]			
Normal score[b]			-5.81
p-value			0.0028

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 5.5	
Unstratified hazard ratio[e]			0.27
(95% CI)			(0.11, 0.67)
p-value			0.0043
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.11, 0.68)
p-value			0.0050

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	26 (23.9)	38 (14.2)	
Unstratified log-rank test			
Normal score[b]			-9.90
p-value			0.0038
Stratified log-rank test[c]			
Normal score[b]			-9.58
p-value			0.0054

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.74, NE	NE, NE	
Min, Max	0.0, 2.3	0.0, 7.6	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.29, 0.80)
p-value			0.0047
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.30, 0.82)
p-value			0.0065

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypokalaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	9 (3.4)	
Unstratified log-rank test			
Normal score[b]			-5.84
p-value			0.0026
Stratified log-rank test[c]			
Normal score[b]			-5.67
p-value			0.0038

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.7	0.1, 1.9	
Unstratified hazard ratio[e]			0.28
(95% CI)			(0.11, 0.68)
p-value			0.0048
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.12, 0.70)
p-value			0.0064

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hyperglycaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	8 (3.0)	
Unstratified log-rank test			
Normal score[b]			-2.91
p-value			0.0901
Stratified log-rank test[c]			
Normal score[b]			-2.96
p-value			0.0828

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 2.0	
Unstratified hazard ratio[e]			0.43
(95% CI)			(0.15, 1.18)
p-value			0.1003
Stratified hazard ratio[c,e]			0.42
(95% CI)			(0.15, 1.16)
p-value			0.0932

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Musculoskeletal and connective tissue disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-1.24
p-value			0.5129
Stratified log-rank test[c]			
Normal score[b]			-0.93
p-value			0.6269

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.7	0.1, 8.6	
Unstratified hazard ratio[e]			0.73
(95% CI)			(0.28, 1.90)
p-value			0.5148
Stratified hazard ratio[c,e]			0.79
(95% CI)			(0.30, 2.07)
p-value			0.6276

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	23 (8.6)	
Unstratified log-rank test			
Normal score[b]			-2.39
p-value			0.3422
Stratified log-rank test[c]			
Normal score[b]			-2.54
p-value			0.3077

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.0, 3.2	
Unstratified hazard ratio[e]			0.70
(95% CI)			(0.34, 1.46)
p-value			0.3438
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.33, 1.42)
p-value			0.3103

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			-4.13
p-value			0.0853
Stratified log-rank test[c]			
Normal score[b]			-4.44
p-value			0.0588

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22MAY2025:23:52) Source data: adam_pa.adsl, adam_pa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.5	0.1, 3.7	
Unstratified hazard ratio[e]			0.53
(95% CI)			(0.25, 1.10)
p-value			0.0902
Stratified hazard ratio[c,e]			0.50
(95% CI)			(0.24, 1.04)
p-value			0.0640

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Vascular disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	9 (3.4)	
Unstratified log-rank test			
Normal score[b]			-2.81
p-value			0.0679
Stratified log-rank test[c]			
Normal score[b]			-2.72
p-value			0.0799

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.2	0.0, 5.7	
Unstratified hazard ratio[e]			0.37
(95% CI)			(0.12, 1.12)
p-value			0.0785
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.13, 1.16)
p-value			0.0903

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
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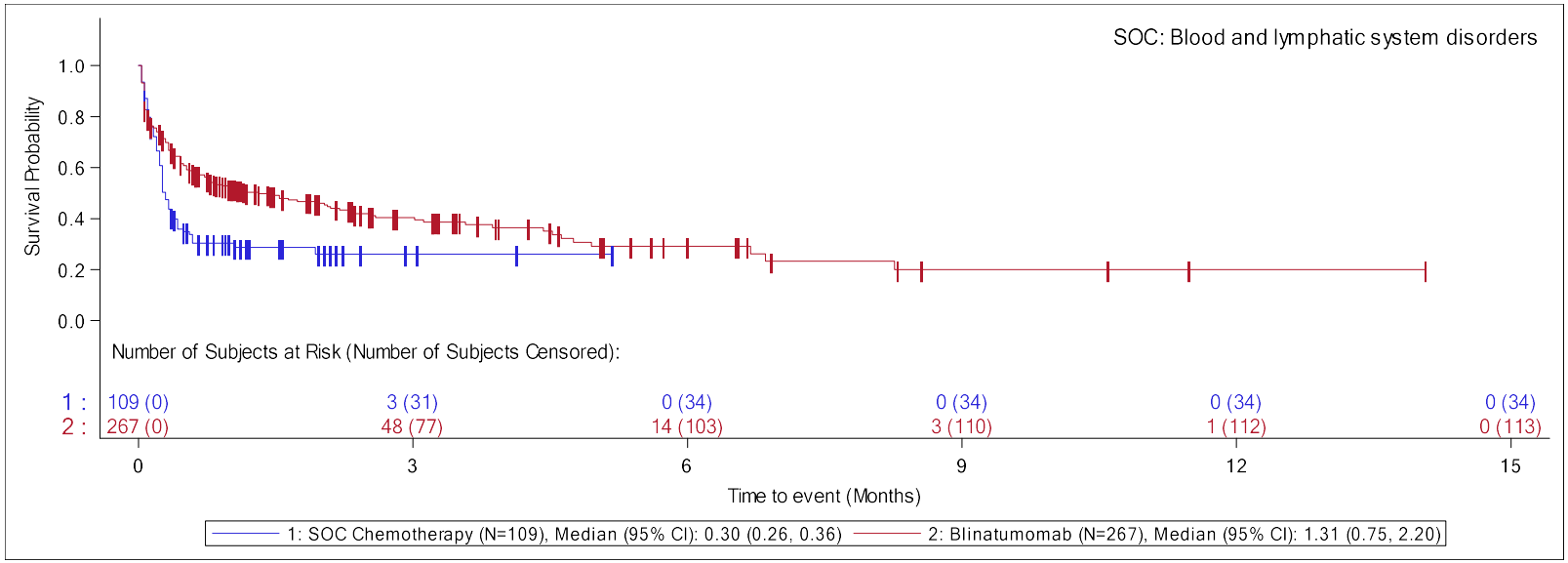
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

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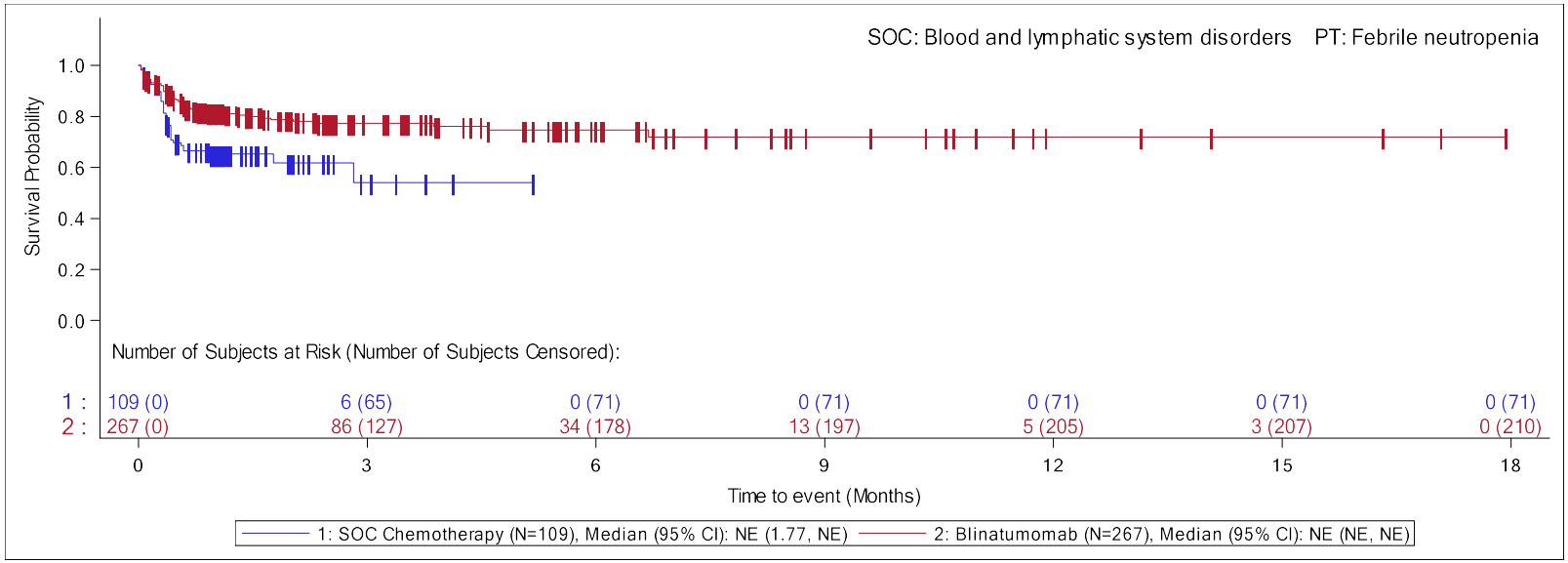
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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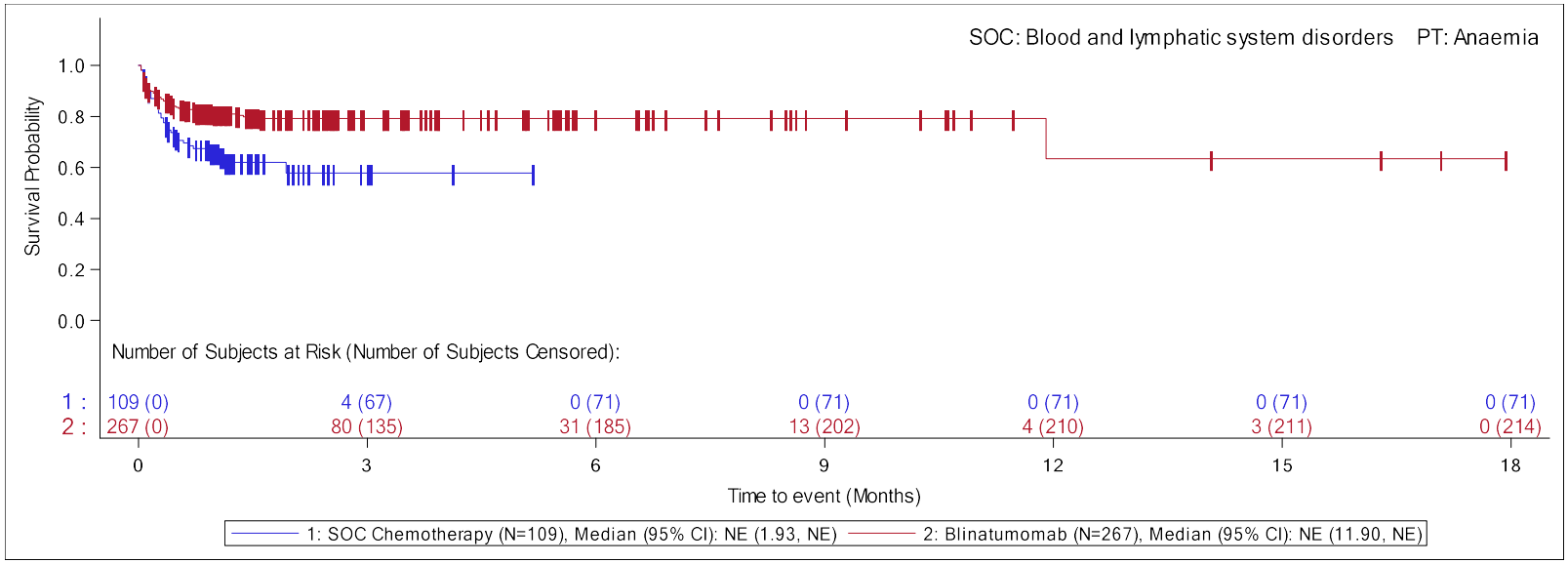

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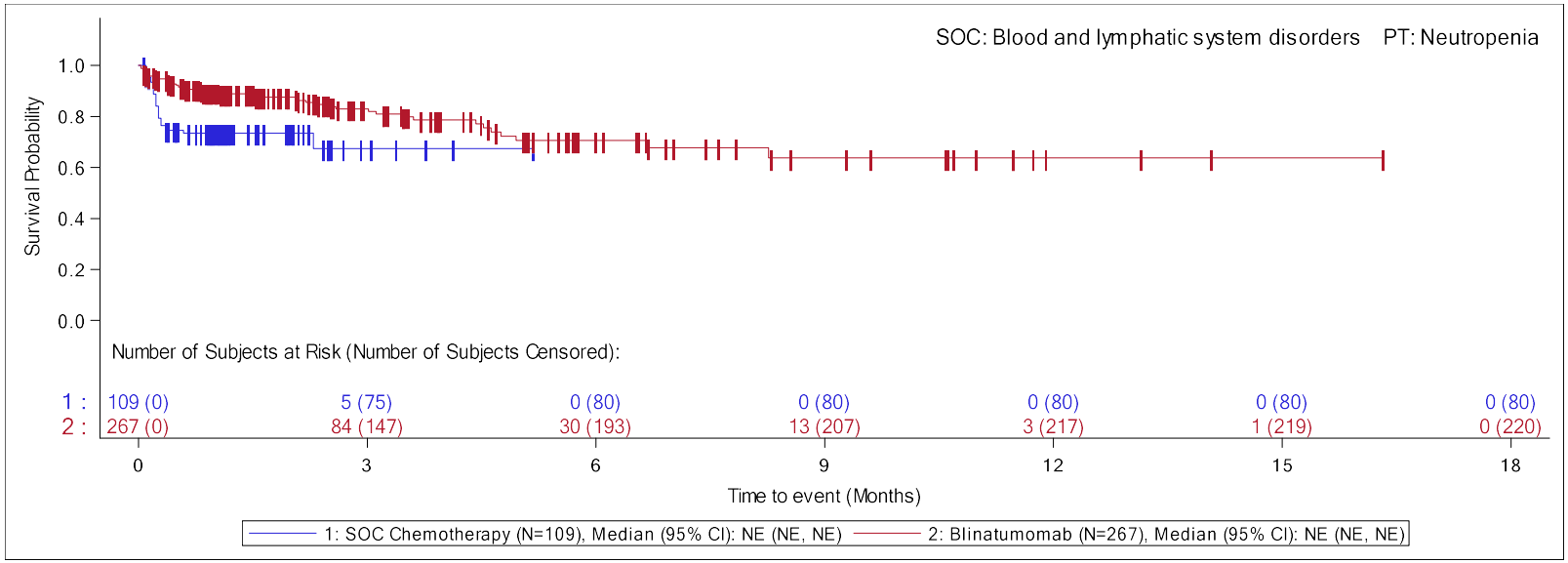

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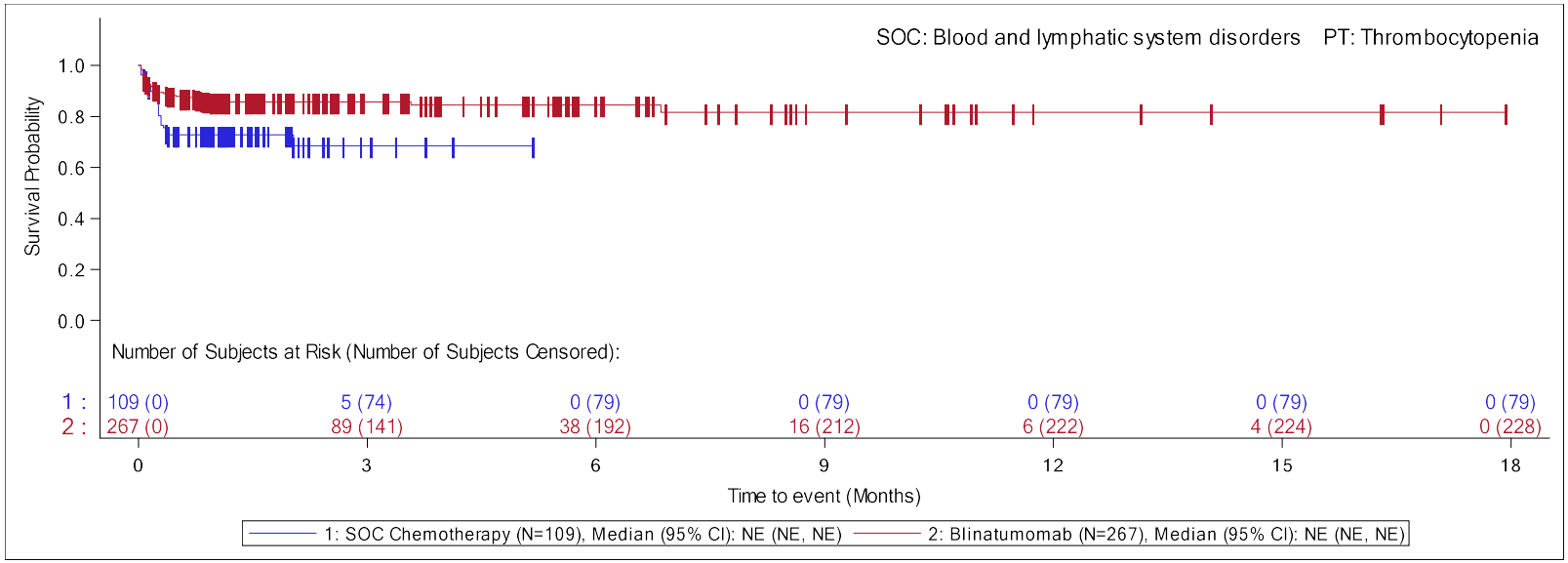

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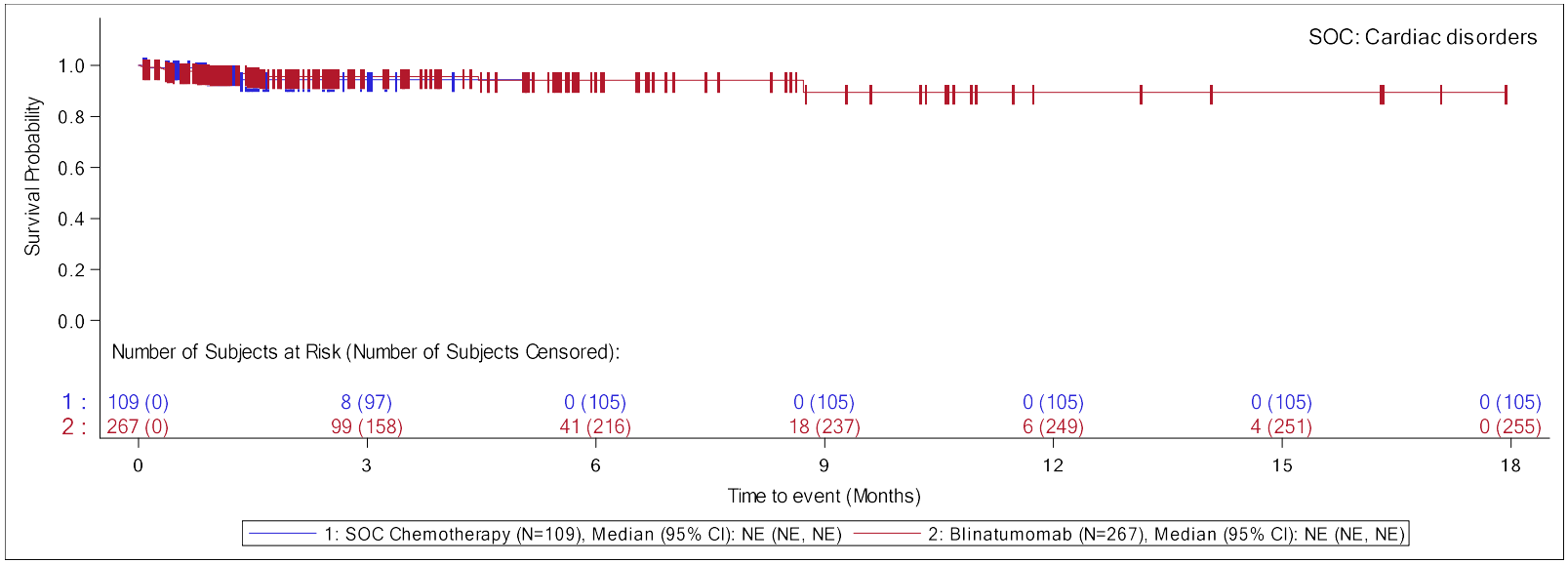

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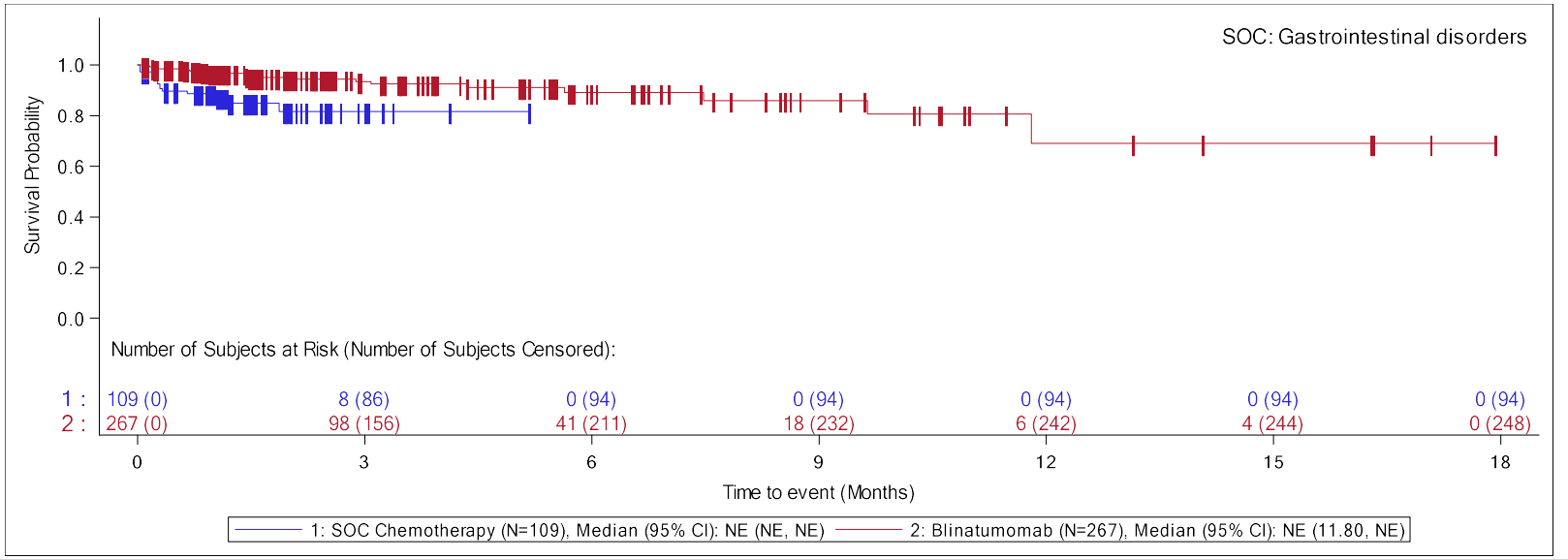

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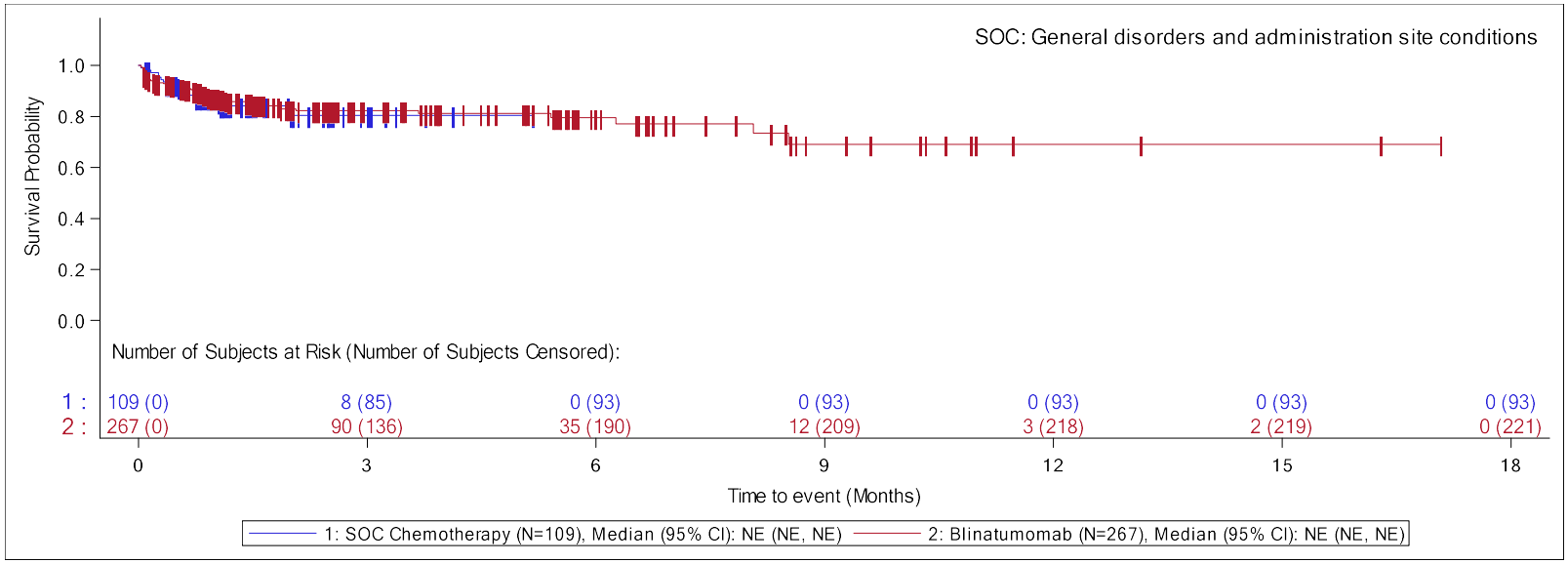

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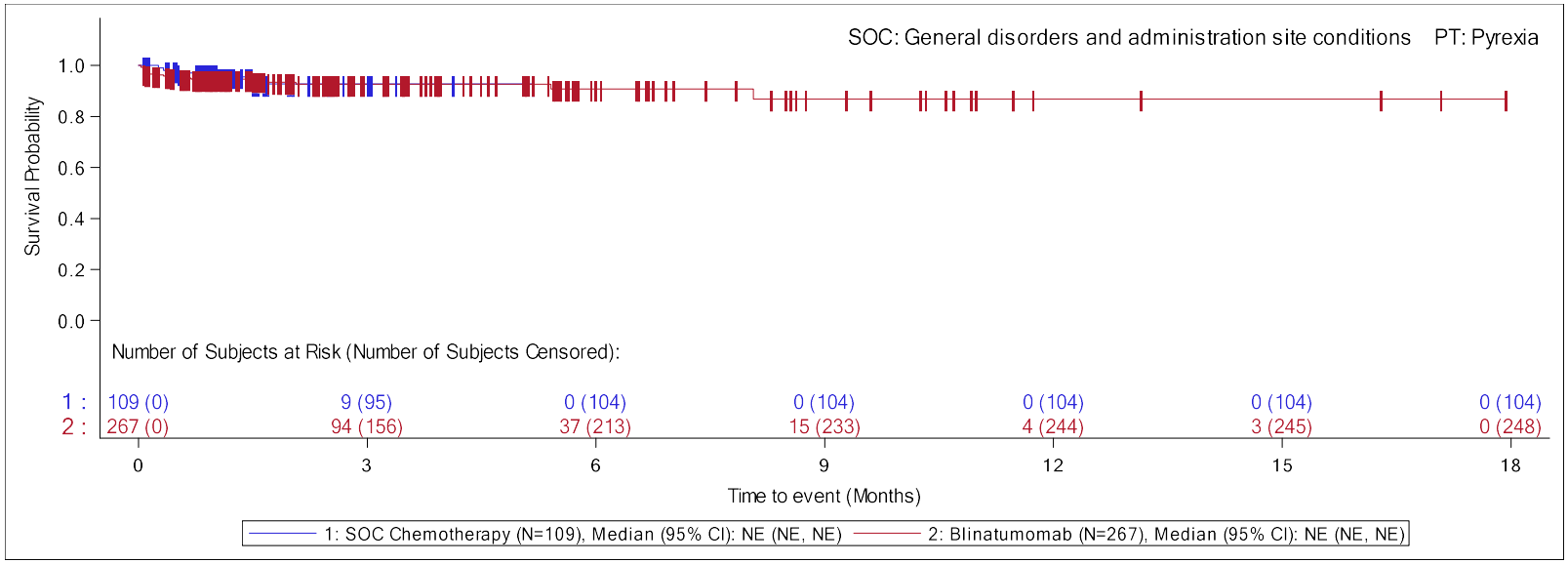

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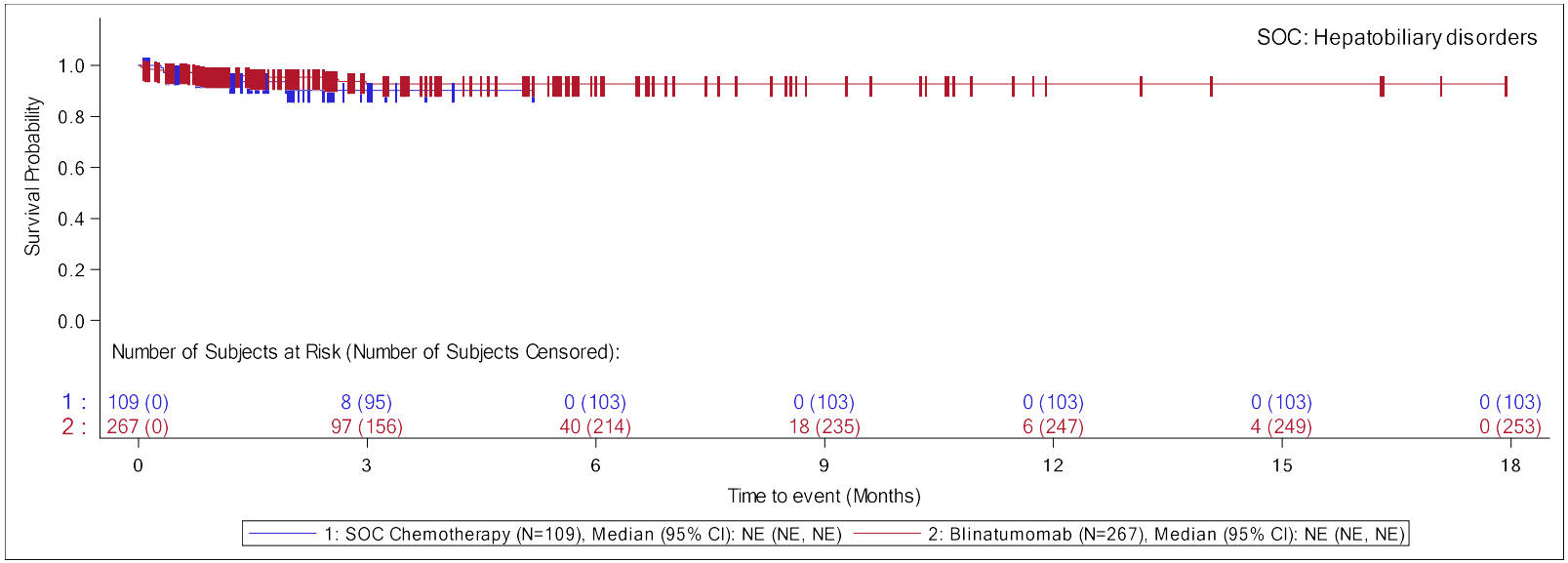

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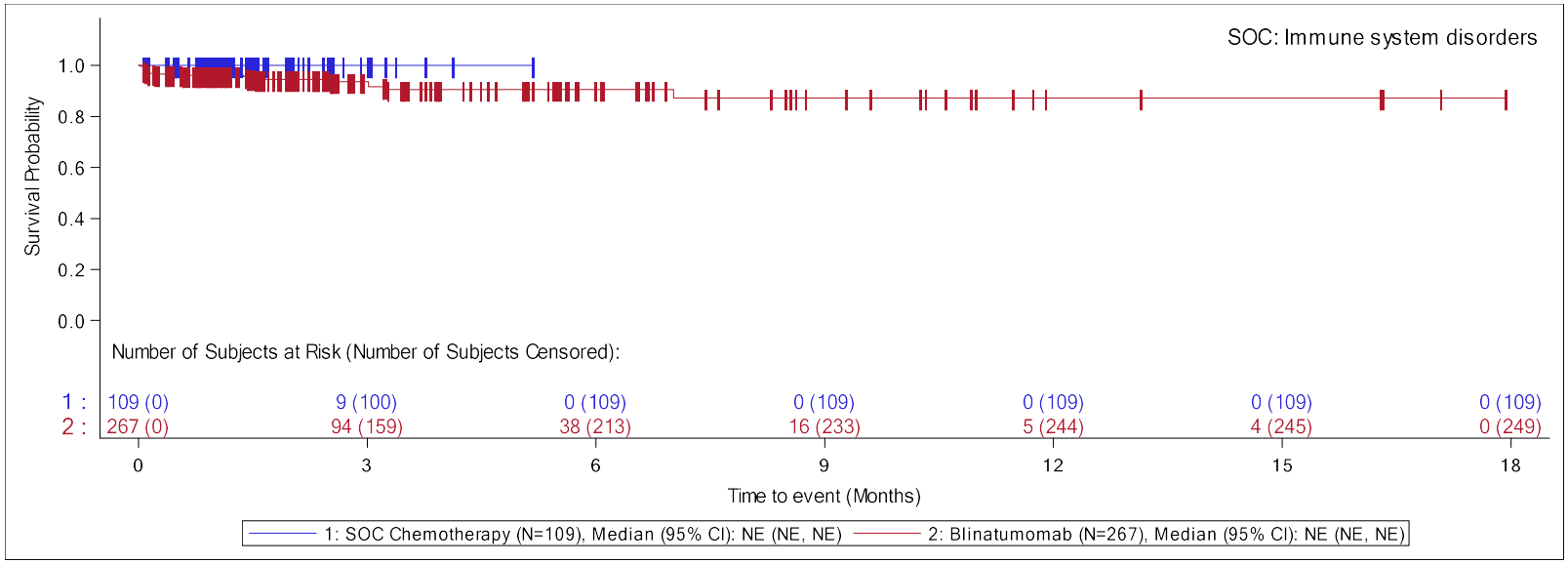

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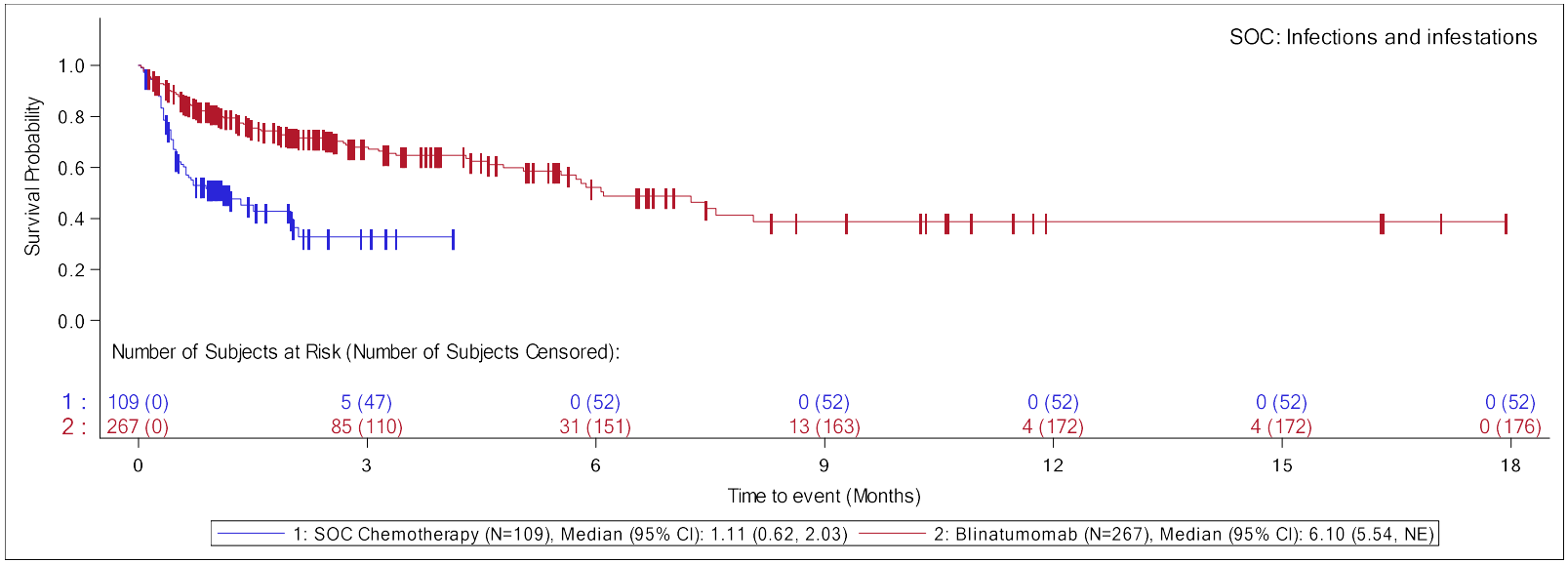

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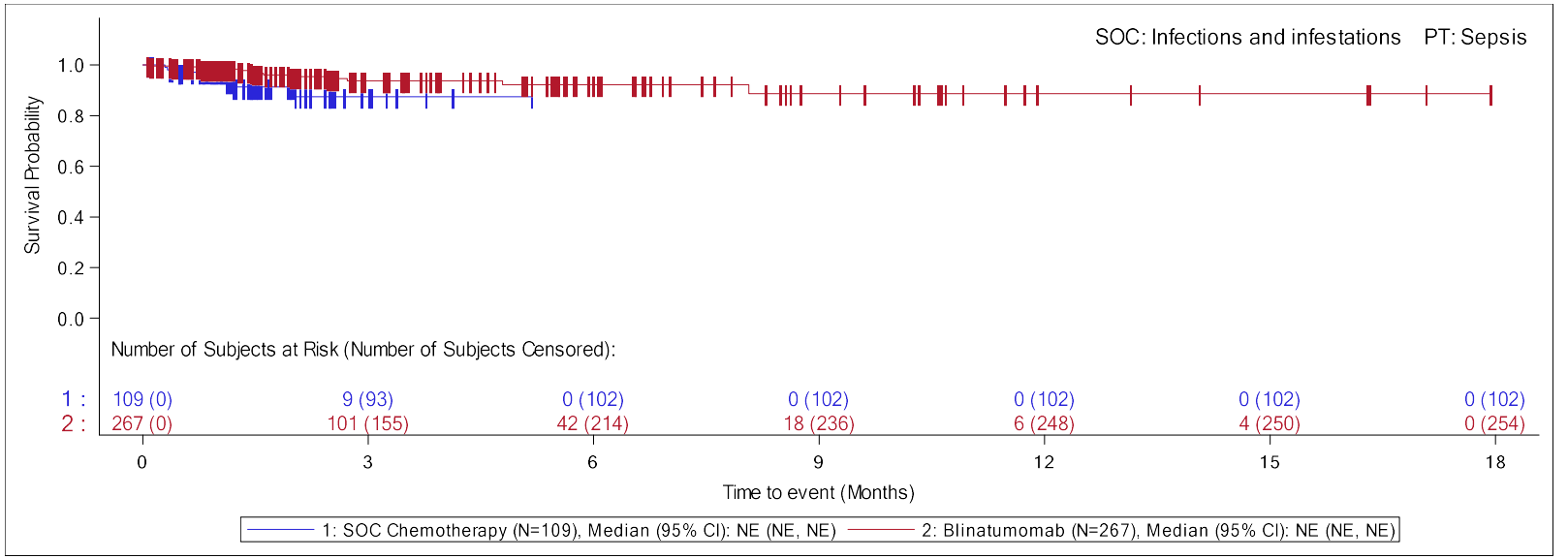

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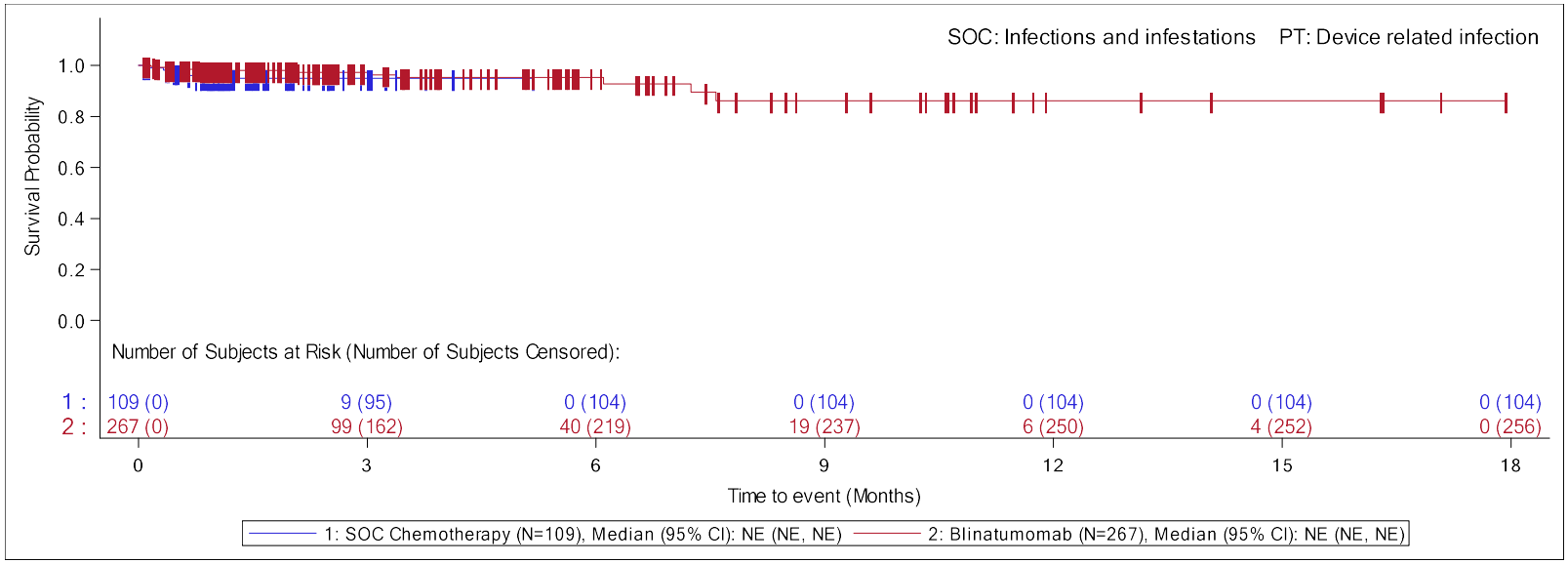

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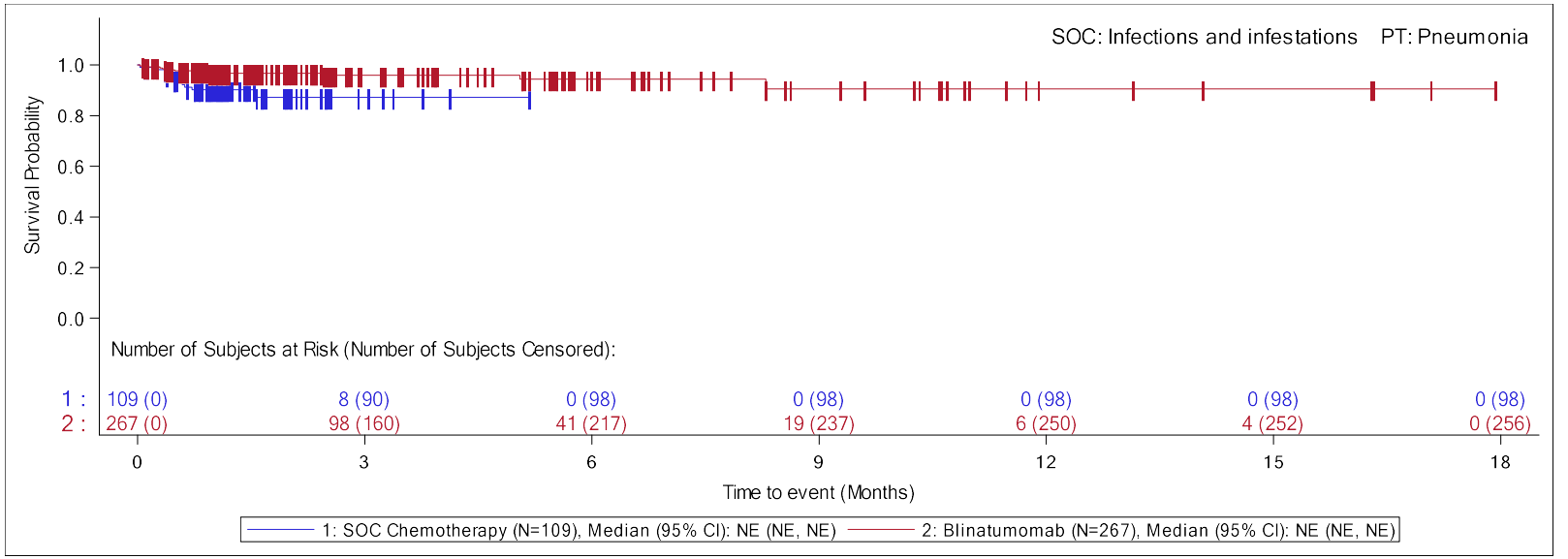

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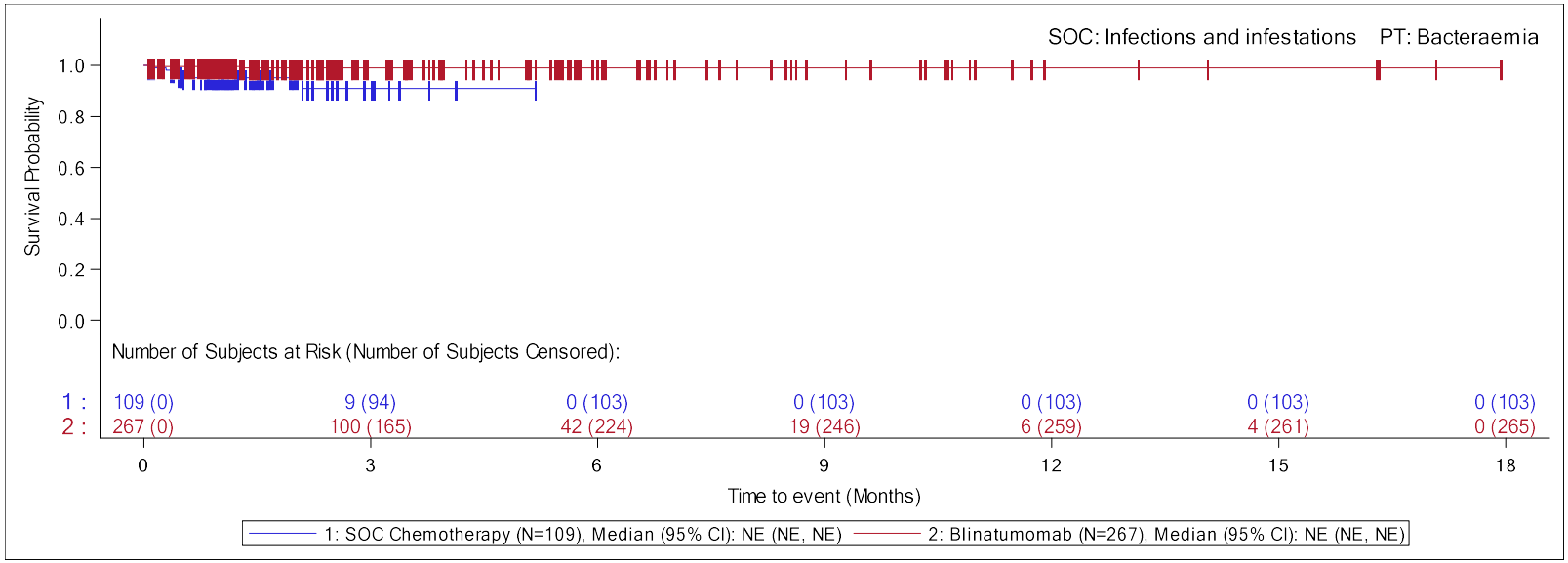

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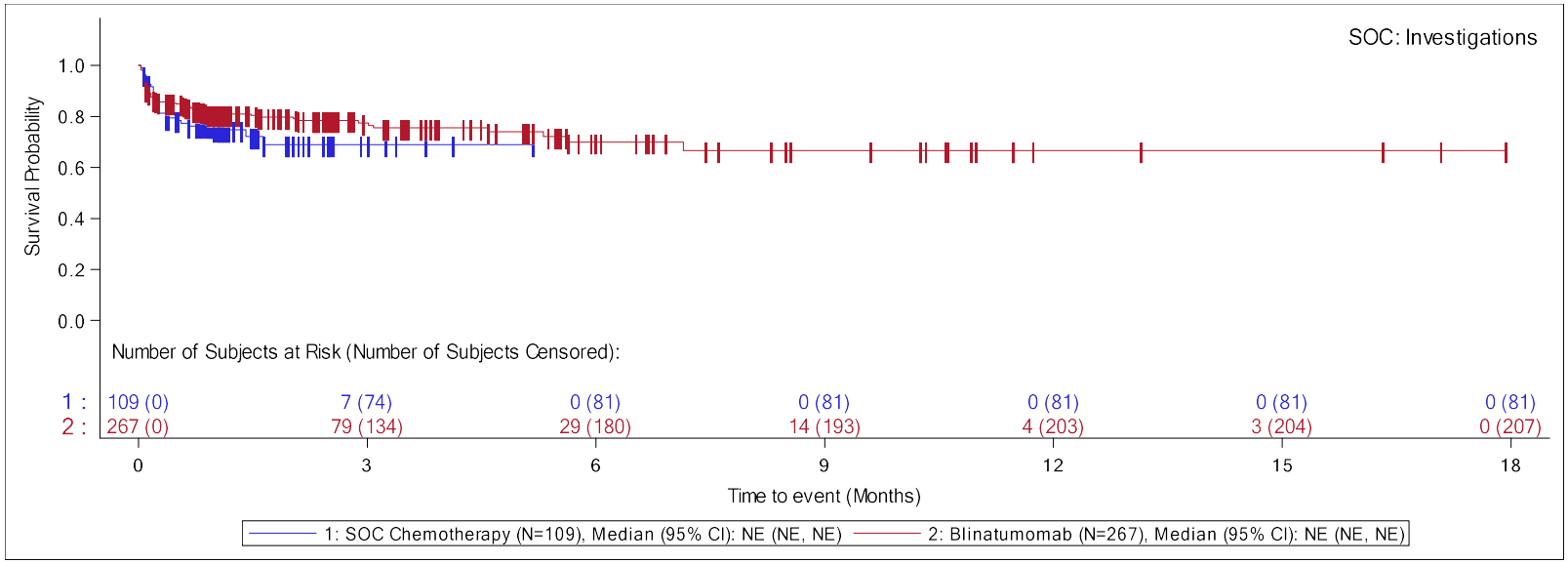
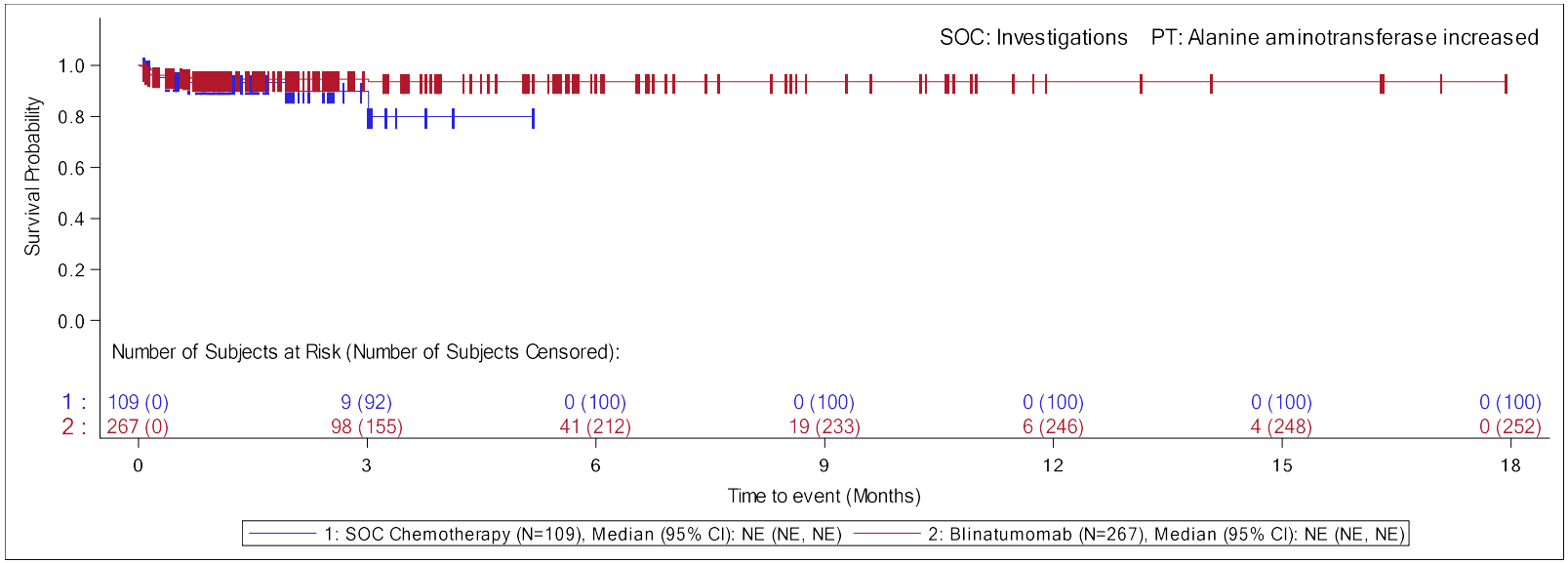
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

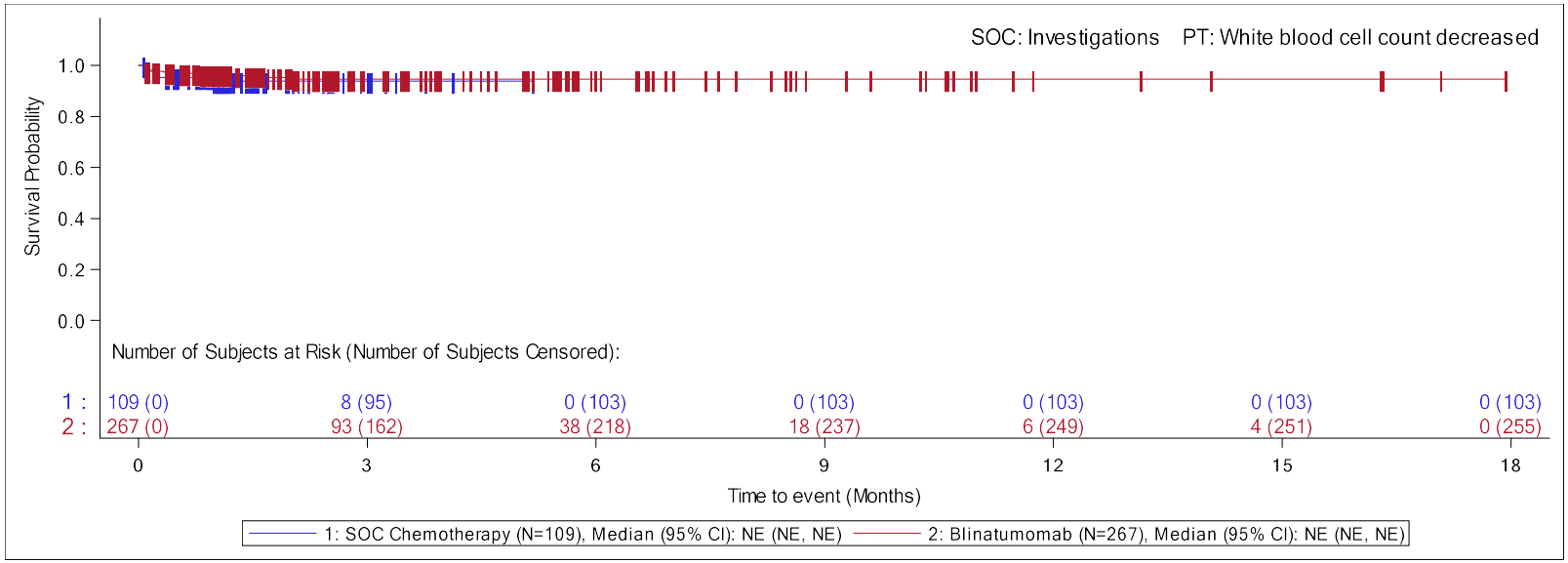
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

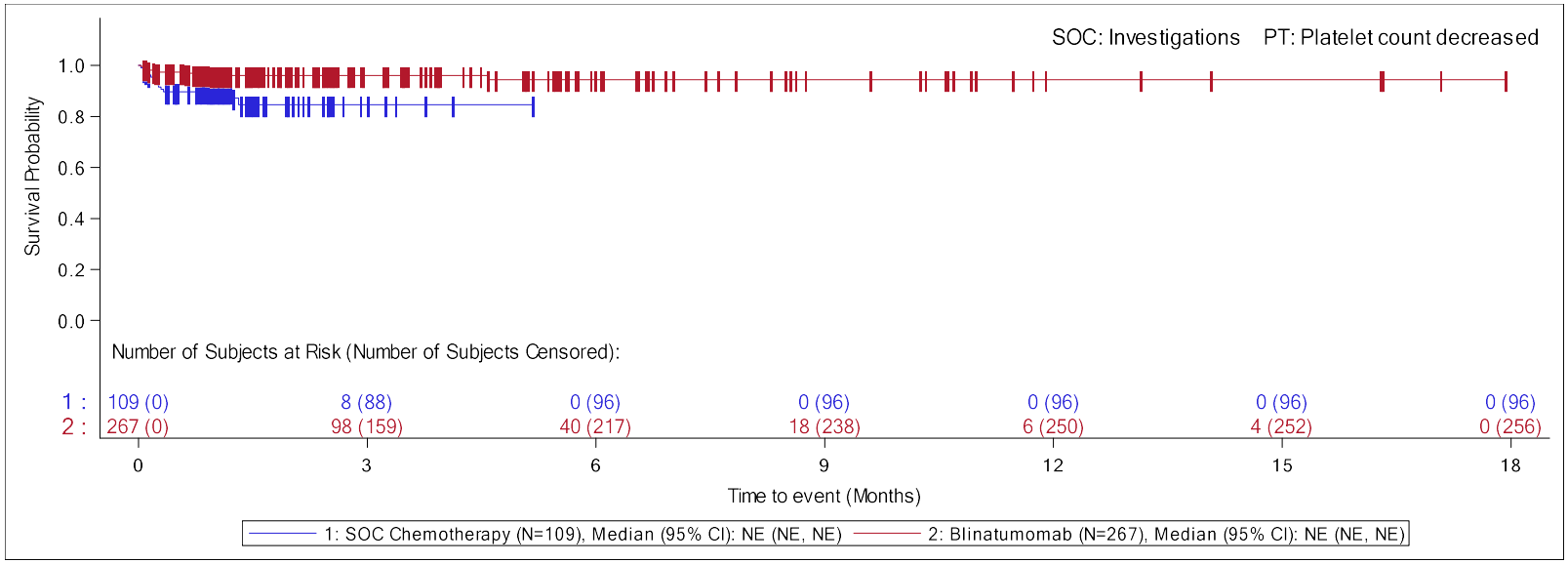
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

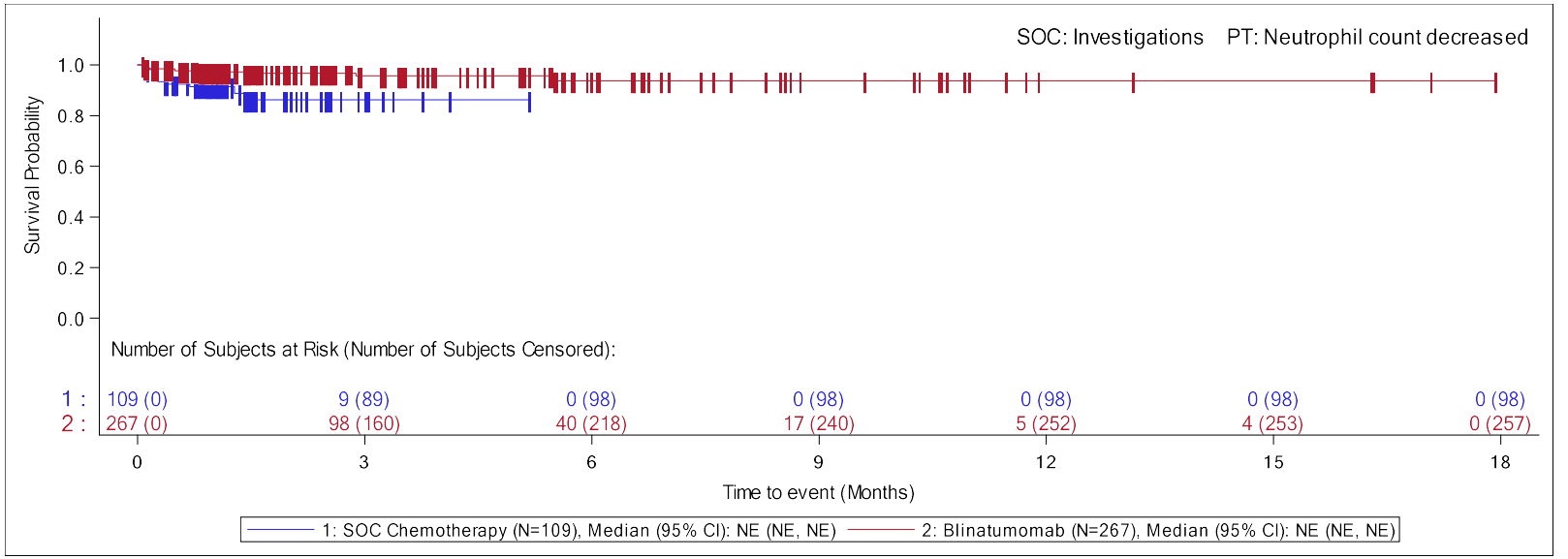
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

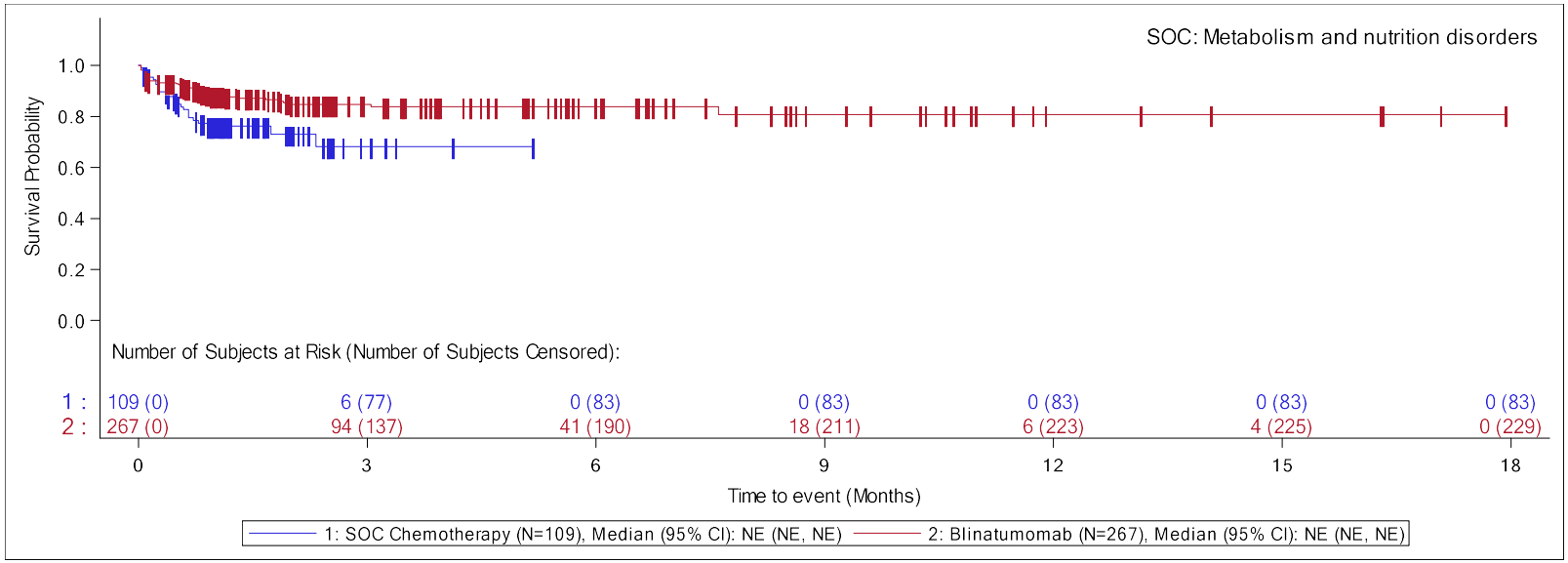
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

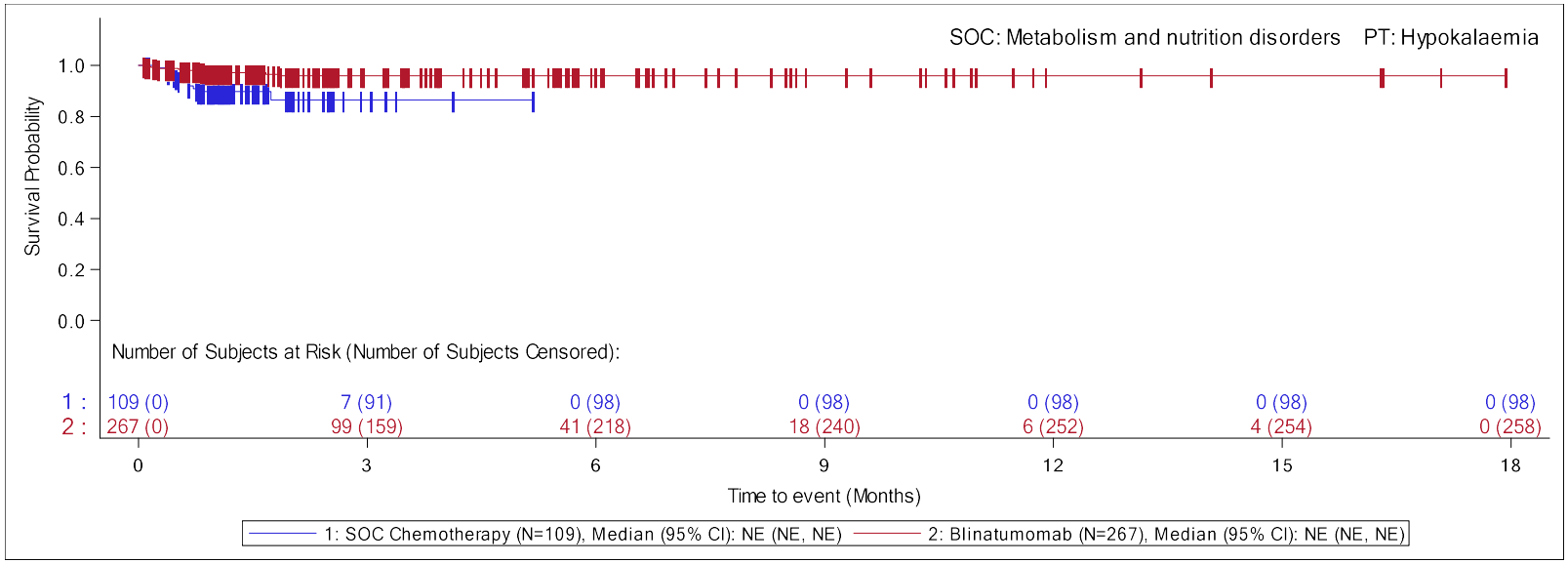
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

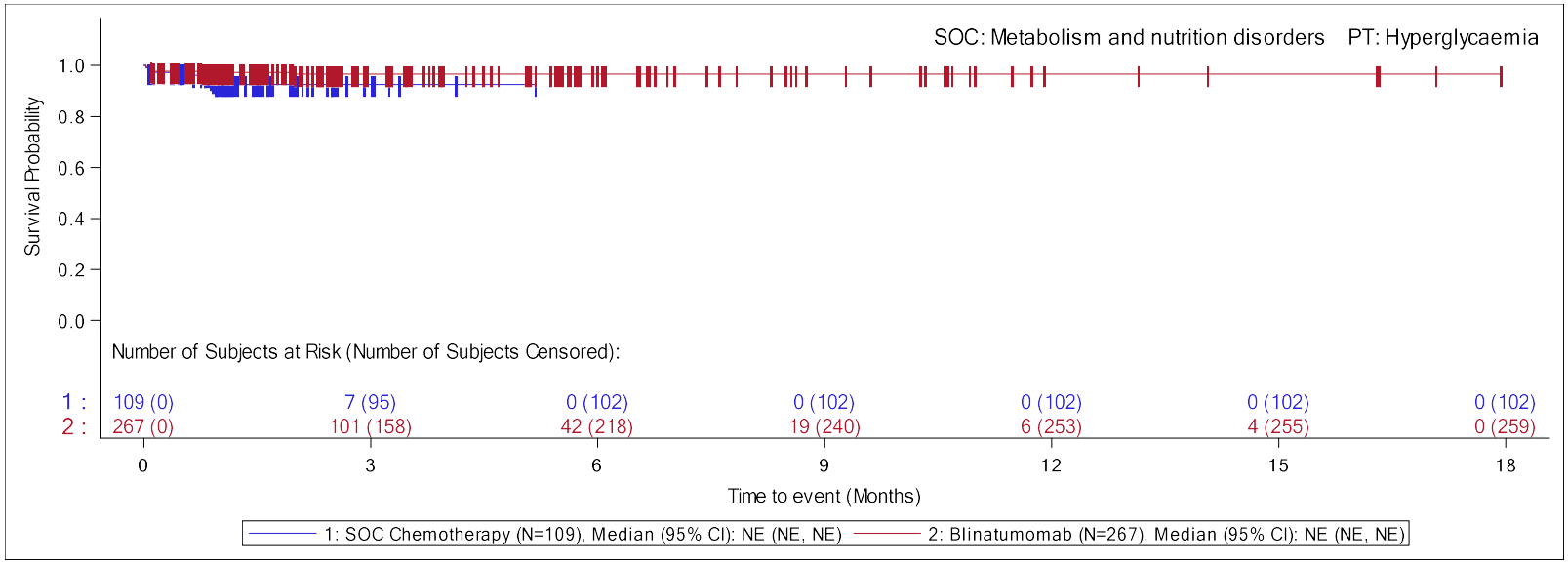
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

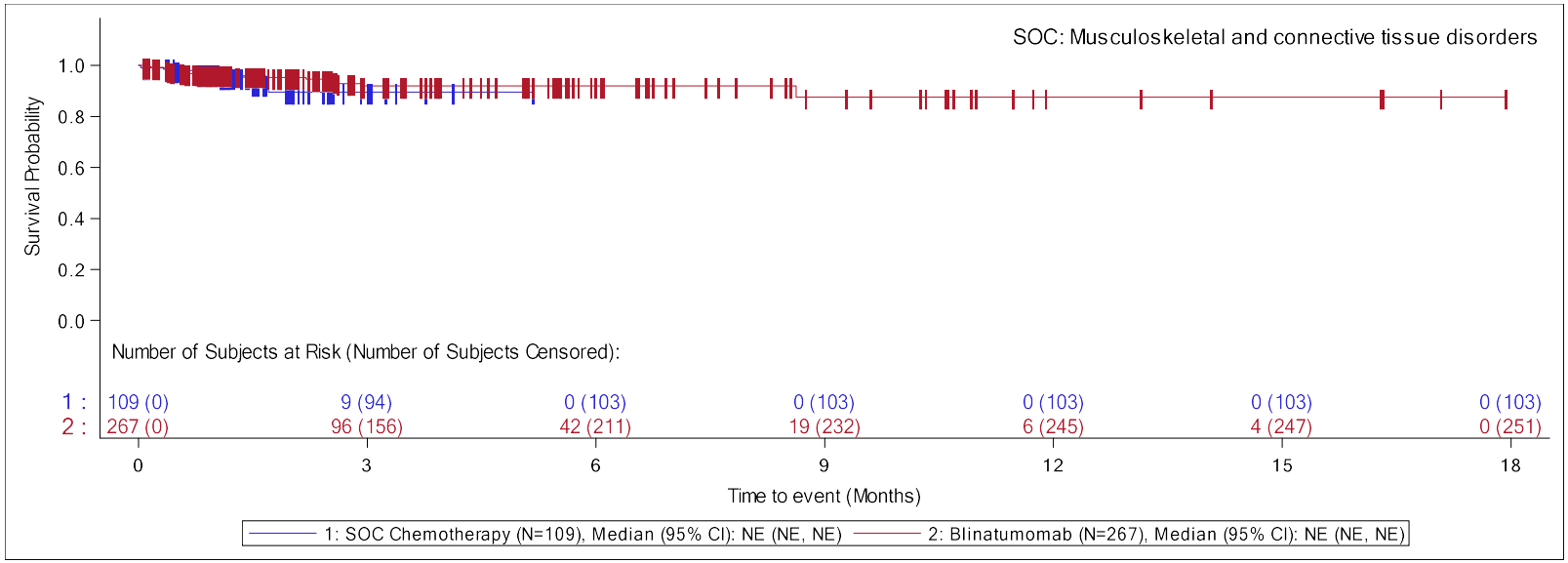
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

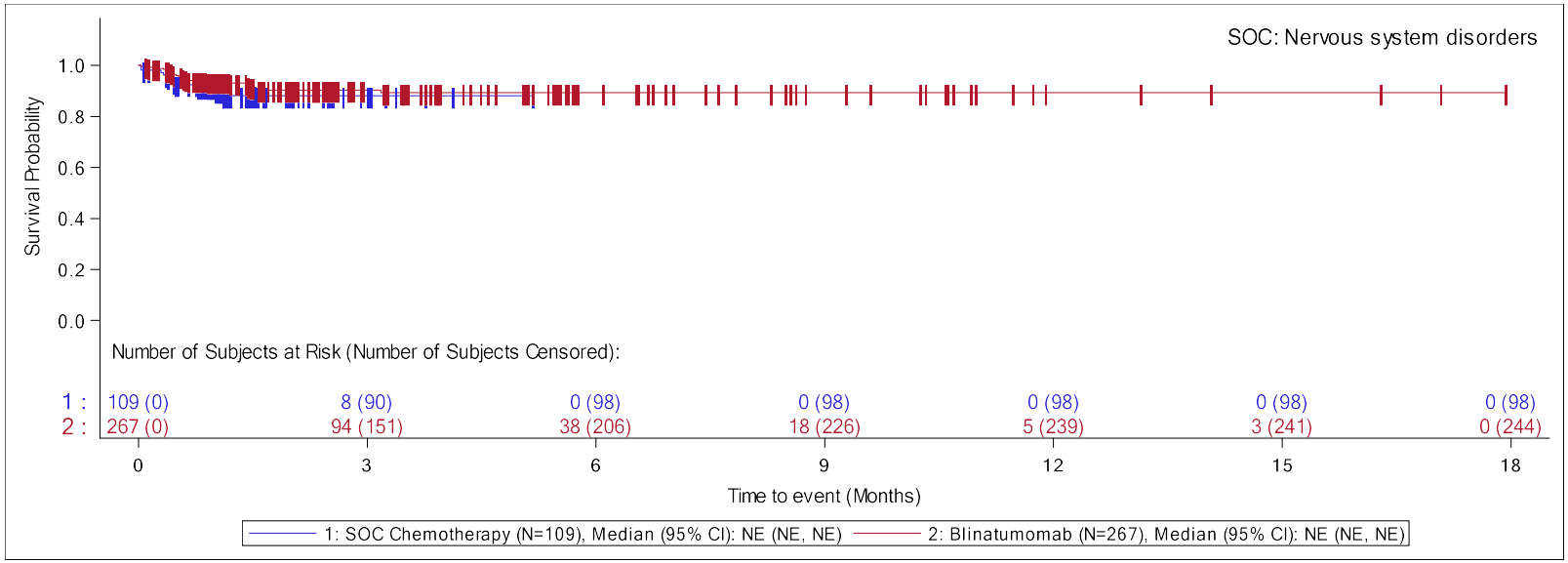
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

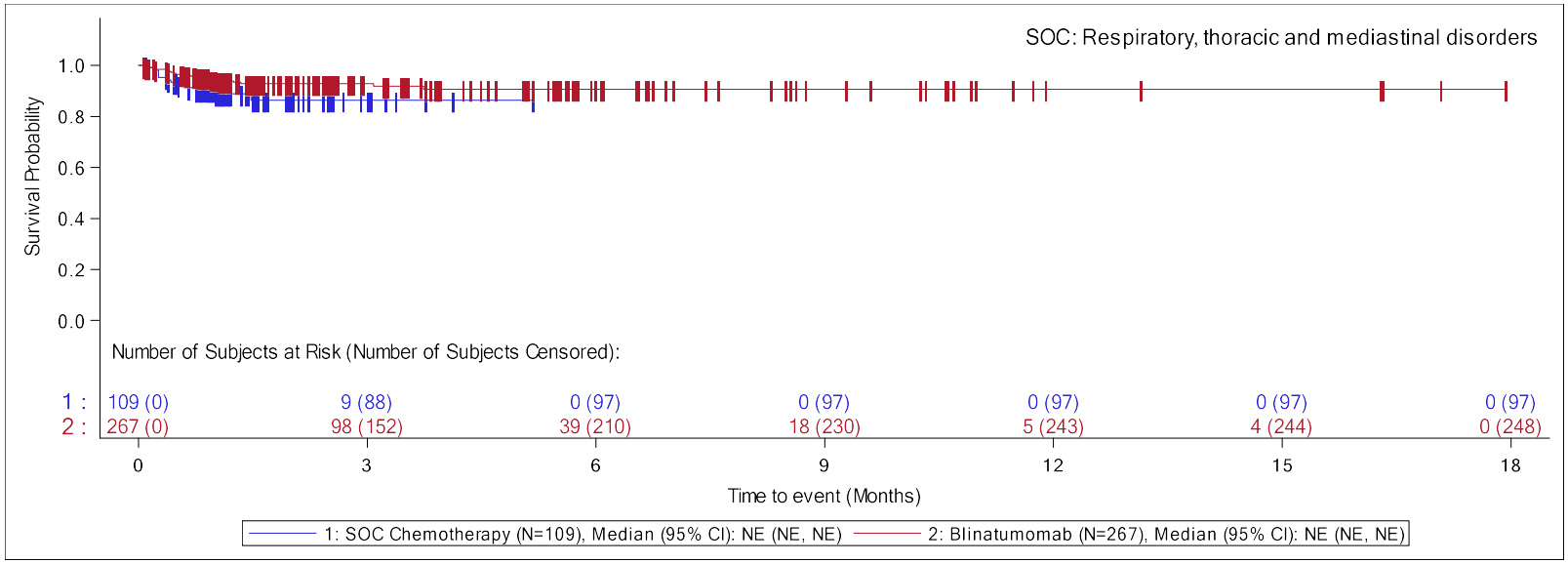
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

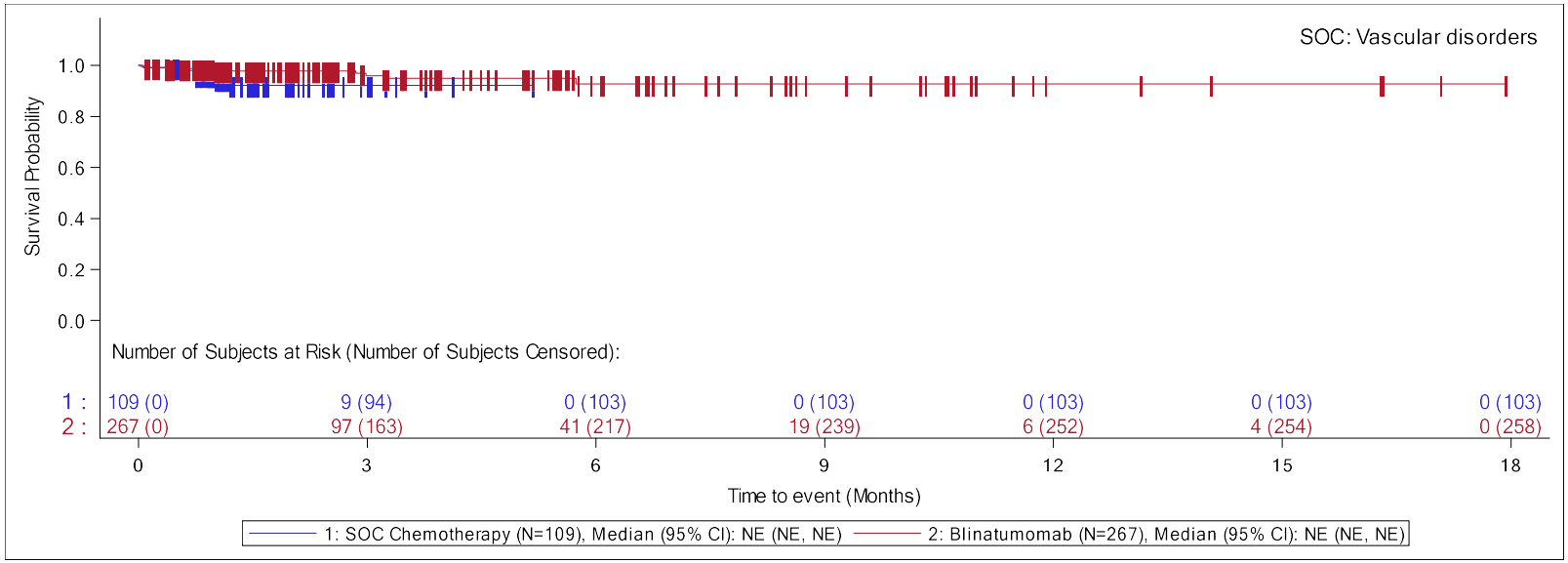
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas
Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, outtab.t_sev_aette_socpref

Anhang 4-G2.9.8: Sicherheit: Abbruchraten aufgrund UE nach SOC, PT

Table 14-6.1.8. Treatment-Emergent Adverse Events Leading to Discontinuation of Investigational Product by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class Preferred Term	SOC Chemotherapy (N = 109) n (%)	Blinatumomab (N = 267) n (%)
Number of subjects reporting treatment-emergent adverse events leading to study drug discontinuation	9 (8.3)	33 (12.4)
Blood and lymphatic system disorders	2 (1.8)	4 (1.5)
Histiocytosis haematophagic	0 (0.0)	2 (0.7)
Lymphadenopathy	0 (0.0)	1 (0.4)
Pancytopenia	0 (0.0)	1 (0.4)
Agranulocytosis	1 (0.9)	0 (0.0)
Febrile neutropenia	1 (0.9)	0 (0.0)
Cardiac disorders	0 (0.0)	2 (0.7)
Acute myocardial infarction	0 (0.0)	1 (0.4)
Cardiac arrest	0 (0.0)	1 (0.4)
Gastrointestinal disorders	1 (0.9)	1 (0.4)
Vomiting	0 (0.0)	1 (0.4)
Diarrhoea	1 (0.9)	0 (0.0)
General disorders and administration site conditions	1 (0.9)	4 (1.5)
Disease progression	0 (0.0)	1 (0.4)
General physical health deterioration	0 (0.0)	1 (0.4)
Multi-organ failure	0 (0.0)	1 (0.4)
Pyrexia	1 (0.9)	1 (0.4)
Hepatobiliary disorders	1 (0.9)	0 (0.0)
Hepatotoxicity	1 (0.9)	0 (0.0)
Immune system disorders	0 (0.0)	3 (1.1)
Anaphylactic shock	0 (0.0)	1 (0.4)
Cytokine release syndrome	0 (0.0)	1 (0.4)
Graft versus host disease in liver	0 (0.0)	1 (0.4)
Infections and infestations	5 (4.6)	9 (3.4)
Bronchopulmonary aspergillosis	0 (0.0)	1 (0.4)
Cytomegalovirus infection	0 (0.0)	1 (0.4)

Page 1 of 3

Adverse events coded using MedDRA version 18.1 . Severity graded using CTCAE v4.03.
Rows are sorted by system organ class (alphabetically) and preferred term within system organ class (in descending order of frequency in the blinatumomab group).

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ae-sum-disip-soc-pref-saf.sas
Output: t14-06-001-008-ae-sum-disip-soc-pref-saf.rtf (Date Generated: 12MAY16:00:42:28) Source: adam.adsl, adam.adae

Table 14-6.1.8. Treatment-Emergent Adverse Events Leading to Discontinuation of Investigational Product by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class Preferred Term	SOC Chemotherapy (N = 109) n (%)	Blinatumomab (N = 267) n (%)
Fungal sepsis	0 (0.0)	1 (0.4)
Infection in an immunocompromised host	0 (0.0)	1 (0.4)
Lung infection	0 (0.0)	1 (0.4)
Mucormycosis	0 (0.0)	1 (0.4)
Neutropenic sepsis	0 (0.0)	1 (0.4)
Progressive multifocal leukoencephalopathy	0 (0.0)	1 (0.4)
Septic shock	1 (0.9)	1 (0.4)
Enterococcal bacteraemia	1 (0.9)	0 (0.0)
Enterococcal infection	1 (0.9)	0 (0.0)
Periodontitis	1 (0.9)	0 (0.0)
Systemic candida	1 (0.9)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	1 (0.4)
Fall	0 (0.0)	1 (0.4)
Investigations	0 (0.0)	1 (0.4)
Blood bilirubin increased	0 (0.0)	1 (0.4)
Metabolism and nutrition disorders	0 (0.0)	1 (0.4)
Tumour lysis syndrome	0 (0.0)	1 (0.4)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (0.4)
Bone pain	0 (0.0)	1 (0.4)
Nervous system disorders	1 (0.9)	8 (3.0)
Cognitive disorder	0 (0.0)	1 (0.4)
Depressed level of consciousness	0 (0.0)	1 (0.4)
Encephalopathy	0 (0.0)	1 (0.4)
Leukoencephalopathy	0 (0.0)	1 (0.4)
Memory impairment	0 (0.0)	1 (0.4)
Neurotoxicity	0 (0.0)	1 (0.4)
Status epilepticus	0 (0.0)	1 (0.4)
Tremor	0 (0.0)	1 (0.4)
Altered state of consciousness	1 (0.9)	0 (0.0)

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Adverse events coded using MedDRA version 18.1 . Severity graded using CTCAE v4.03.
Rows are sorted by system organ class (alphabetically) and preferred term within system organ class (in descending order of frequency in the blinatumomab group).

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ae-sum-disip-soc-pref-saf.sas
Output: t14-06-001-008-ae-sum-disip-soc-pref-saf.rtf (Date Generated: 12MAY16:00:42:28) Source: adam.adsl, adam.adae

Table 14-6.1.8. Treatment-Emergent Adverse Events Leading to Discontinuation of Investigational Product by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class Preferred Term	SOC Chemotherapy (N = 109) n (%)	Blinatumomab (N = 267) n (%)
Psychiatric disorders	0 (0.0)	1 (0.4)
Completed suicide	0 (0.0)	1 (0.4)
Renal and urinary disorders	1 (0.9)	0 (0.0)
Acute kidney injury	1 (0.9)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	1 (0.9)	2 (0.7)
Haemoptysis	0 (0.0)	1 (0.4)
Respiratory failure	1 (0.9)	1 (0.4)
Stridor	0 (0.0)	1 (0.4)
Vascular disorders	0 (0.0)	1 (0.4)
Haematoma	0 (0.0)	1 (0.4)

Page 3 of 3

Adverse events coded using MedDRA version 18.1 . Severity graded using CTCAE v4.03.
Rows are sorted by system organ class (alphabetically) and preferred term within system organ class (in descending order of frequency in the blinatumomab group).

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary/tables/program/t-ae-sum-disip-soc-pref-saf.sas
Output: t14-06-001-008-ae-sum-disip-soc-pref-saf.rtf (Date Generated: 12MAY16:00:42:28) Source: adam.adsl, adam.adae

Anhang 4-G3: Subgruppenanalysen zum primären Datenschnitt

Anhang 4-G3.1: Subgruppenanalysen zum Gesamtüberleben

Table 14-4.5.1. Overall Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6736
<35 years	34/60 (56.7)	4.49 (2.49, 6.43)	68/123 (55.3)	9.87 (7.11, 11.51)	0.70 (0.46, 1.06)	0.0867	
≥35 years	53/74 (71.6)	3.79 (2.56, 5.48)	96/148 (64.9)	5.57 (3.93, 8.30)	0.77 (0.55, 1.08)	0.1310	
Age group 2							0.7894
<35 years	34/60 (56.7)	4.49 (2.49, 6.43)	69/124 (55.6)	9.64 (7.11, 11.15)	0.71 (0.47, 1.07)	0.1019	
35 - 54 years	22/33 (66.7)	2.66 (1.97, 6.95)	49/80 (61.3)	6.13 (4.07, 10.16)	0.67 (0.40, 1.11)	0.1213	
55 - 64 years	21/26 (80.8)	3.72 (2.23, 5.31)	24/34 (70.6)	4.15 (2.46, 10.10)	0.77 (0.43, 1.39)	0.3867	
≥65 years	10/15 (66.7)	3.97 (1.34, NE)	22/33 (66.7)	5.67 (2.46, 10.10)	1.04 (0.49, 2.19)	0.9283	
Sex							0.9186
Male	50/77 (64.9)	3.70 (2.56, 5.48)	102/162 (63.0)	6.89 (4.85, 9.64)	0.72 (0.51, 1.01)	0.0572	
Female	37/57 (64.9)	4.49 (2.56, 6.79)	62/109 (56.9)	8.39 (5.08, 13.02)	0.75 (0.50, 1.13)	0.1661	

Page 1 of 3

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Overall Survival (OS) is calculated from time of randomization until death due to any cause.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-os-fas.sas
Output: t14-04-005-001-tte-sub-os-fas.rtf (Date generated: 28MAY2025:05:05) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Table 14-4.5.1. Overall Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.5467
USA	11/15 (73.3)	3.74 (1.64, 20.23)	24/31 (77.4)	7.11 (3.21, 10.39)	1.00 (0.49, 2.06)	0.9988	
Europe	56/85 (65.9)	4.46 (2.89, 6.39)	109/180 (60.6)	7.67 (5.08, 9.64)	0.75 (0.54, 1.04)	0.0839	
Rest of the world	20/34 (58.8)	3.70 (1.25, 6.43)	31/60 (51.7)	10.10 (4.00, 14.62)	0.62 (0.35, 1.09)	0.0918	
Prior salvage therapy							0.5306
Yes	55/80 (68.8)	3.21 (2.23, 4.43)	112/164 (68.3)	5.08 (3.21, 7.70)	0.79 (0.57, 1.09)	0.1439	
No	32/54 (59.3)	5.51 (3.70, 9.05)	52/107 (48.6)	10.16 (7.87, 15.57)	0.64 (0.41, 0.99)	0.0447	
Number of salvage therapies							0.1578
0	39/65 (60.0)	5.31 (3.70, 9.05)	53/114 (46.5)	11.11 (8.30, NE)	0.60 (0.39, 0.91)	0.0144	
1	32/43 (74.4)	3.31 (1.87, 4.07)	61/91 (67.0)	5.08 (3.21, 8.39)	0.59 (0.38, 0.91)	0.0151	
≥2	16/26 (61.5)	3.05 (1.70, 6.03)	50/66 (75.8)	3.67 (1.90, 6.89)	1.13 (0.64, 1.99)	0.6678	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Overall Survival (OS) is calculated from time of randomization until death due to any cause.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-os-fas.sas
Output: t14-04-005-001-tte-sub-os-fas.rtf (Date generated: 28MAY2025:05:05) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Table 14-4.5.1. Overall Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.5980
Yes	26/46 (56.5)	5.31 (1.87, 9.05)	58/94 (61.7)	7.70 (3.93, 10.16)	0.81 (0.51, 1.29)	0.3803	
No	61/88 (69.3)	3.70 (2.82, 5.31)	106/177 (59.9)	7.67 (5.08, 10.10)	0.70 (0.51, 0.96)	0.0278	
Race							0.9375
Caucasian	75/112 (67.0)	4.07 (2.89, 5.48)	141/228 (61.8)	7.67 (5.31, 9.57)	0.73 (0.55, 0.97)	0.0301	
Others	12/22 (54.5)	3.70 (1.25, NE)	23/43 (53.5)	11.51 (3.61, 13.48)	0.79 (0.39, 1.59)	0.5027	
Central laboratory baseline bone marrow blasts							0.2706
<50%	19/36 (52.8)	6.79 (2.13, NE)	33/73 (45.2)	11.11 (9.87, NE)	0.57 (0.33, 1.01)	0.0505	
≥50%	63/93 (67.7)	3.74 (2.66, 5.31)	113/170 (66.5)	4.85 (3.61, 6.89)	0.85 (0.62, 1.16)	0.3038	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Overall Survival (OS) is calculated from time of randomization until death due to any cause.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-os-fas.sas
Output: t14-04-005-001-tte-sub-os-fas.rtf (Date generated: 28MAY2025:05:05) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Anhang 4-G3.2: Subgruppenanalysen zum Ereignisfreien Überleben

Table 14-4.5.2. Event Free Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6849
<35 years	53/60 (88.3)	0.03 (NE, NE)	92/123 (74.8)	0.03 (0.03, 3.25)	0.67 (0.48, 0.95)	0.0327	
≥35 years	66/74 (89.2)	0.03 (NE, NE)	117/148 (79.1)	0.03 (0.03, 2.56)	0.58 (0.43, 0.79)	0.0003	
Age group 2							0.3229
<35 years	53/60 (88.3)	0.03 (NE, NE)	93/124 (75.0)	0.03 (0.03, 3.25)	0.68 (0.48, 0.95)	0.0354	
35 - 54 years	29/33 (87.9)	0.03 (NE, NE)	60/80 (75.0)	0.03 (0.03, 4.69)	0.50 (0.32, 0.79)	0.0049	
55 - 64 years	25/26 (96.2)	0.03 (NE, NE)	27/34 (79.4)	0.03 (0.03, 4.03)	0.53 (0.30, 0.93)	0.0225	
≥65 years	12/15 (80.0)	2.56 (0.03, 2.79)	29/33 (87.9)	0.03 (0.03, 2.56)	0.98 (0.49, 1.94)	0.6996	
Sex							0.1270
Male	67/77 (87.0)	0.03 (NE, NE)	134/162 (82.7)	0.03 (NE, NE)	0.73 (0.54, 0.98)	0.0340	
Female	52/57 (91.2)	0.03 (NE, NE)	75/109 (68.8)	3.31 (0.03, 5.70)	0.52 (0.36, 0.74)	0.0007	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
EFS is calculated from the time of randomization until the date of a disease assessment indicating a relapse event or death, whichever occurs first.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-efs-fas.sas
Output: t14-04-005-002-tte-sub-efs-fas.rtf (Date generated: 28MAY2025:05:05) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Table 14-4.5.2. Event Free Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.0729
USA	12/15 (80.0)	0.03 (0.03, 2.82)	28/31 (90.3)	0.03 (0.03, 3.97)	1.28 (0.63, 2.60)	0.3999	
Europe	75/85 (88.2)	0.03 (NE, NE)	132/180 (73.3)	0.03 (0.03, 2.98)	0.59 (0.44, 0.79)	0.0005	
Rest of the world	32/34 (94.1)	0.03 (NE, NE)	49/60 (81.7)	0.03 (0.03, 5.15)	0.53 (0.34, 0.85)	0.0030	
Prior salvage therapy							0.4768
Yes	77/80 (96.3)	0.03 (NE, NE)	138/164 (84.1)	0.03 (NE, NE)	0.56 (0.42, 0.75)	<0.0001	
No	42/54 (77.8)	0.03 (0.03, 2.23)	71/107 (66.4)	3.57 (0.03, 6.52)	0.70 (0.48, 1.03)	0.0791	
Number of salvage therapies							0.4752
0	51/65 (78.5)	0.03 (NE, NE)	78/114 (68.4)	2.82 (0.03, 5.70)	0.71 (0.50, 1.01)	0.0887	
1	42/43 (97.7)	0.03 (NE, NE)	73/91 (80.2)	0.03 (NE, NE)	0.51 (0.35, 0.76)	0.0002	
≥2	26/26 (100.0)	0.03 (NE, NE)	58/66 (87.9)	0.03 (NE, NE)	0.48 (0.29, 0.79)	0.0005	

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
EFS is calculated from the time of randomization until the date of a disease assessment indicating a relapse event or death, whichever occurs first.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-efs-fas.sas
Output: t14-04-005-002-tte-sub-efs-fas.rtf (Date generated: 28MAY2025:05:05) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Table 14-4.5.2. Event Free Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0118
Yes	45/46 (97.8)	0.03 (NE, NE)	72/94 (76.6)	0.03 (0.03, 2.95)	0.44 (0.30, 0.66)	<0.0001	
No	74/88 (84.1)	0.03 (NE, NE)	137/177 (77.4)	0.03 (0.03, 2.82)	0.76 (0.57, 1.01)	0.0866	
Race							0.5060
Caucasian	100/112 (89.3)	0.03 (NE, NE)	173/228 (75.9)	0.03 (0.03, 2.30)	0.61 (0.48, 0.79)	0.0001	
Others	19/22 (86.4)	0.03 (NE, NE)	36/43 (83.7)	0.03 (0.03, 4.69)	0.74 (0.42, 1.30)	0.4689	
Central laboratory baseline bone marrow blasts							0.2452
<50%	29/36 (80.6)	0.03 (NE, NE)	47/73 (64.4)	5.54 (3.31, 7.11)	0.48 (0.30, 0.77)	0.0052	
≥50%	85/93 (91.4)	0.03 (NE, NE)	141/170 (82.9)	0.03 (NE, NE)	0.72 (0.55, 0.94)	0.0090	

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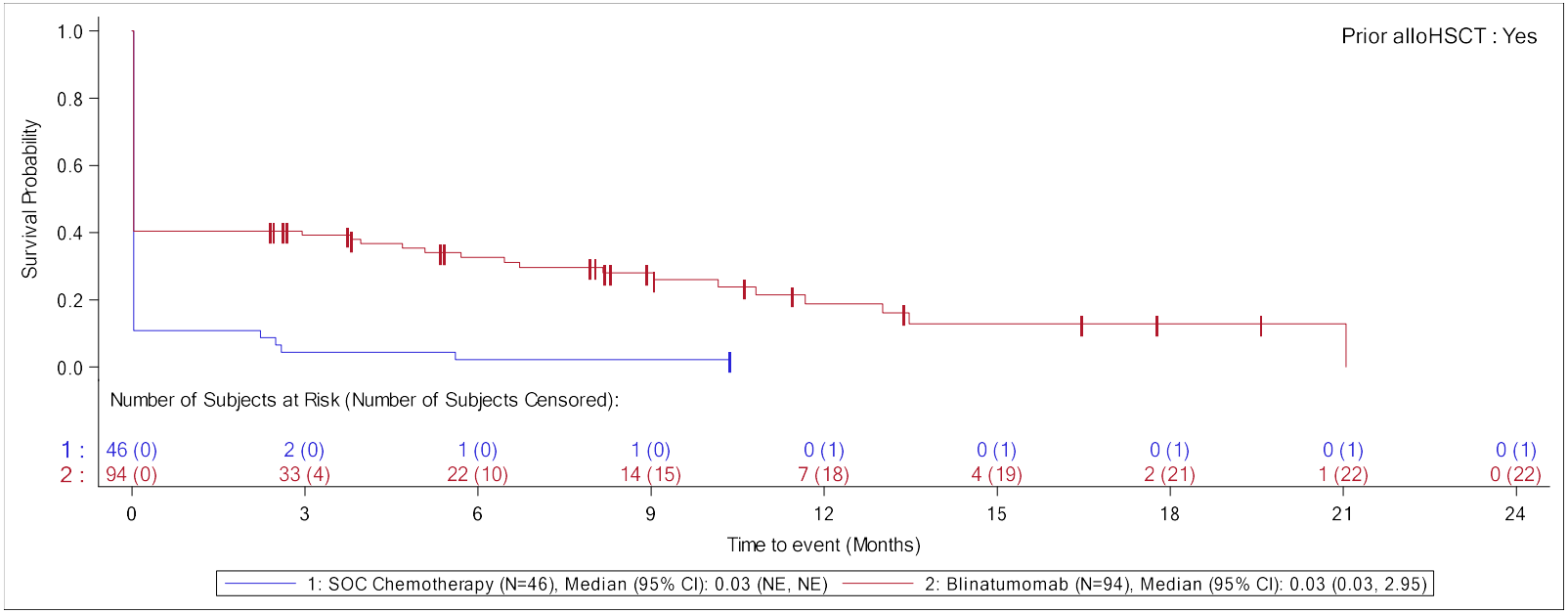
Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
EFS is calculated from the time of randomization until the date of a disease assessment indicating a relapse event or death, whichever occurs first.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-efs-fas.sas
Output: t14-04-005-002-tte-sub-efs-fas.rtf (Date generated: 28MAY2025:05:05) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

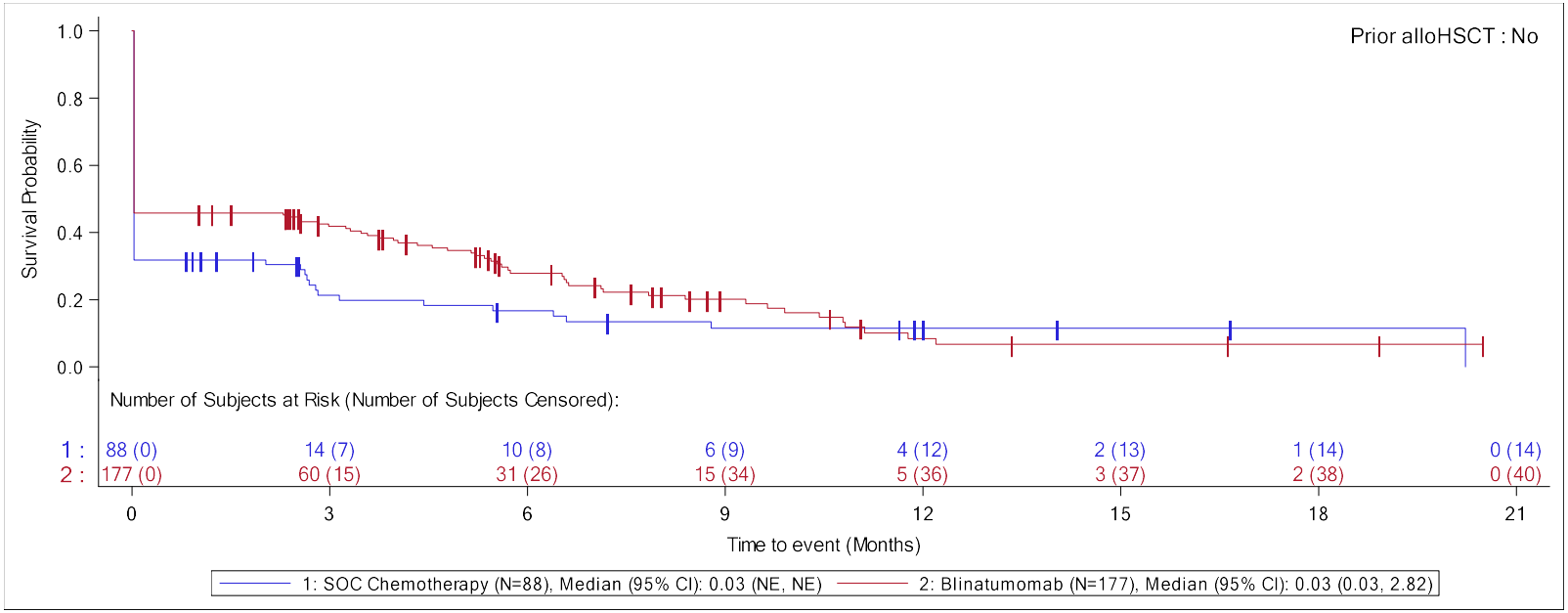
Figure 14-4.5.2. Kaplan-Meier plot for Event Free Survival - Subgroup Analysis (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-efs-fas.sas
Output: f14-04-005-002-km-sub-efs-fas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Figure 14-4.5.2. Kaplan-Meier plot for Event Free Survival - Subgroup Analysis (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-efs-fas.sas
Output: f14-04-005-002-km-sub-efs-fas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adtteeff

Anhang 4-G3.3: Subgruppenanalysen zur kompletten Remission

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1				0.5342
Age group 1: <35 years	60	123		
Number of subjects assessed[c]	32	94		
Events - n (%)	8 (25.0)	42 (44.7)	19.7	
Unstratified odds ratio[a]			2.42	
(95% CI)			(0.99, 5.95)	
p-value			0.0533	
Unstratified risk ratio[a]			1.79	
(95% CI)			(0.94, 3.39)	
p-value			0.0758	
Absolute risk reduction			0.20	
(95% CI)			(0.02, 0.38)	
p-value			0.0327	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1: ≥35 years	74	148		
Number of subjects assessed[c]	40	110		
Events - n (%)	13 (32.5)	49 (44.5)	12.0	
Unstratified odds ratio[a]			1.67	
(95% CI)			(0.78, 3.57)	
p-value			0.1875	
Unstratified risk ratio[a]			1.37	
(95% CI)			(0.84, 2.24)	
p-value			0.2100	
Absolute risk reduction			0.12	
(95% CI)			(-0.05, 0.29)	
p-value			0.1707	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2				0.5071
Age group 2: <35 years	60	124		
Number of subjects assessed[c]	32	94		
Events - n (%)	8 (25.0)	42 (44.7)	19.7	
Unstratified odds ratio[a]			2.42	
(95% CI)			(0.99, 5.95)	
p-value			0.0533	
Unstratified risk ratio[a]			1.79	
(95% CI)			(0.94, 3.39)	
p-value			0.0758	
Absolute risk reduction			0.20	
(95% CI)			(0.02, 0.38)	
p-value			0.0327	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 35 - 54 years	33	80		
Number of subjects assessed[c]	15	63		
Events - n (%)	5 (33.3)	27 (42.9)	9.5	
Unstratified odds ratio[a]			1.50	
(95% CI)			(0.46, 4.90)	
p-value			0.5021	
Unstratified risk ratio[a]			1.29	
(95% CI)			(0.60, 2.78)	
p-value			0.5226	
Absolute risk reduction			0.10	
(95% CI)			(-0.17, 0.36)	
p-value			0.4862	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 55 - 64 years	26	34		
Number of subjects assessed[c]	14	26		
Events - n (%)	2 (14.3)	11 (42.3)	28.0	
Unstratified odds ratio[a]			4.40	
(95% CI)			(0.81, 23.77)	
p-value			0.0852	
Unstratified risk ratio[a]			2.96	
(95% CI)			(0.76, 11.53)	
p-value			0.1175	
Absolute risk reduction			0.28	
(95% CI)			(0.02, 0.54)	
p-value			0.0374	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: ≥65 years	15	33		
Number of subjects assessed[c]	11	21		
Events - n (%)	6 (54.5)	11 (52.4)	-2.2	
Unstratified odds ratio[a]			0.92	
(95% CI)			(0.21, 3.96)	
p-value			0.9073	
Unstratified risk ratio[a]			0.96	
(95% CI)			(0.49, 1.89)	
p-value			0.9066	
Absolute risk reduction			-0.02	
(95% CI)			(-0.39, 0.34)	
p-value			0.9071	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex				0.5210
Sex: Male	77	162		
Number of subjects assessed[c]	43	117		
Events - n (%)	13 (30.2)	49 (41.9)	11.6	
Unstratified odds ratio[a]			1.66	
(95% CI)			(0.79, 3.51)	
p-value			0.1823	
Unstratified risk ratio[a]			1.39	
(95% CI)			(0.84, 2.29)	
p-value			0.2030	
Absolute risk reduction			0.12	
(95% CI)			(-0.05, 0.28)	
p-value			0.1634	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex: Female	57	109		
Number of subjects assessed[c]	29	87		
Events - n (%)	8 (27.6)	42 (48.3)	20.7	
Unstratified odds ratio[a]			2.45	
(95% CI)			(0.98, 6.13)	
p-value			0.0553	
Unstratified risk ratio[a]			1.75	
(95% CI)			(0.93, 3.28)	
p-value			0.0810	
Absolute risk reduction			0.21	
(95% CI)			(0.01, 0.40)	
p-value			0.0362	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region				0.7900
Region: USA	15	31		
Number of subjects assessed[c]	10	22		
Events - n (%)	4 (40.0)	10 (45.5)	5.5	
Unstratified odds ratio[a]			1.25	
(95% CI)			(0.27, 5.70)	
p-value			0.7733	
Unstratified risk ratio[a]			1.14	
(95% CI)			(0.47, 2.76)	
p-value			0.7774	
Absolute risk reduction			0.05	
(95% CI)			(-0.31, 0.42)	
p-value			0.7715	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Europe	85	180		
Number of subjects assessed[c]	47	138		
Events - n (%)	14 (29.8)	64 (46.4)	16.6	
Unstratified odds ratio[a]			2.04	
(95% CI)			(1.00, 4.14)	
p-value			0.0490	
Unstratified risk ratio[a]			1.56	
(95% CI)			(0.97, 2.50)	
p-value			0.0673	
Absolute risk reduction			0.17	
(95% CI)			(0.01, 0.32)	
p-value			0.0359	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Rest of the world	34	60		
Number of subjects assessed[c]	15	44		
Events - n (%)	3 (20.0)	17 (38.6)	18.6	
Unstratified odds ratio[a]			2.52	
(95% CI)			(0.62, 10.25)	
p-value			0.1970	
Unstratified risk ratio[a]			1.93	
(95% CI)			(0.66, 5.68)	
p-value			0.2314	
Absolute risk reduction			0.19	
(95% CI)			(-0.06, 0.43)	
p-value			0.1413	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy				0.1200
Prior salvage therapy: Yes	80	164		
Number of subjects assessed[c]	36	117		
Events - n (%)	5 (13.9)	45 (38.5)	24.6	
Unstratified odds ratio[a]			3.87	
(95% CI)			(1.40, 10.69)	
p-value			0.0089	
Unstratified risk ratio[a]			2.77	
(95% CI)			(1.19, 6.45)	
p-value			0.0182	
Absolute risk reduction			0.25	
(95% CI)			(0.10, 0.39)	
p-value			0.0008	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy: No	54	107		
Number of subjects assessed[c]	36	87		
Events - n (%)	16 (44.4)	46 (52.9)	8.4	
Unstratified odds ratio[a]			1.40	
(95% CI)			(0.64, 3.06)	
p-value			0.3958	
Unstratified risk ratio[a]			1.19	
(95% CI)			(0.79, 1.80)	
p-value			0.4128	
Absolute risk reduction			0.08	
(95% CI)			(-0.11, 0.28)	
p-value			0.3926	

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[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies				0.2422
Number of salvage therapies: 0	65	114		
Number of subjects assessed[c]	39	92		
Events - n (%)	18 (46.2)	51 (55.4)	9.3	
Unstratified odds ratio[a]			1.45	
(95% CI)			(0.68, 3.08)	
p-value			0.3317	
Unstratified risk ratio[a]			1.20	
(95% CI)			(0.82, 1.77)	
p-value			0.3514	
Absolute risk reduction			0.09	
(95% CI)			(-0.09, 0.28)	
p-value			0.3295	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: 1	43	91		
Number of subjects assessed[c]	20	66		
Events - n (%)	3 (15.0)	25 (37.9)	22.9	
Unstratified odds ratio[a]			3.46	
(95% CI)			(0.92, 12.99)	
p-value			0.0665	
Unstratified risk ratio[a]			2.53	
(95% CI)			(0.85, 7.50)	
p-value			0.0952	
Absolute risk reduction			0.23	
(95% CI)			(0.03, 0.42)	
p-value			0.0217	

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[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: ≥2	26	66		
Number of subjects assessed[c]	13	46		
Events - n (%)	0 (0.0)	15 (32.6)	32.6	
Unstratified odds ratio[a]			13.29	
(95% CI)			(0.74, 238.44)	
p-value			0.0791	
Unstratified risk ratio[a]			9.23	
(95% CI)			(0.59, 144.76)	
p-value			0.1134	
Absolute risk reduction			0.29	
(95% CI)			(0.13, 0.46)	
p-value			0.0005	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT				0.1804
Prior alloHSCT: Yes	46	94		
Number of subjects assessed[c]	19	71		
Events - n (%)	2 (10.5)	27 (38.0)	27.5	
Unstratified odds ratio[a]			5.22	
(95% CI)			(1.12, 24.37)	
p-value			0.0357	
Unstratified risk ratio[a]			3.61	
(95% CI)			(0.94, 13.85)	
p-value			0.0611	
Absolute risk reduction			0.28	
(95% CI)			(0.10, 0.45)	
p-value			0.0025	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT: No	88	177		
Number of subjects assessed[c]	53	133		
Events - n (%)	19 (35.8)	64 (48.1)	12.3	
Unstratified odds ratio[a]			1.66	
(95% CI)			(0.86, 3.20)	
p-value			0.1303	
Unstratified risk ratio[a]			1.34	
(95% CI)			(0.90, 2.00)	
p-value			0.1502	
Absolute risk reduction			0.12	
(95% CI)			(-0.03, 0.28)	
p-value			0.1196	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race				0.3139
Race: Caucasian	112	228		
Number of subjects assessed[c]	61	171		
Events - n (%)	17 (27.9)	79 (46.2)	18.3	
Unstratified odds ratio[a]			2.22	
(95% CI)			(1.18, 4.20)	
p-value			0.0138	
Unstratified risk ratio[a]			1.66	
(95% CI)			(1.07, 2.56)	
p-value			0.0227	
Absolute risk reduction			0.18	
(95% CI)			(0.05, 0.32)	
p-value			0.0078	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race: Others	22	43		
Number of subjects assessed[c]	11	33		
Events - n (%)	4 (36.4)	12 (36.4)	0.0	
Unstratified odds ratio[a]			1.00	
(95% CI)			(0.24, 4.13)	
p-value			>0.9999	
Unstratified risk ratio[a]			1.00	
(95% CI)			(0.41, 2.47)	
p-value			>0.9999	
Absolute risk reduction			-0.00	
(95% CI)			(-0.33, 0.33)	
p-value			>0.9999	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts				0.6636
Central laboratory baseline bone marrow blasts: <50%	36	73		
Number of subjects assessed[c]	22	68		
Events - n (%)	9 (40.9)	41 (60.3)	19.4	
Unstratified odds ratio[a]			2.19	
(95% CI)			(0.82, 5.84)	
p-value			0.1158	
Unstratified risk ratio[a]			1.47	
(95% CI)			(0.86, 2.52)	
p-value			0.1576	
Absolute risk reduction			0.19	
(95% CI)			(-0.04, 0.43)	
p-value			0.1075	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts: ≥50%	93	170		
Number of subjects assessed[c]	49	120		
Events - n (%)	11 (22.4)	39 (32.5)	10.1	
Unstratified odds ratio[a]			1.66	
(95% CI)			(0.77, 3.60)	
p-value			0.1967	
Unstratified risk ratio[a]			1.45	
(95% CI)			(0.81, 2.59)	
p-value			0.2118	
Absolute risk reduction			0.10	
(95% CI)			(-0.04, 0.24)	
p-value			0.1706	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Anhang 4-G3.4: Subgruppenanalysen zur Remission der minimalen Resterkrankung

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1				0.4826
Age group 1: <35 years	60	123		
Number of subjects assessed[c]	29	73		
Events - n (%)	7 (24.1)	31 (42.5)	18.3	
Unstratified odds ratio[a]			2.32	
(95% CI)			(0.88, 6.11)	
p-value			0.0887	
Unstratified risk ratio[a]			1.76	
(95% CI)			(0.88, 3.54)	
p-value			0.1128	
Absolute risk reduction			0.18	
(95% CI)			(-0.01, 0.38)	
p-value			0.0622	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 05JUN2025:02:11) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1: ≥35 years	74	148		
Number of subjects assessed[c]	40	93		
Events - n (%)	5 (12.5)	33 (35.5)	23.0	
Unstratified odds ratio[a]			3.85	
(95% CI)			(1.38, 10.77)	
p-value			0.0102	
Unstratified risk ratio[a]			2.84	
(95% CI)			(1.20, 6.74)	
p-value			0.0180	
Absolute risk reduction			0.23	
(95% CI)			(0.09, 0.37)	
p-value			0.0014	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 05JUN2025:02:11) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2				0.4957
Age group 2: <35 years	60	124		
Number of subjects assessed[c]	29	73		
Events - n (%)	7 (24.1)	31 (42.5)	18.3	
Unstratified odds ratio[a]			2.32	
(95% CI)			(0.88, 6.11)	
p-value			0.0887	
Unstratified risk ratio[a]			1.76	
(95% CI)			(0.88, 3.54)	
p-value			0.1128	
Absolute risk reduction			0.18	
(95% CI)			(-0.01, 0.38)	
p-value			0.0622	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 35 - 54 years	33	80		
Number of subjects assessed[c]	17	50		
Events - n (%)	2 (11.8)	19 (38.0)	26.2	
Unstratified odds ratio[a]			4.59	
(95% CI)			(0.94, 22.35)	
p-value			0.0588	
Unstratified risk ratio[a]			3.23	
(95% CI)			(0.84, 12.45)	
p-value			0.0885	
Absolute risk reduction			0.26	
(95% CI)			(0.06, 0.47)	
p-value			0.0117	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 55 - 64 years	26	34		
Number of subjects assessed[c]	11	23		
Events - n (%)	0 (0.0)	8 (34.8)	34.8	
Unstratified odds ratio[a]			12.61	
(95% CI)			(0.66, 241.29)	
p-value			0.0924	
Unstratified risk ratio[a]			8.50	
(95% CI)			(0.53, 135.20)	
p-value			0.1295	
Absolute risk reduction			0.31	
(95% CI)			(0.09, 0.53)	
p-value			0.0059	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: ≥65 years	15	33		
Number of subjects assessed[c]	12	20		
Events - n (%)	3 (25.0)	6 (30.0)	5.0	
Unstratified odds ratio[a]			1.29	
(95% CI)			(0.25, 6.49)	
p-value			0.7610	
Unstratified risk ratio[a]			1.20	
(95% CI)			(0.37, 3.93)	
p-value			0.7633	
Absolute risk reduction			0.05	
(95% CI)			(-0.27, 0.37)	
p-value			0.7571	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex				0.7171
Sex: Male	77	162		
Number of subjects assessed[c]	42	95		
Events - n (%)	5 (11.9)	30 (31.6)	19.7	
Unstratified odds ratio[a]			3.42	
(95% CI)			(1.22, 9.56)	
p-value			0.0193	
Unstratified risk ratio[a]			2.65	
(95% CI)			(1.11, 6.36)	
p-value			0.0288	
Absolute risk reduction			0.20	
(95% CI)			(0.06, 0.33)	
p-value			0.0044	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex: Female	57	109		
Number of subjects assessed[c]	27	71		
Events - n (%)	7 (25.9)	34 (47.9)	22.0	
Unstratified odds ratio[a]			2.63	
(95% CI)			(0.99, 6.99)	
p-value			0.0532	
Unstratified risk ratio[a]			1.85	
(95% CI)			(0.93, 3.65)	
p-value			0.0779	
Absolute risk reduction			0.22	
(95% CI)			(0.02, 0.42)	
p-value			0.0331	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region				0.2252
Region: USA	15	31		
Number of subjects assessed[c]	8	19		
Events - n (%)	5 (62.5)	11 (57.9)	-4.6	
Unstratified odds ratio[a]			0.83	
(95% CI)			(0.15, 4.50)	
p-value			0.8241	
Unstratified risk ratio[a]			0.93	
(95% CI)			(0.48, 1.79)	
p-value			0.8201	
Absolute risk reduction			-0.05	
(95% CI)			(-0.45, 0.36)	
p-value			0.8225	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Europe	85	180		
Number of subjects assessed[c]	45	112		
Events - n (%)	5 (11.1)	41 (36.6)	25.5	
Unstratified odds ratio[a]			4.62	
(95% CI)			(1.69, 12.63)	
p-value			0.0029	
Unstratified risk ratio[a]			3.29	
(95% CI)			(1.39, 7.80)	
p-value			0.0067	
Absolute risk reduction			0.25	
(95% CI)			(0.13, 0.38)	
p-value			<0.0001	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 05JUN2025:02:11) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Rest of the world	34	60		
Number of subjects assessed[c]	16	35		
Events - n (%)	2 (12.5)	12 (34.3)	21.8	
Unstratified odds ratio[a]			3.65	
(95% CI)			(0.71, 18.78)	
p-value			0.1211	
Unstratified risk ratio[a]			2.74	
(95% CI)			(0.69, 10.85)	
p-value			0.1504	
Absolute risk reduction			0.22	
(95% CI)			(-0.01, 0.44)	
p-value			0.0586	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy				0.0485
Prior salvage therapy: Yes	80	164		
Number of subjects assessed[c]	35	93		
Events - n (%)	2 (5.7)	34 (36.6)	30.8	
Unstratified odds ratio[a]			9.51	
(95% CI)			(2.15, 42.11)	
p-value			0.0030	
Unstratified risk ratio[a]			6.40	
(95% CI)			(1.62, 25.23)	
p-value			0.0080	
Absolute risk reduction			0.31	
(95% CI)			(0.18, 0.43)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy: No	54	107		
Number of subjects assessed[c]	34	73		
Events - n (%)	10 (29.4)	30 (41.1)	11.7	
Unstratified odds ratio[a]			1.67	
(95% CI)			(0.70, 4.01)	
p-value			0.2471	
Unstratified risk ratio[a]			1.40	
(95% CI)			(0.78, 2.52)	
p-value			0.2654	
Absolute risk reduction			0.12	
(95% CI)			(-0.07, 0.31)	
p-value			0.2287	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies				0.1772
Number of salvage therapies: 0	65	114		
Number of subjects assessed[c]	40	83		
Events - n (%)	11 (27.5)	33 (39.8)	12.3	
Unstratified odds ratio[a]			1.74	
(95% CI)			(0.77, 3.96)	
p-value			0.1865	
Unstratified risk ratio[a]			1.45	
(95% CI)			(0.82, 2.55)	
p-value			0.2038	
Absolute risk reduction			0.12	
(95% CI)			(-0.05, 0.30)	
p-value			0.1670	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: 1	43	91		
Number of subjects assessed[c]	18	50		
Events - n (%)	0 (0.0)	16 (32.0)	32.0	
Unstratified odds ratio[a]			17.70	
(95% CI)			(1.00, 311.97)	
p-value			0.0497	
Unstratified risk ratio[a]			12.29	
(95% CI)			(0.78, 194.97)	
p-value			0.0752	
Absolute risk reduction			0.30	
(95% CI)			(0.15, 0.44)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: ≥2	26	66		
Number of subjects assessed[c]	11	33		
Events - n (%)	1 (9.1)	15 (45.5)	36.4	
Unstratified odds ratio[a]			8.33	
(95% CI)			(0.95, 72.75)	
p-value			0.0551	
Unstratified risk ratio[a]			5.00	
(95% CI)			(0.74, 33.62)	
p-value			0.0979	
Absolute risk reduction			0.36	
(95% CI)			(0.12, 0.60)	
p-value			0.0030	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT				0.3594
Prior alloHSCT: Yes	46	94		
Number of subjects assessed[c]	19	53		
Events - n (%)	2 (10.5)	21 (39.6)	29.1	
Unstratified odds ratio[a]			5.58	
(95% CI)			(1.17, 26.68)	
p-value			0.0314	
Unstratified risk ratio[a]			3.76	
(95% CI)			(0.97, 14.55)	
p-value			0.0547	
Absolute risk reduction			0.29	
(95% CI)			(0.10, 0.48)	
p-value			0.0028	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT: No	88	177		
Number of subjects assessed[c]	50	113		
Events - n (%)	10 (20.0)	43 (38.1)	18.1	
Unstratified odds ratio[a]			2.46	
(95% CI)			(1.11, 5.42)	
p-value			0.0258	
Unstratified risk ratio[a]			1.90	
(95% CI)			(1.04, 3.47)	
p-value			0.0363	
Absolute risk reduction			0.18	
(95% CI)			(0.04, 0.32)	
p-value			0.0130	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race				0.1516
Race: Caucasian	112	228		
Number of subjects assessed[c]	60	138		
Events - n (%)	8 (13.3)	51 (37.0)	23.6	
Unstratified odds ratio[a]			3.81	
(95% CI)			(1.68, 8.66)	
p-value			0.0014	
Unstratified risk ratio[a]			2.77	
(95% CI)			(1.40, 5.48)	
p-value			0.0033	
Absolute risk reduction			0.24	
(95% CI)			(0.12, 0.35)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race: Others	22	43		
Number of subjects assessed[c]	9	28		
Events - n (%)	4 (44.4)	13 (46.4)	2.0	
Unstratified odds ratio[a]			1.08	
(95% CI)			(0.24, 4.90)	
p-value			0.9174	
Unstratified risk ratio[a]			1.04	
(95% CI)			(0.45, 2.40)	
p-value			0.9180	
Absolute risk reduction			0.02	
(95% CI)			(-0.35, 0.39)	
p-value			0.9171	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts				0.7824
Central laboratory baseline bone marrow blasts: <50%	36	73		
Number of subjects assessed[c]	22	60		
Events - n (%)	4 (18.2)	23 (38.3)	20.2	
Unstratified odds ratio[a]			2.80	
(95% CI)			(0.84, 9.31)	
p-value			0.0935	
Unstratified risk ratio[a]			2.11	
(95% CI)			(0.82, 5.41)	
p-value			0.1210	
Absolute risk reduction			0.20	
(95% CI)			(-0.00, 0.40)	
p-value			0.0514	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts: ≥50%	93	170		
Number of subjects assessed[c]	46	94		
Events - n (%)	7 (15.2)	36 (38.3)	23.1	
Unstratified odds ratio[a]			3.46	
(95% CI)			(1.40, 8.55)	
p-value			0.0073	
Unstratified risk ratio[a]			2.52	
(95% CI)			(1.21, 5.22)	
p-value			0.0131	
Absolute risk reduction			0.23	
(95% CI)			(0.09, 0.37)	
p-value			0.0016	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1				0.1315
Age group 1: <35 years	60	123		
Number of subjects assessed[c]	29	73		
Events - n (%)	11 (37.9)	35 (47.9)	10.0	
Unstratified odds ratio[a]			1.51	
(95% CI)			(0.63, 3.63)	
p-value			0.3606	
Unstratified risk ratio[a]			1.26	
(95% CI)			(0.75, 2.13)	
p-value			0.3803	
Absolute risk reduction			0.10	
(95% CI)			(-0.11, 0.31)	
p-value			0.3512	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1: ≥35 years	74	148		
Number of subjects assessed[c]	40	93		
Events - n (%)	8 (20.0)	46 (49.5)	29.5	
Unstratified odds ratio[a]			3.91	
(95% CI)			(1.63, 9.39)	
p-value			0.0022	
Unstratified risk ratio[a]			2.47	
(95% CI)			(1.29, 4.75)	
p-value			0.0066	
Absolute risk reduction			0.29	
(95% CI)			(0.13, 0.45)	
p-value			0.0003	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2				0.1605
Age group 2: <35 years	60	124		
Number of subjects assessed[c]	29	73		
Events - n (%)	11 (37.9)	35 (47.9)	10.0	
Unstratified odds ratio[a]			1.51	
(95% CI)			(0.63, 3.63)	
p-value			0.3606	
Unstratified risk ratio[a]			1.26	
(95% CI)			(0.75, 2.13)	
p-value			0.3803	
Absolute risk reduction			0.10	
(95% CI)			(-0.11, 0.31)	
p-value			0.3512	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 35 - 54 years	33	80		
Number of subjects assessed[c]	17	50		
Events - n (%)	3 (17.6)	25 (50.0)	32.4	
Unstratified odds ratio[a]			4.67	
(95% CI)			(1.19, 18.26)	
p-value			0.0269	
Unstratified risk ratio[a]			2.83	
(95% CI)			(0.98, 8.21)	
p-value			0.0550	
Absolute risk reduction			0.32	
(95% CI)			(0.10, 0.55)	
p-value			0.0054	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 55 - 64 years	26	34		
Number of subjects assessed[c]	11	23		
Events - n (%)	0 (0.0)	12 (52.2)	52.2	
Unstratified odds ratio[a]			25.00	
(95% CI)			(1.32, 474.08)	
p-value			0.0320	
Unstratified risk ratio[a]			12.50	
(95% CI)			(0.81, 193.67)	
p-value			0.0709	
Absolute risk reduction			0.48	
(95% CI)			(0.25, 0.71)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: ≥65 years	15	33		
Number of subjects assessed[c]	12	20		
Events - n (%)	5 (41.7)	9 (45.0)	3.3	
Unstratified odds ratio[a]			1.15	
(95% CI)			(0.27, 4.87)	
p-value			0.8540	
Unstratified risk ratio[a]			1.08	
(95% CI)			(0.47, 2.47)	
p-value			0.8552	
Absolute risk reduction			0.03	
(95% CI)			(-0.32, 0.39)	
p-value			0.8536	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex				0.7990
Sex: Male	77	162		
Number of subjects assessed[c]	42	95		
Events - n (%)	10 (23.8)	40 (42.1)	18.3	
Unstratified odds ratio[a]			2.33	
(95% CI)			(1.03, 5.28)	
p-value			0.0431	
Unstratified risk ratio[a]			1.77	
(95% CI)			(0.98, 3.19)	
p-value			0.0583	
Absolute risk reduction			0.18	
(95% CI)			(0.02, 0.35)	
p-value			0.0275	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex: Female	57	109		
Number of subjects assessed[c]	27	71		
Events - n (%)	9 (33.3)	41 (57.7)	24.4	
Unstratified odds ratio[a]			2.73	
(95% CI)			(1.08, 6.92)	
p-value			0.0338	
Unstratified risk ratio[a]			1.73	
(95% CI)			(0.98, 3.06)	
p-value			0.0585	
Absolute risk reduction			0.24	
(95% CI)			(0.03, 0.46)	
p-value			0.0238	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region				0.1852
Region: USA	15	31		
Number of subjects assessed[c]	8	19		
Events - n (%)	5 (62.5)	11 (57.9)	-4.6	
Unstratified odds ratio[a]			0.83	
(95% CI)			(0.15, 4.50)	
p-value			0.8241	
Unstratified risk ratio[a]			0.93	
(95% CI)			(0.48, 1.79)	
p-value			0.8201	
Absolute risk reduction			-0.05	
(95% CI)			(-0.45, 0.36)	
p-value			0.8225	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Europe	85	180		
Number of subjects assessed[c]	45	112		
Events - n (%)	12 (26.7)	52 (46.4)	19.8	
Unstratified odds ratio[a]			2.38	
(95% CI)			(1.12, 5.09)	
p-value			0.0247	
Unstratified risk ratio[a]			1.74	
(95% CI)			(1.03, 2.94)	
p-value			0.0380	
Absolute risk reduction			0.20	
(95% CI)			(0.04, 0.36)	
p-value			0.0147	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Rest of the world	34	60		
Number of subjects assessed[c]	16	35		
Events - n (%)	2 (12.5)	18 (51.4)	38.9	
Unstratified odds ratio[a]			7.41	
(95% CI)			(1.46, 37.57)	
p-value			0.0156	
Unstratified risk ratio[a]			4.11	
(95% CI)			(1.08, 15.65)	
p-value			0.0379	
Absolute risk reduction			0.39	
(95% CI)			(0.16, 0.62)	
p-value			0.0010	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy				0.0755
Prior salvage therapy: Yes	80	164		
Number of subjects assessed[c]	35	93		
Events - n (%)	6 (17.1)	46 (49.5)	32.3	
Unstratified odds ratio[a]			4.73	
(95% CI)			(1.80, 12.46)	
p-value			0.0017	
Unstratified risk ratio[a]			2.89	
(95% CI)			(1.35, 6.15)	
p-value			0.0061	
Absolute risk reduction			0.32	
(95% CI)			(0.16, 0.48)	
p-value			<0.0001	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Data cut-off date: 04JAN2016

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy: No	54	107		
Number of subjects assessed[c]	34	73		
Events - n (%)	13 (38.2)	35 (47.9)	9.7	
Unstratified odds ratio[a]			1.49	
(95% CI)			(0.65, 3.41)	
p-value			0.3482	
Unstratified risk ratio[a]			1.25	
(95% CI)			(0.77, 2.05)	
p-value			0.3649	
Absolute risk reduction			0.10	
(95% CI)			(-0.10, 0.30)	
p-value			0.3402	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies				0.1310
Number of salvage therapies: 0	65	114		
Number of subjects assessed[c]	40	83		
Events - n (%)	15 (37.5)	40 (48.2)	10.7	
Unstratified odds ratio[a]			1.55	
(95% CI)			(0.72, 3.35)	
p-value			0.2652	
Unstratified risk ratio[a]			1.29	
(95% CI)			(0.81, 2.03)	
p-value			0.2831	
Absolute risk reduction			0.11	
(95% CI)			(-0.08, 0.29)	
p-value			0.2562	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: 1	43	91		
Number of subjects assessed[c]	18	50		
Events - n (%)	1 (5.6)	22 (44.0)	38.4	
Unstratified odds ratio[a]			13.35	
(95% CI)			(1.65, 108.22)	
p-value			0.0152	
Unstratified risk ratio[a]			7.92	
(95% CI)			(1.15, 54.58)	
p-value			0.0356	
Absolute risk reduction			0.38	
(95% CI)			(0.21, 0.56)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: ≥2	26	66		
Number of subjects assessed[c]	11	33		
Events - n (%)	3 (27.3)	19 (57.6)	30.3	
Unstratified odds ratio[a]			3.62	
(95% CI)			(0.81, 16.15)	
p-value			0.0919	
Unstratified risk ratio[a]			2.11	
(95% CI)			(0.77, 5.79)	
p-value			0.1464	
Absolute risk reduction			0.30	
(95% CI)			(-0.01, 0.62)	
p-value			0.0574	

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT				0.2867
Prior alloHSCT: Yes	46	94		
Number of subjects assessed[c]	19	53		
Events - n (%)	3 (15.8)	25 (47.2)	31.4	
Unstratified odds ratio[a]			4.76	
(95% CI)			(1.24, 18.29)	
p-value			0.0231	
Unstratified risk ratio[a]			2.99	
(95% CI)			(1.02, 8.77)	
p-value			0.0464	
Absolute risk reduction			0.31	
(95% CI)			(0.10, 0.53)	
p-value			0.0037	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT: No	88	177		
Number of subjects assessed[c]	50	113		
Events - n (%)	16 (32.0)	56 (49.6)	17.6	
Unstratified odds ratio[a]			2.09	
(95% CI)			(1.04, 4.20)	
p-value			0.0391	
Unstratified risk ratio[a]			1.55	
(95% CI)			(0.99, 2.42)	
p-value			0.0539	
Absolute risk reduction			0.18	
(95% CI)			(0.02, 0.33)	
p-value			0.0302	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race				0.5766
Race: Caucasian	112	228		
Number of subjects assessed[c]	60	138		
Events - n (%)	15 (25.0)	65 (47.1)	22.1	
Unstratified odds ratio[a]			2.67	
(95% CI)			(1.36, 5.24)	
p-value			0.0042	
Unstratified risk ratio[a]			1.88	
(95% CI)			(1.17, 3.02)	
p-value			0.0086	
Absolute risk reduction			0.22	
(95% CI)			(0.08, 0.36)	
p-value			0.0016	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race: Others	22	43		
Number of subjects assessed[c]	9	28		
Events - n (%)	4 (44.4)	16 (57.1)	12.7	
Unstratified odds ratio[a]			1.67	
(95% CI)			(0.37, 7.57)	
p-value			0.5081	
Unstratified risk ratio[a]			1.29	
(95% CI)			(0.58, 2.86)	
p-value			0.5369	
Absolute risk reduction			0.13	
(95% CI)			(-0.25, 0.50)	
p-value			0.5044	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts				0.8920
Central laboratory baseline bone marrow blasts: <50%	36	73		
Number of subjects assessed[c]	22	60		
Events - n (%)	6 (27.3)	31 (51.7)	24.4	
Unstratified odds ratio[a]			2.85	
(95% CI)			(0.98, 8.28)	
p-value			0.0541	
Unstratified risk ratio[a]			1.89	
(95% CI)			(0.92, 3.91)	
p-value			0.0841	
Absolute risk reduction			0.24	
(95% CI)			(0.02, 0.47)	
p-value			0.0336	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts: ≥50%	93	170		
Number of subjects assessed[c]	46	94		
Events - n (%)	12 (26.1)	45 (47.9)	21.8	
Unstratified odds ratio[a]			2.60	
(95% CI)			(1.20, 5.63)	
p-value			0.0153	
Unstratified risk ratio[a]			1.84	
(95% CI)			(1.08, 3.12)	
p-value			0.0248	
Absolute risk reduction			0.22	
(95% CI)			(0.06, 0.38)	
p-value			0.0085	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 04JUN2025:23:56) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adrs

Anhang 4-G3.5: Subgruppenanalysen zu Symptomatik

Anhang 4-G3.5.1: Subgruppenanalysen zu EORTC QLQ-C30 (Symptomatik)

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.2506
<35 years	30/40 (75.0)	0.26 (0.26, 0.49)	60/112 (53.6)	0.98 (0.49, 4.36)	0.46 (0.29, 0.71)	0.0002	
≥35 years	39/54 (72.2)	0.46 (0.26, 0.95)	79/130 (60.8)	0.95 (0.49, 1.51)	0.59 (0.40, 0.87)	0.0041	
Age group 2							0.0428
<35 years	30/40 (75.0)	0.26 (0.26, 0.49)	60/112 (53.6)	0.98 (0.49, 4.36)	0.46 (0.29, 0.71)	0.0002	
35 - 54 years	17/22 (77.3)	0.30 (0.26, 1.05)	46/73 (63.0)	0.95 (0.49, 1.41)	0.53 (0.30, 0.93)	0.0148	
55 - 64 years	16/20 (80.0)	0.28 (0.26, 0.49)	15/30 (50.0)	2.33 (0.56, NE)	0.29 (0.14, 0.62)	0.0007	
≥65 years	6/12 (50.0)	1.48 (0.46, NE)	18/27 (66.7)	0.49 (0.26, 2.26)	1.58 (0.62, 4.03)	0.3527	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0196
Male	38/55 (69.1)	0.49 (0.26, 0.52)	92/146 (63.0)	0.52 (0.49, 0.98)	0.70 (0.48, 1.03)	0.0475	
Female	31/39 (79.5)	0.30 (0.26, 0.49)	47/96 (49.0)	2.26 (0.98, NE)	0.33 (0.20, 0.53)	<0.0001	
Region							0.7253
USA	9/12 (75.0)	0.39 (0.26, NE)	11/26 (42.3)	2.10 (0.52, NE)	0.44 (0.18, 1.07)	0.0795	
Europe	43/59 (72.9)	0.30 (0.26, 0.49)	95/158 (60.1)	0.98 (0.49, 1.51)	0.50 (0.35, 0.72)	<0.0001	
Rest of the world	17/23 (73.9)	0.46 (0.26, 1.05)	33/58 (56.9)	0.52 (0.49, 4.36)	0.64 (0.35, 1.16)	0.0763	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.6318
Yes	38/53 (71.7)	0.30 (0.26, 0.52)	84/146 (57.5)	0.95 (0.49, 1.54)	0.56 (0.38, 0.82)	0.0020	
No	31/41 (75.6)	0.36 (0.26, 0.49)	55/96 (57.3)	1.41 (0.52, 3.05)	0.47 (0.30, 0.74)	0.0005	
Number of salvage therapies							0.6365
0	37/49 (75.5)	0.30 (0.26, 0.49)	60/104 (57.7)	1.41 (0.52, 2.33)	0.46 (0.30, 0.69)	<0.0001	
1	19/28 (67.9)	0.46 (0.26, 1.05)	45/82 (54.9)	0.52 (0.49, 3.05)	0.63 (0.36, 1.07)	0.0537	
≥2	13/17 (76.5)	0.30 (0.26, 1.08)	34/56 (60.7)	0.72 (0.49, 2.10)	0.56 (0.29, 1.07)	0.0734	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1197
Yes	25/28 (89.3)	0.28 (0.26, 0.49)	48/84 (57.1)	0.95 (0.49, 3.05)	0.37 (0.23, 0.61)	<0.0001	
No	44/66 (66.7)	0.46 (0.26, 0.95)	91/158 (57.6)	1.41 (0.52, 2.26)	0.61 (0.42, 0.88)	0.0048	
Race							0.5913
Caucasian	60/78 (76.9)	0.30 (0.26, 0.49)	122/204 (59.8)	0.95 (0.49, 1.48)	0.49 (0.36, 0.67)	<0.0001	
Others	9/16 (56.3)	0.95 (0.26, NE)	17/38 (44.7)	2.10 (0.52, NE)	0.65 (0.29, 1.48)	0.3075	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5495
<50%	14/25 (56.0)	0.49 (0.36, NE)	34/65 (52.3)	2.33 (0.52, NE)	0.63 (0.34, 1.20)	0.1540	
≥50%	52/66 (78.8)	0.30 (0.26, 0.49)	89/153 (58.2)	0.95 (0.49, 1.41)	0.50 (0.35, 0.71)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.3272
<35 years	30/41 (73.2)	0.49 (0.30, 0.89)	61/112 (54.5)	1.64 (1.34, 4.03)	0.46 (0.30, 0.73)	0.0003	
≥35 years	37/53 (69.8)	0.49 (0.46, 1.18)	74/133 (55.6)	1.41 (0.95, 2.36)	0.62 (0.41, 0.92)	0.0112	
Age group 2							0.5054
<35 years	30/41 (73.2)	0.49 (0.30, 0.89)	61/112 (54.5)	1.64 (1.34, 4.03)	0.46 (0.30, 0.73)	0.0003	
35 - 54 years	16/21 (76.2)	0.49 (0.30, 1.15)	40/75 (53.3)	0.95 (0.52, 5.08)	0.51 (0.28, 0.93)	0.0145	
55 - 64 years	14/20 (70.0)	0.72 (0.26, 1.54)	18/30 (60.0)	1.87 (0.95, 2.46)	0.55 (0.26, 1.14)	0.0937	
≥65 years	7/12 (58.3)	1.70 (0.26, NE)	16/28 (57.1)	1.41 (0.95, NE)	1.01 (0.41, 2.47)	0.9935	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9381
Male	41/56 (73.2)	0.49 (0.46, 1.08)	80/147 (54.4)	1.54 (0.95, 2.79)	0.56 (0.38, 0.82)	0.0012	
Female	26/38 (68.4)	0.39 (0.26, 1.18)	55/98 (56.1)	1.41 (0.95, 2.56)	0.51 (0.32, 0.82)	0.0040	
Region							0.5416
USA	8/12 (66.7)	1.31 (0.26, NE)	10/26 (38.5)	2.46 (0.95, NE)	0.60 (0.23, 1.52)	0.2460	
Europe	44/59 (74.6)	0.49 (0.30, 0.49)	91/160 (56.9)	1.41 (0.95, 2.00)	0.47 (0.33, 0.68)	<0.0001	
Rest of the world	15/23 (65.2)	0.95 (0.39, 1.44)	34/59 (57.6)	1.41 (0.49, 4.36)	0.72 (0.39, 1.33)	0.2404	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1697
Yes	36/54 (66.7)	0.52 (0.39, 1.15)	82/148 (55.4)	1.41 (0.95, 1.90)	0.64 (0.43, 0.96)	0.0159	
No	31/40 (77.5)	0.49 (0.30, 0.89)	53/97 (54.6)	1.87 (1.34, 4.98)	0.42 (0.26, 0.66)	<0.0001	
Number of salvage therapies							0.3997
0	36/48 (75.0)	0.49 (0.36, 0.89)	58/105 (55.2)	1.87 (0.95, 4.59)	0.42 (0.27, 0.64)	<0.0001	
1	19/29 (65.5)	0.52 (0.39, 1.54)	47/83 (56.6)	1.41 (0.95, 1.87)	0.69 (0.40, 1.19)	0.1251	
≥2	12/17 (70.6)	0.49 (0.26, 1.44)	30/57 (52.6)	1.41 (0.49, NE)	0.60 (0.31, 1.18)	0.0952	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1872
Yes	21/29 (72.4)	0.46 (0.30, 0.49)	44/84 (52.4)	1.90 (0.95, 4.98)	0.41 (0.24, 0.71)	0.0005	
No	46/65 (70.8)	0.49 (0.46, 1.15)	91/161 (56.5)	1.41 (0.95, 2.36)	0.61 (0.43, 0.87)	0.0040	
Race							0.1958
Caucasian	58/78 (74.4)	0.49 (0.39, 0.89)	112/206 (54.4)	1.54 (1.34, 2.00)	0.50 (0.36, 0.69)	<0.0001	
Others	9/16 (56.3)	0.95 (0.46, NE)	23/39 (59.0)	1.11 (0.56, 2.56)	0.80 (0.37, 1.75)	0.5698	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6749
<50%	18/25 (72.0)	0.49 (0.30, 1.70)	37/67 (55.2)	2.79 (1.41, 5.08)	0.42 (0.23, 0.76)	0.0026	
≥50%	48/66 (72.7)	0.49 (0.39, 1.02)	81/154 (52.6)	1.41 (0.95, 1.87)	0.54 (0.37, 0.77)	0.0003	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0099
<35 years	26/40 (65.0)	0.39 (0.26, 1.11)	32/111 (28.8)	6.26 (3.28, NE)	0.21 (0.12, 0.37)	<0.0001	
≥35 years	28/54 (51.9)	1.25 (0.30, NE)	60/131 (45.8)	3.25 (2.10, 6.46)	0.53 (0.33, 0.84)	0.0082	
Age group 2							0.0156
<35 years	26/40 (65.0)	0.39 (0.26, 1.11)	32/111 (28.8)	6.26 (3.28, NE)	0.21 (0.12, 0.37)	<0.0001	
35 - 54 years	16/22 (72.7)	0.30 (0.26, 1.25)	36/74 (48.6)	2.79 (1.38, NE)	0.29 (0.15, 0.54)	<0.0001	
55 - 64 years	7/20 (35.0)	NE (0.26, NE)	15/30 (50.0)	2.56 (0.52, 6.46)	0.94 (0.37, 2.41)	0.9448	
≥65 years	5/12 (41.7)	NE (0.26, NE)	9/27 (33.3)	5.41 (2.33, NE)	0.49 (0.15, 1.58)	0.2300	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
Output: t14-04-004-010-tte-sub-de-eortc-nvs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1663
Male	26/55 (47.3)	1.87 (0.46, NE)	51/145 (35.2)	4.23 (2.79, NE)	0.45 (0.27, 0.73)	0.0013	
Female	28/39 (71.8)	0.30 (0.26, 1.11)	41/97 (42.3)	4.16 (2.33, NE)	0.29 (0.17, 0.48)	<0.0001	
Region							0.7426
USA	8/12 (66.7)	0.51 (0.26, NE)	10/26 (38.5)	2.56 (0.95, NE)	0.41 (0.16, 1.05)	0.0674	
Europe	34/59 (57.6)	0.49 (0.26, 1.87)	60/159 (37.7)	4.16 (3.25, 6.46)	0.32 (0.20, 0.50)	<0.0001	
Rest of the world	12/23 (52.2)	2.79 (0.26, NE)	22/57 (38.6)	5.41 (1.87, NE)	0.48 (0.23, 1.00)	0.0403	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
Output: t14-04-004-010-tte-sub-de-eortc-nvs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1510
Yes	27/53 (50.9)	1.11 (0.49, NE)	53/146 (36.3)	5.41 (2.43, NE)	0.46 (0.29, 0.74)	0.0014	
No	27/41 (65.9)	0.30 (0.26, 1.87)	39/96 (40.6)	4.03 (3.02, NE)	0.27 (0.16, 0.45)	<0.0001	
Number of salvage therapies							0.2271
0	35/49 (71.4)	0.26 (0.26, 0.49)	48/104 (46.2)	3.28 (2.33, 5.67)	0.29 (0.18, 0.46)	<0.0001	
1	11/28 (39.3)	NE (0.49, NE)	22/82 (26.8)	6.49 (6.26, NE)	0.45 (0.21, 0.95)	0.0339	
≥2	8/17 (47.1)	1.11 (0.26, NE)	22/56 (39.3)	2.56 (1.41, NE)	0.61 (0.27, 1.39)	0.2327	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
Output: t14-04-004-010-tte-sub-de-eortc-nvs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1005
Yes	20/28 (71.4)	0.41 (0.26, 1.11)	33/84 (39.3)	5.67 (2.79, NE)	0.24 (0.13, 0.44)	<0.0001	
No	34/66 (51.5)	1.25 (0.30, NE)	59/158 (37.3)	4.16 (2.56, NE)	0.44 (0.29, 0.68)	0.0003	
Race							0.2052
Caucasian	44/78 (56.4)	0.75 (0.36, 1.87)	82/205 (40.0)	4.03 (3.15, 6.26)	0.39 (0.26, 0.57)	<0.0001	
Others	10/16 (62.5)	0.28 (0.26, NE)	10/37 (27.0)	NE (2.56, NE)	0.26 (0.11, 0.64)	0.0022	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
Output: t14-04-004-010-tte-sub-de-eortc-nvs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9964
<50%	13/25 (52.0)	1.87 (0.26, NE)	24/64 (37.5)	6.46 (3.15, NE)	0.40 (0.20, 0.82)	0.0101	
≥50%	39/66 (59.1)	0.52 (0.26, 1.77)	56/154 (36.4)	3.38 (2.43, 6.26)	0.35 (0.23, 0.54)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
Output: t14-04-004-010-tte-sub-de-eortc-nvs-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.8207
<35 years	15/40 (37.5)	NE (0.75, NE)	32/111 (28.8)	NE (5.31, NE)	0.66 (0.36, 1.23)	0.1680	
≥35 years	24/53 (45.3)	2.33 (0.95, NE)	43/130 (33.1)	NE (2.79, NE)	0.55 (0.33, 0.93)	0.0199	
Age group 2							0.7720
<35 years	15/40 (37.5)	NE (0.75, NE)	32/111 (28.8)	NE (5.31, NE)	0.66 (0.36, 1.23)	0.1680	
35 - 54 years	8/21 (38.1)	1.54 (0.95, NE)	26/72 (36.1)	NE (1.48, NE)	0.75 (0.34, 1.67)	0.4555	
55 - 64 years	11/20 (55.0)	2.46 (0.30, NE)	9/30 (30.0)	NE (2.00, NE)	0.33 (0.13, 0.82)	0.0142	
≥65 years	5/12 (41.7)	2.33 (0.26, NE)	8/28 (28.6)	NE (1.87, NE)	0.62 (0.20, 1.97)	0.4040	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
Output: t14-04-004-011-tte-sub-de-eortc-dys-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7695
Male	22/55 (40.0)	2.56 (0.95, NE)	45/146 (30.8)	NE (NE, NE)	0.65 (0.39, 1.09)	0.0901	
Female	17/38 (44.7)	1.77 (1.05, NE)	30/95 (31.6)	NE (4.52, NE)	0.53 (0.29, 0.98)	0.0335	
Region							0.1638
USA	8/12 (66.7)	0.89 (0.26, NE)	6/26 (23.1)	NE (1.11, NE)	0.29 (0.10, 0.85)	0.0177	
Europe	23/58 (39.7)	2.46 (1.38, NE)	47/157 (29.9)	NE (NE, NE)	0.59 (0.36, 0.98)	0.0332	
Rest of the world	8/23 (34.8)	NE (0.52, NE)	22/58 (37.9)	5.31 (1.21, NE)	1.05 (0.46, 2.40)	0.9493	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
Output: t14-04-004-011-tte-sub-de-eortc-dys-eqcas.rtf (Date generated: 05JUN2025:02:31) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.9431
Yes	20/53 (37.7)	2.46 (1.05, NE)	42/145 (29.0)	NE (5.31, NE)	0.58 (0.34, 1.00)	0.0416	
No	19/40 (47.5)	2.33 (0.89, NE)	33/96 (34.4)	NE (4.52, NE)	0.63 (0.36, 1.12)	0.1031	
Number of salvage therapies							0.4967
0	22/48 (45.8)	1.77 (0.95, NE)	33/104 (31.7)	NE (NE, NE)	0.56 (0.32, 0.97)	0.0308	
1	13/29 (44.8)	2.46 (0.52, NE)	25/82 (30.5)	NE (2.00, NE)	0.50 (0.25, 1.00)	0.0403	
≥2	4/16 (25.0)	NE (0.89, NE)	17/55 (30.9)	NE (1.57, NE)	1.10 (0.37, 3.31)	0.8964	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
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Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6515
Yes	11/29 (37.9)	NE (0.95, NE)	21/83 (25.3)	NE (NE, NE)	0.55 (0.26, 1.14)	0.0931	
No	28/64 (43.8)	2.33 (0.95, NE)	54/158 (34.2)	NE (2.79, NE)	0.63 (0.40, 1.01)	0.0434	
Race							0.7017
Caucasian	31/77 (40.3)	2.46 (1.54, NE)	59/204 (28.9)	NE (NE, NE)	0.59 (0.38, 0.91)	0.0145	
Others	8/16 (50.0)	0.95 (0.52, NE)	16/37 (43.2)	4.52 (0.95, NE)	0.71 (0.30, 1.70)	0.3868	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7559
<50%	7/25 (28.0)	2.56 (2.33, NE)	16/64 (25.0)	NE (NE, NE)	0.60 (0.24, 1.52)	0.2703	
≥50%	32/65 (49.2)	1.38 (0.89, NE)	50/153 (32.7)	NE (2.43, NE)	0.56 (0.36, 0.88)	0.0076	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0085
<35 years	26/40 (65.0)	0.46 (0.26, 1.08)	41/111 (36.9)	5.05 (2.36, NE)	0.22 (0.13, 0.38)	<0.0001	
≥35 years	33/53 (62.3)	0.95 (0.36, 1.25)	69/130 (53.1)	2.33 (0.98, 3.25)	0.61 (0.40, 0.93)	0.0175	
Age group 2							0.0334
<35 years	26/40 (65.0)	0.46 (0.26, 1.08)	41/111 (36.9)	5.05 (2.36, NE)	0.22 (0.13, 0.38)	<0.0001	
35 - 54 years	15/21 (71.4)	0.36 (0.26, 1.15)	40/73 (54.8)	1.87 (0.72, 3.25)	0.46 (0.25, 0.84)	0.0084	
55 - 64 years	13/20 (65.0)	0.72 (0.26, NE)	14/30 (46.7)	2.56 (1.48, NE)	0.41 (0.18, 0.91)	0.0255	
≥65 years	5/12 (41.7)	NE (0.49, NE)	15/27 (55.6)	3.25 (0.49, NE)	1.33 (0.47, 3.77)	0.6215	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0632
Male	33/55 (60.0)	0.95 (0.46, 1.44)	68/145 (46.9)	3.15 (1.48, 3.70)	0.51 (0.33, 0.78)	0.0013	
Female	26/38 (68.4)	0.46 (0.26, 1.05)	42/96 (43.8)	3.34 (1.44, NE)	0.30 (0.18, 0.51)	<0.0001	
Region							0.8125
USA	9/12 (75.0)	0.51 (0.26, NE)	14/26 (53.8)	2.03 (0.95, 3.25)	0.51 (0.22, 1.18)	0.1223	
Europe	34/58 (58.6)	0.49 (0.30, 2.56)	69/158 (43.7)	4.23 (2.46, 8.13)	0.43 (0.28, 0.66)	<0.0001	
Rest of the world	16/23 (69.6)	0.49 (0.26, 1.11)	27/57 (47.4)	2.36 (0.95, NE)	0.39 (0.20, 0.75)	0.0027	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.8010
Yes	34/53 (64.2)	0.92 (0.39, 1.11)	64/145 (44.1)	3.15 (1.44, 6.26)	0.43 (0.28, 0.66)	<0.0001	
No	25/40 (62.5)	0.46 (0.26, NE)	46/96 (47.9)	3.25 (1.97, 5.05)	0.40 (0.24, 0.66)	0.0002	
Number of salvage therapies							0.4246
0	31/48 (64.6)	0.46 (0.26, 0.95)	48/104 (46.2)	3.70 (1.97, NE)	0.35 (0.22, 0.57)	<0.0001	
1	19/28 (67.9)	0.92 (0.26, 1.25)	38/82 (46.3)	2.36 (1.38, NE)	0.46 (0.26, 0.80)	0.0043	
≥2	9/17 (52.9)	1.08 (0.26, NE)	24/55 (43.6)	2.56 (1.21, NE)	0.55 (0.25, 1.21)	0.1220	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0207
Yes	21/28 (75.0)	0.36 (0.26, 0.52)	37/84 (44.0)	3.44 (1.44, 6.26)	0.21 (0.11, 0.37)	<0.0001	
No	38/65 (58.5)	0.95 (0.46, 1.44)	73/157 (46.5)	3.15 (1.97, 4.23)	0.53 (0.36, 0.80)	0.0017	
Race							0.5127
Caucasian	47/77 (61.0)	0.52 (0.39, 1.15)	93/204 (45.6)	3.25 (2.03, 5.05)	0.43 (0.30, 0.62)	<0.0001	
Others	12/16 (75.0)	0.46 (0.26, 0.95)	17/37 (45.9)	2.56 (0.52, NE)	0.34 (0.16, 0.74)	0.0039	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
Output: t14-04-004-012-tte-sub-de-eortc-aps-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3647
<50%	15/25 (60.0)	0.49 (0.26, NE)	24/64 (37.5)	6.26 (3.25, NE)	0.34 (0.17, 0.68)	0.0014	
≥50%	42/65 (64.6)	0.52 (0.39, 1.05)	73/153 (47.7)	2.36 (1.44, 3.70)	0.42 (0.28, 0.62)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
Output: t14-04-004-012-tte-sub-de-eortc-aps-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0012
<35 years	25/40 (62.5)	0.49 (0.26, 2.13)	48/112 (42.9)	5.41 (2.00, 6.92)	0.39 (0.23, 0.64)	<0.0001	
≥35 years	23/54 (42.6)	2.46 (0.92, NE)	71/130 (54.6)	0.95 (0.62, 3.70)	1.30 (0.81, 2.08)	0.3219	
Age group 2							0.0012
<35 years	25/40 (62.5)	0.49 (0.26, 2.13)	48/112 (42.9)	5.41 (2.00, 6.92)	0.39 (0.23, 0.64)	<0.0001	
35 - 54 years	12/22 (54.5)	0.95 (0.49, NE)	36/73 (49.3)	3.15 (0.75, NE)	0.70 (0.36, 1.36)	0.2560	
55 - 64 years	9/20 (45.0)	2.46 (0.30, NE)	18/30 (60.0)	0.52 (0.30, NE)	1.48 (0.66, 3.31)	0.3508	
≥65 years	2/12 (16.7)	NE (0.92, NE)	17/27 (63.0)	0.95 (0.26, 1.61)	5.93 (1.36, 25.81)	0.0066	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1653
Male	26/55 (47.3)	1.15 (0.92, NE)	75/146 (51.4)	1.64 (0.95, 5.41)	0.93 (0.59, 1.46)	0.6519	
Female	22/39 (56.4)	0.52 (0.39, NE)	44/96 (45.8)	3.70 (1.15, NE)	0.57 (0.34, 0.97)	0.0294	
Region							0.5679
USA	8/12 (66.7)	0.82 (0.26, NE)	13/26 (50.0)	1.44 (0.49, NE)	0.70 (0.29, 1.68)	0.4232	
Europe	28/59 (47.5)	2.26 (0.49, NE)	71/158 (44.9)	4.75 (1.54, 10.00)	0.69 (0.44, 1.07)	0.0839	
Rest of the world	12/23 (52.2)	0.92 (0.39, NE)	35/58 (60.3)	0.62 (0.26, 3.93)	1.10 (0.56, 2.14)	0.9420	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.5220
Yes	25/53 (47.2)	1.15 (0.75, 2.46)	69/146 (47.3)	4.75 (0.98, 6.92)	0.84 (0.53, 1.33)	0.3781	
No	23/41 (56.1)	0.52 (0.30, NE)	50/96 (52.1)	2.00 (0.95, 5.41)	0.68 (0.41, 1.12)	0.1141	
Number of salvage therapies							0.4470
0	28/49 (57.1)	0.49 (0.36, NE)	56/104 (53.8)	2.00 (0.95, 5.41)	0.67 (0.42, 1.07)	0.0788	
1	11/28 (39.3)	2.46 (0.92, NE)	38/82 (46.3)	2.00 (0.95, NE)	1.09 (0.55, 2.14)	0.9036	
≥2	9/17 (52.9)	0.75 (0.33, NE)	25/56 (44.6)	4.75 (0.52, NE)	0.66 (0.30, 1.43)	0.2680	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0030
Yes	19/28 (67.9)	0.49 (0.30, 1.05)	36/84 (42.9)	5.41 (1.64, NE)	0.36 (0.20, 0.65)	0.0002	
No	29/66 (43.9)	2.13 (0.92, NE)	83/158 (52.5)	1.44 (0.95, 3.70)	1.08 (0.70, 1.65)	0.7965	
Race							0.9863
Caucasian	40/78 (51.3)	0.95 (0.49, NE)	101/204 (49.5)	2.00 (1.15, 5.41)	0.76 (0.52, 1.10)	0.1125	
Others	8/16 (50.0)	0.95 (0.30, NE)	18/38 (47.4)	6.23 (0.49, NE)	0.83 (0.35, 1.94)	0.5520	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
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Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0755
<50%	7/25 (28.0)	NE (2.13, NE)	31/65 (47.7)	3.93 (1.44, NE)	1.32 (0.57, 3.06)	0.5069	
≥50%	38/66 (57.6)	0.92 (0.49, 1.15)	72/153 (47.1)	1.64 (0.95, 10.00)	0.65 (0.44, 0.97)	0.0240	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
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Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.1121
<35 years	20/40 (50.0)	1.21 (0.52, NE)	27/110 (24.5)	NE (NE, NE)	0.38 (0.21, 0.68)	0.0006	
≥35 years	23/54 (42.6)	1.97 (0.98, NE)	46/130 (35.4)	5.05 (3.28, NE)	0.62 (0.37, 1.03)	0.0615	
Age group 2							0.1159
<35 years	20/40 (50.0)	1.21 (0.52, NE)	27/110 (24.5)	NE (NE, NE)	0.38 (0.21, 0.68)	0.0006	
35 - 54 years	6/22 (27.3)	NE (1.08, NE)	27/73 (37.0)	5.05 (2.62, NE)	0.99 (0.40, 2.45)	0.9826	
55 - 64 years	8/20 (40.0)	NE (0.26, NE)	11/30 (36.7)	4.30 (1.64, NE)	0.74 (0.29, 1.88)	0.5476	
≥65 years	9/12 (75.0)	0.95 (0.26, 1.97)	8/27 (29.6)	NE (2.33, NE)	0.28 (0.10, 0.77)	0.0061	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0291
Male	27/55 (49.1)	1.70 (0.49, NE)	35/145 (24.1)	NE (NE, NE)	0.35 (0.21, 0.59)	<0.0001	
Female	16/39 (41.0)	1.54 (0.98, NE)	38/95 (40.0)	4.30 (2.49, NE)	0.77 (0.42, 1.40)	0.3242	
Region							0.5819
USA	5/12 (41.7)	1.70 (0.75, NE)	8/26 (30.8)	3.48 (1.87, NE)	0.60 (0.19, 1.90)	0.3784	
Europe	25/58 (43.1)	1.97 (0.89, NE)	48/157 (30.6)	NE (4.62, NE)	0.55 (0.34, 0.90)	0.0160	
Rest of the world	13/24 (54.2)	1.21 (0.46, NE)	17/57 (29.8)	NE (2.62, NE)	0.35 (0.16, 0.75)	0.0038	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
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Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1648
Yes	19/53 (35.8)	NE (0.98, NE)	43/144 (29.9)	NE (NE, NE)	0.69 (0.40, 1.19)	0.1712	
No	24/41 (58.5)	1.41 (0.49, 1.97)	30/96 (31.3)	NE (4.30, NE)	0.34 (0.19, 0.60)	<0.0001	
Number of salvage therapies							0.1935
0	27/49 (55.1)	1.21 (0.49, 1.97)	31/104 (29.8)	NE (4.62, NE)	0.33 (0.19, 0.56)	<0.0001	
1	10/29 (34.5)	NE (0.98, NE)	23/81 (28.4)	NE (2.62, NE)	0.75 (0.36, 1.59)	0.4279	
≥2	6/16 (37.5)	NE (0.26, NE)	19/55 (34.5)	NE (3.28, NE)	0.80 (0.32, 2.01)	0.6109	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.4258
Yes	11/29 (37.9)	NE (0.62, NE)	26/83 (31.3)	NE (NE, NE)	0.74 (0.36, 1.50)	0.3845	
No	32/65 (49.2)	1.54 (0.89, NE)	47/157 (29.9)	NE (4.23, NE)	0.42 (0.26, 0.66)	0.0001	
Race							0.9682
Caucasian	36/77 (46.8)	1.54 (0.75, NE)	63/203 (31.0)	NE (5.05, NE)	0.52 (0.34, 0.79)	0.0015	
Others	7/17 (41.2)	1.70 (0.46, NE)	10/37 (27.0)	4.30 (2.62, NE)	0.32 (0.11, 0.93)	0.0275	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.8920
<50%	14/25 (56.0)	0.98 (0.46, NE)	23/64 (35.9)	NE (3.48, NE)	0.44 (0.22, 0.88)	0.0130	
≥50%	29/66 (43.9)	1.54 (0.95, NE)	39/152 (25.7)	NE (4.30, NE)	0.45 (0.27, 0.73)	0.0009	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
Output: t14-04-004-014-tte-sub-de-eortc-cos-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4630
<35 years	24/41 (58.5)	0.52 (0.49, 2.49)	34/110 (30.9)	5.54 (4.36, NE)	0.26 (0.15, 0.46)	<0.0001	
≥35 years	28/53 (52.8)	0.95 (0.49, NE)	44/130 (33.8)	NE (3.02, NE)	0.42 (0.26, 0.69)	0.0004	
Age group 2							0.3660
<35 years	24/41 (58.5)	0.52 (0.49, 2.49)	34/110 (30.9)	5.54 (4.36, NE)	0.26 (0.15, 0.46)	<0.0001	
35 - 54 years	13/22 (59.1)	0.49 (0.30, NE)	26/73 (35.6)	3.28 (2.46, NE)	0.27 (0.13, 0.55)	0.0001	
55 - 64 years	8/19 (42.1)	NE (0.26, NE)	12/29 (41.4)	3.41 (0.56, NE)	0.76 (0.30, 1.92)	0.5753	
≥65 years	7/12 (58.3)	0.95 (0.26, NE)	6/28 (21.4)	NE (NE, NE)	0.33 (0.11, 1.00)	0.0367	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0954
Male	30/55 (54.5)	0.95 (0.49, NE)	52/146 (35.6)	4.43 (2.56, NE)	0.43 (0.27, 0.68)	0.0003	
Female	22/39 (56.4)	0.49 (0.36, NE)	26/94 (27.7)	NE (5.05, NE)	0.26 (0.14, 0.47)	<0.0001	
Region							0.1287
USA	6/12 (50.0)	1.08 (0.26, NE)	13/26 (50.0)	1.44 (0.95, 3.25)	0.97 (0.37, 2.55)	0.9793	
Europe	33/58 (56.9)	0.49 (0.49, NE)	44/157 (28.0)	NE (5.05, NE)	0.30 (0.19, 0.48)	<0.0001	
Rest of the world	13/24 (54.2)	0.59 (0.39, NE)	21/57 (36.8)	4.36 (1.67, NE)	0.31 (0.14, 0.65)	0.0012	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.8913
Yes	27/53 (50.9)	1.05 (0.49, NE)	42/145 (29.0)	NE (4.36, NE)	0.35 (0.21, 0.58)	<0.0001	
No	25/41 (61.0)	0.49 (0.36, 2.49)	36/95 (37.9)	5.05 (2.89, NE)	0.34 (0.20, 0.58)	<0.0001	
Number of salvage therapies							0.7104
0	30/49 (61.2)	0.49 (0.39, 0.95)	38/103 (36.9)	5.05 (3.25, NE)	0.31 (0.19, 0.52)	<0.0001	
1	15/28 (53.6)	0.92 (0.39, NE)	25/81 (30.9)	NE (2.33, NE)	0.42 (0.22, 0.80)	0.0070	
≥2	7/17 (41.2)	4.13 (0.49, NE)	15/56 (26.8)	5.97 (2.46, NE)	0.38 (0.15, 0.95)	0.0345	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0580
Yes	21/29 (72.4)	0.49 (0.26, 1.05)	26/80 (32.5)	5.05 (3.28, NE)	0.18 (0.10, 0.33)	<0.0001	
No	31/65 (47.7)	0.95 (0.49, NE)	52/160 (32.5)	NE (3.25, NE)	0.48 (0.30, 0.75)	0.0013	
Race							0.4115
Caucasian	45/77 (58.4)	0.49 (0.49, 2.49)	66/203 (32.5)	5.97 (3.28, NE)	0.32 (0.21, 0.47)	<0.0001	
Others	7/17 (41.2)	NE (0.30, NE)	12/37 (32.4)	NE (1.11, NE)	0.54 (0.21, 1.42)	0.2008	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5095
<50%	13/25 (52.0)	0.49 (0.36, NE)	21/65 (32.3)	5.05 (3.28, NE)	0.24 (0.11, 0.51)	0.0001	
≥50%	38/66 (57.6)	0.75 (0.49, 2.49)	51/152 (33.6)	5.97 (2.56, NE)	0.40 (0.26, 0.62)	<0.0001	

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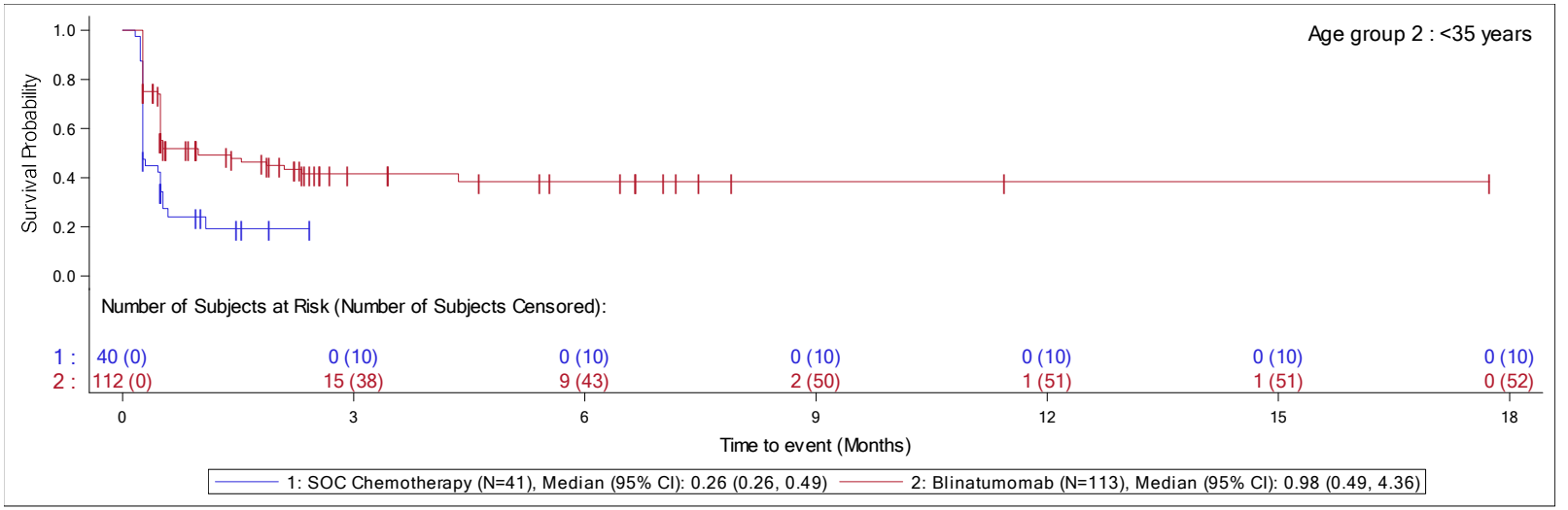
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

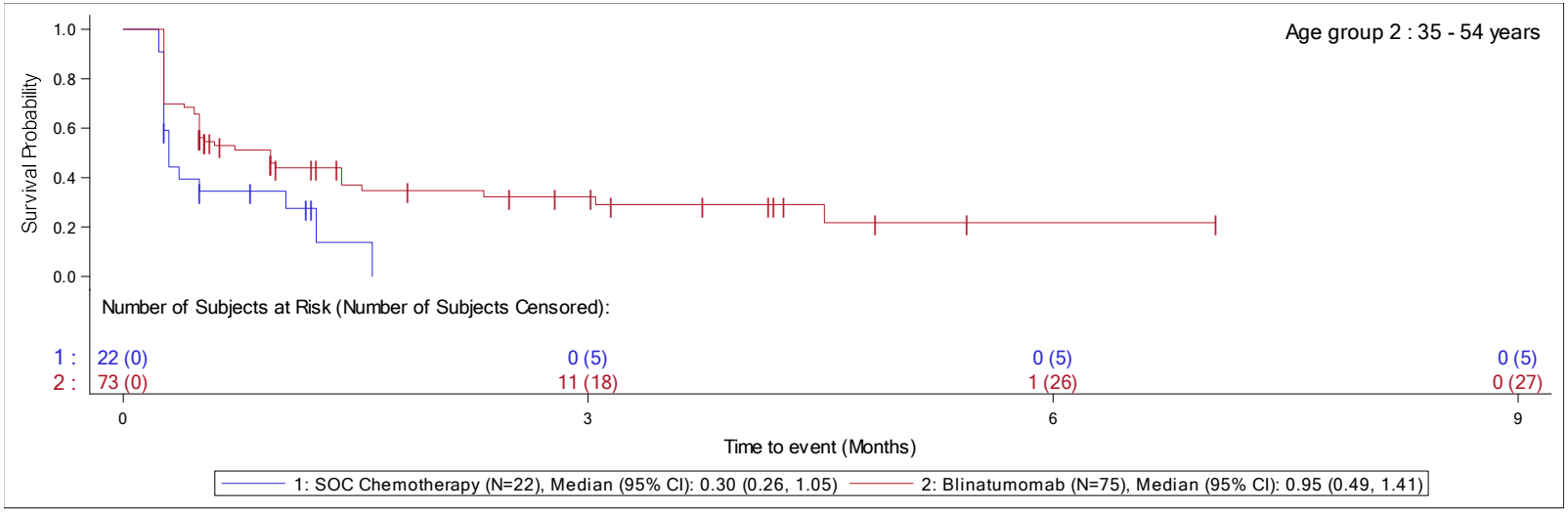
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

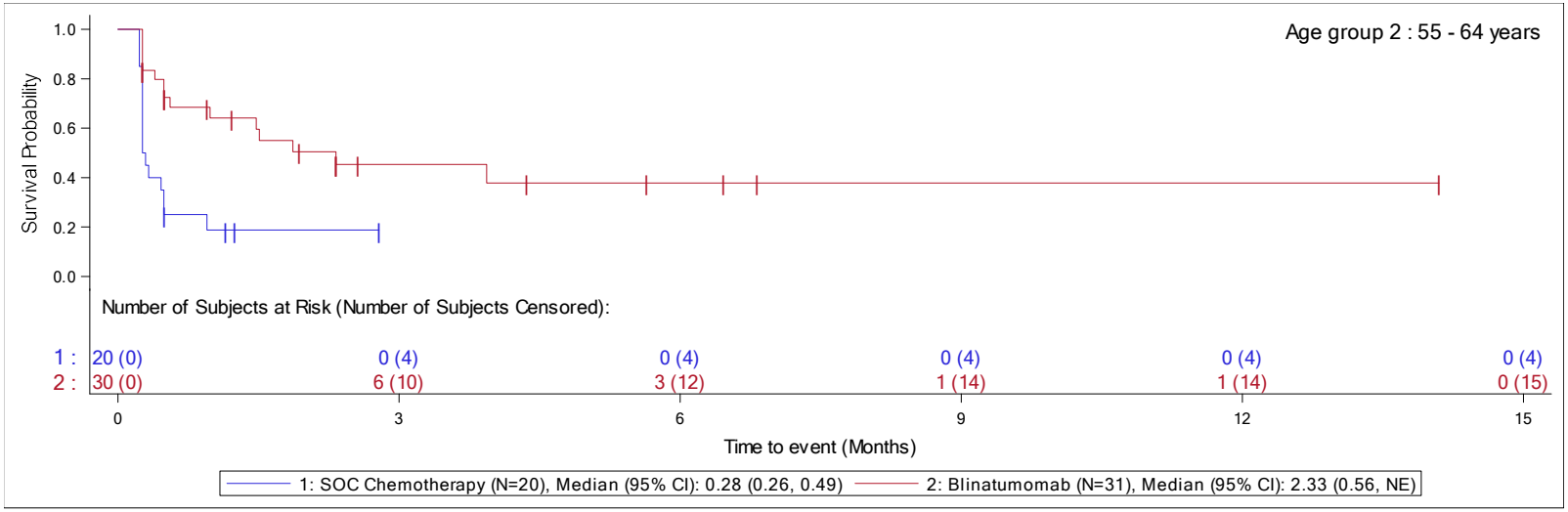
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

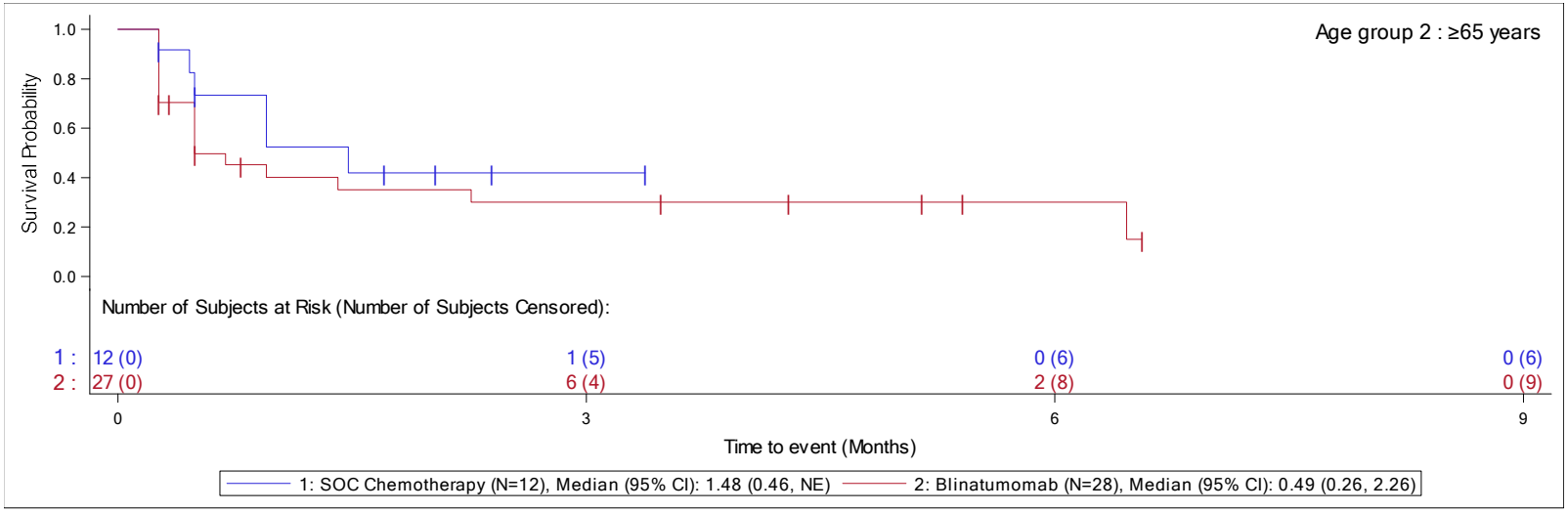
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

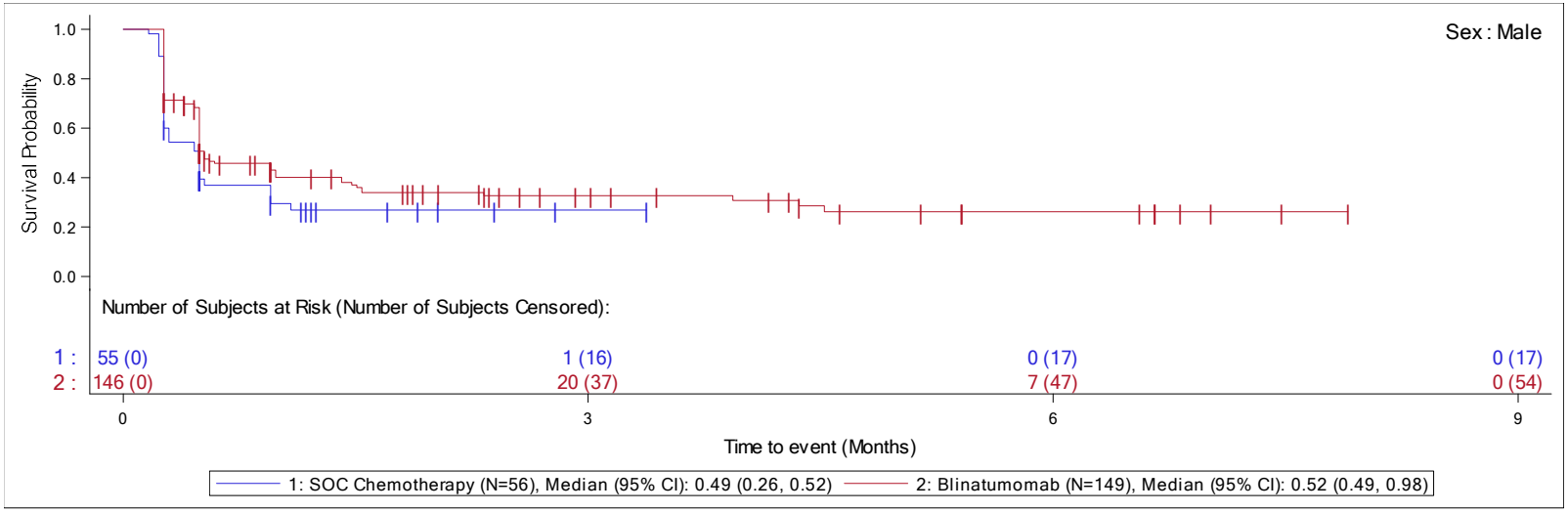
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

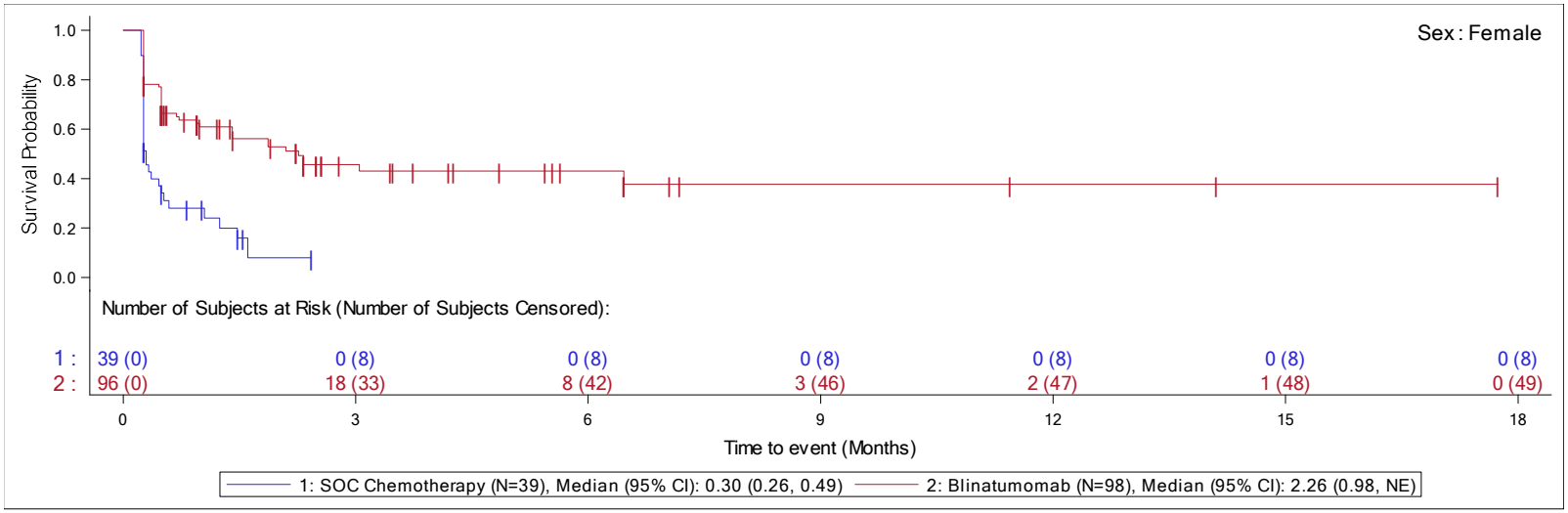
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

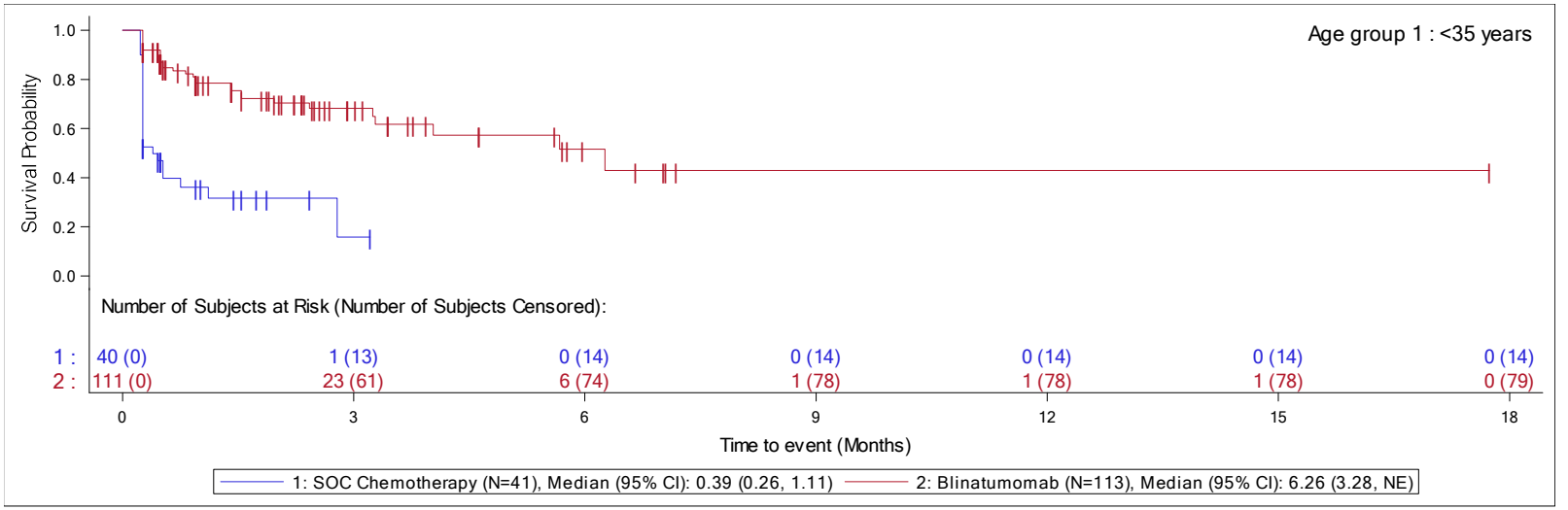
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

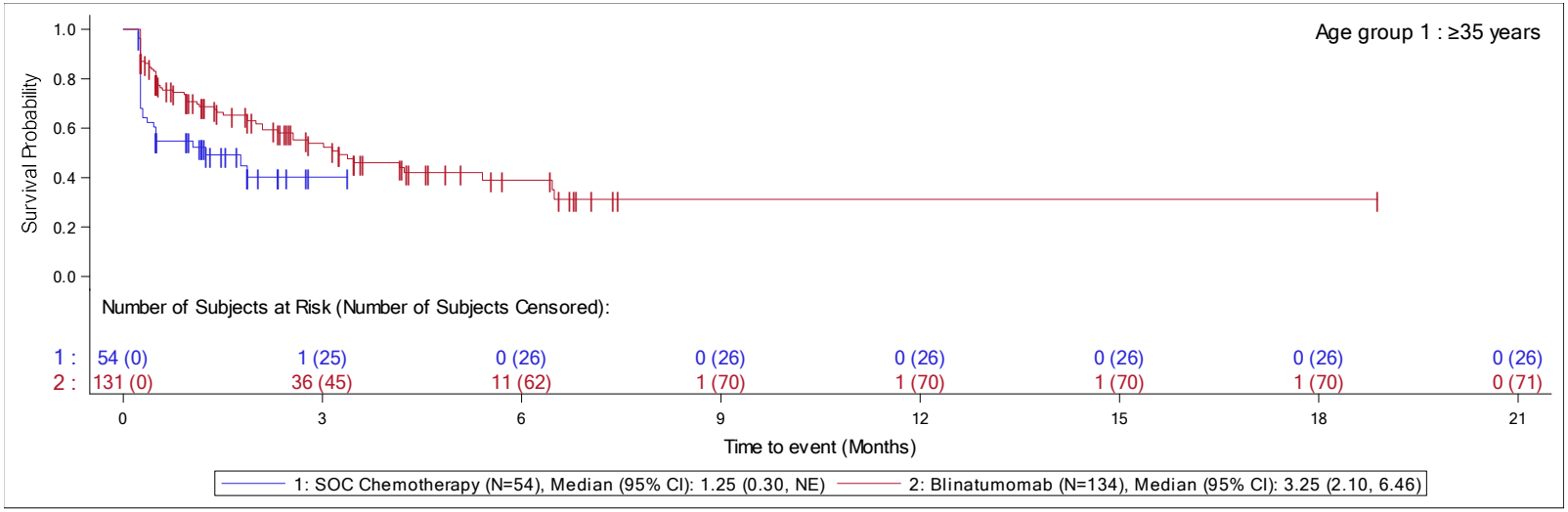
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

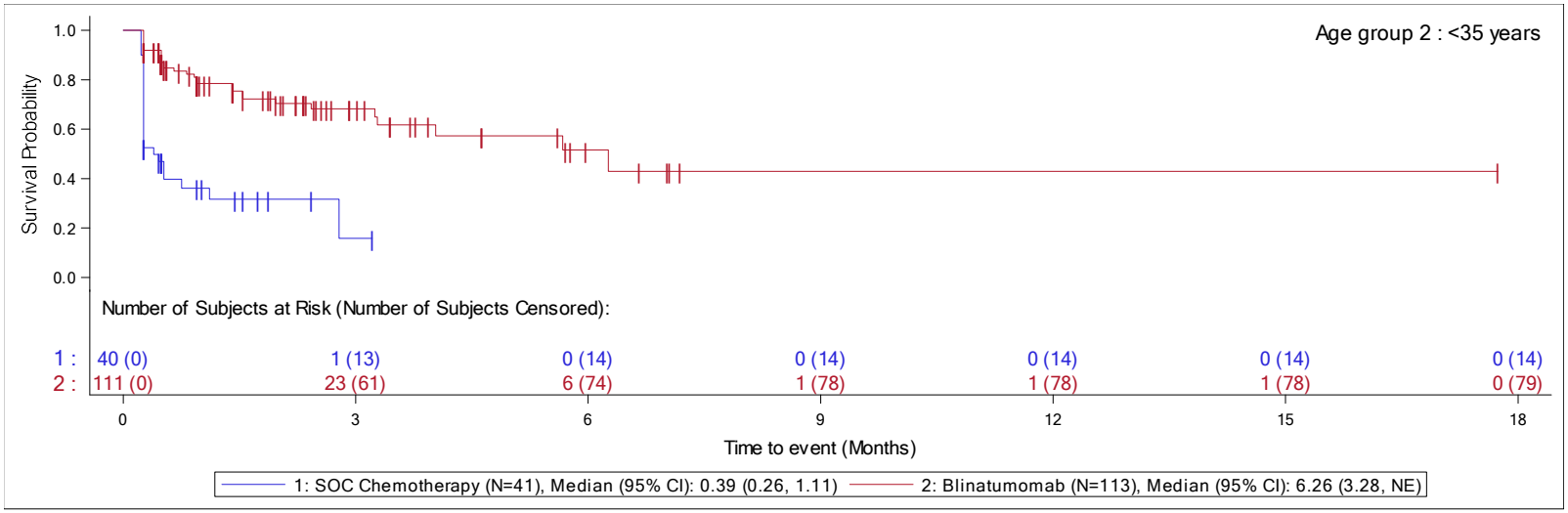
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

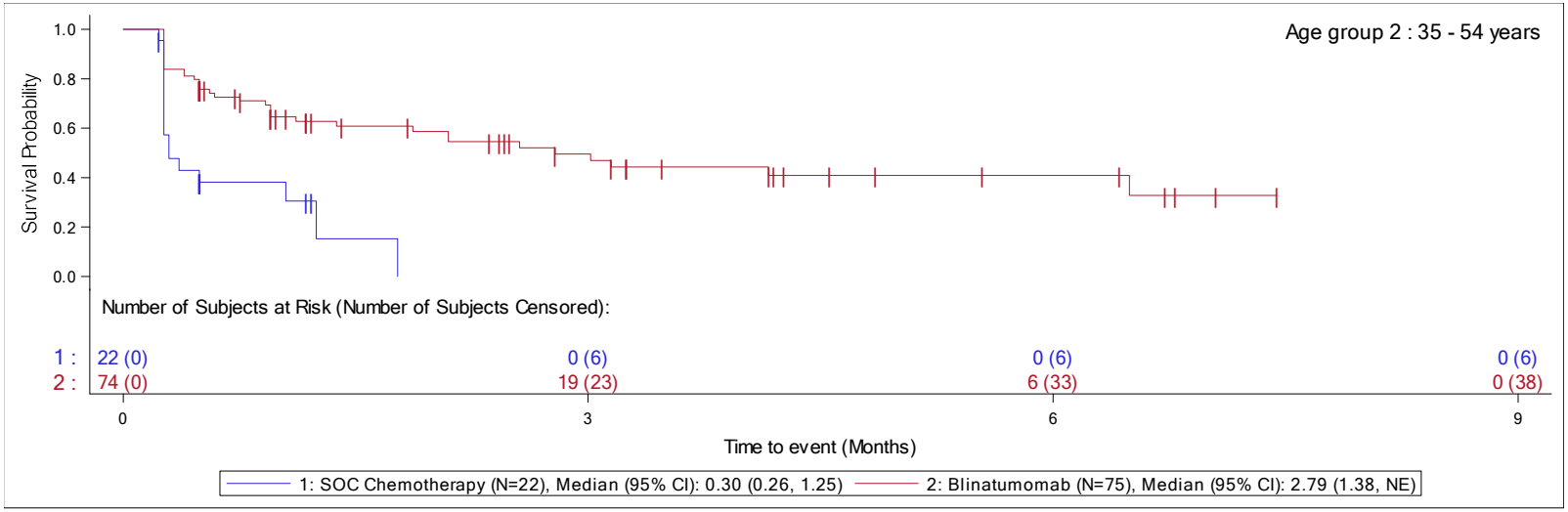
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

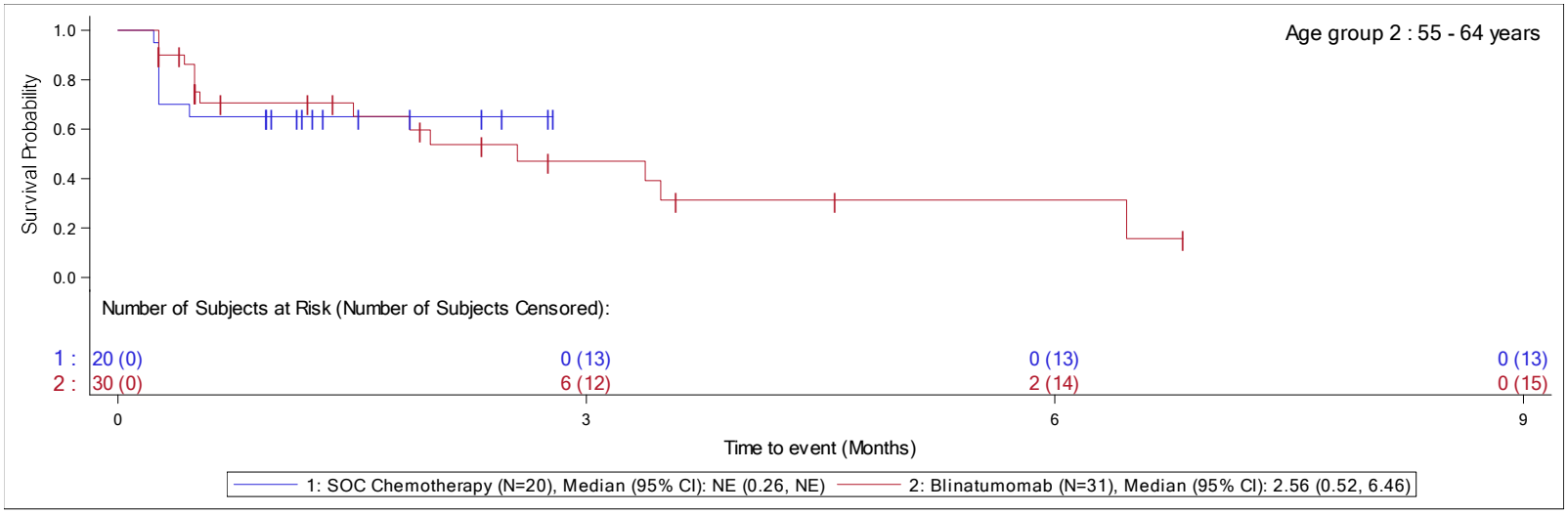
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

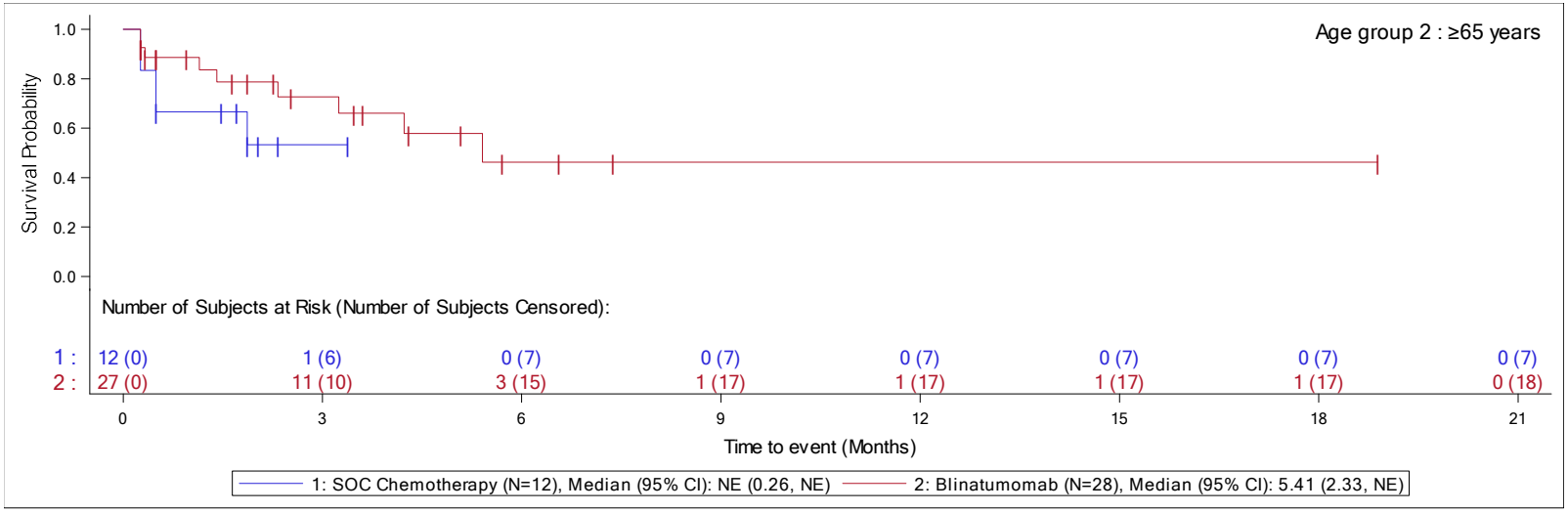
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

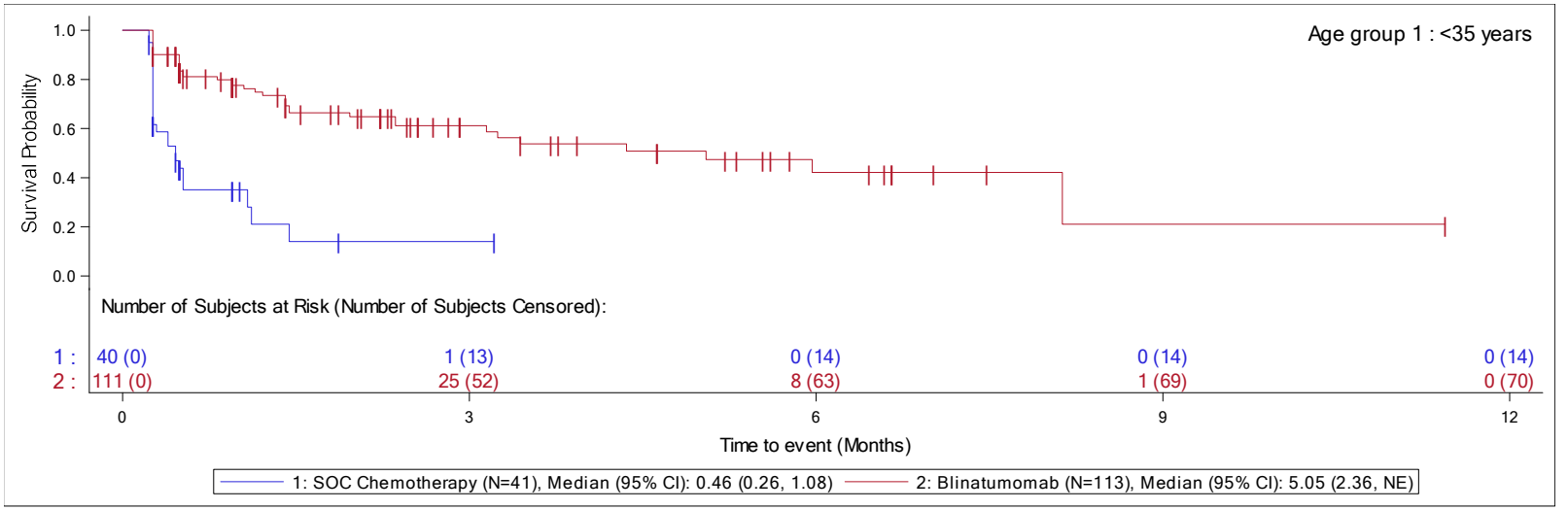
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

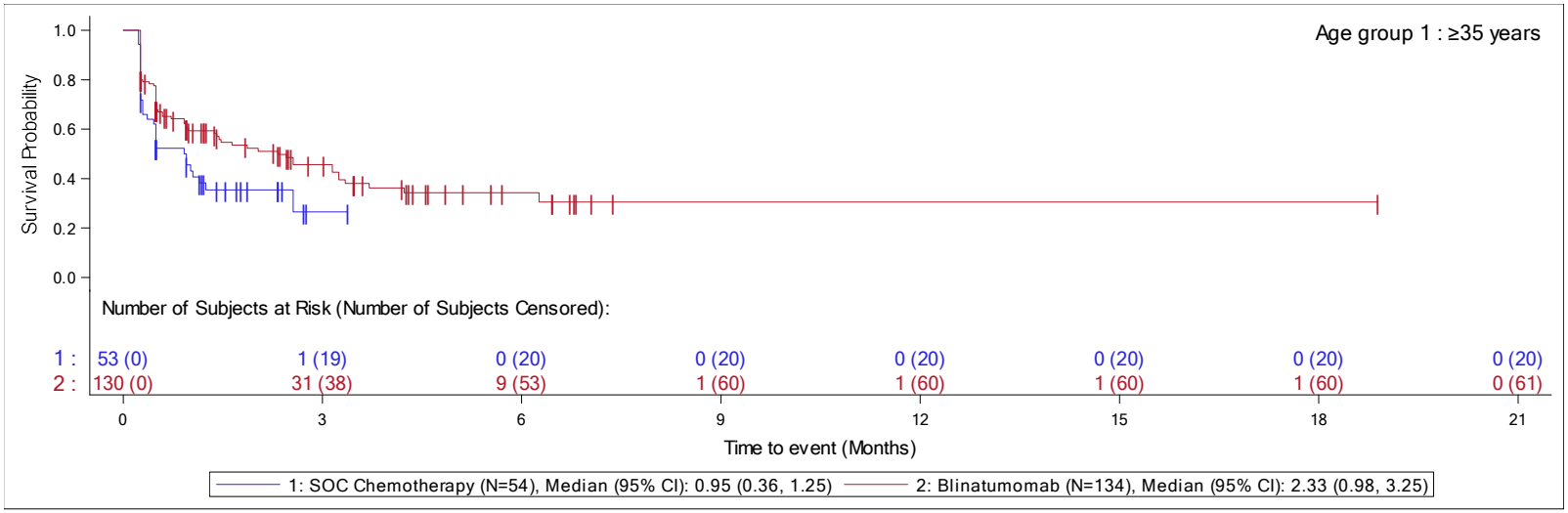
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

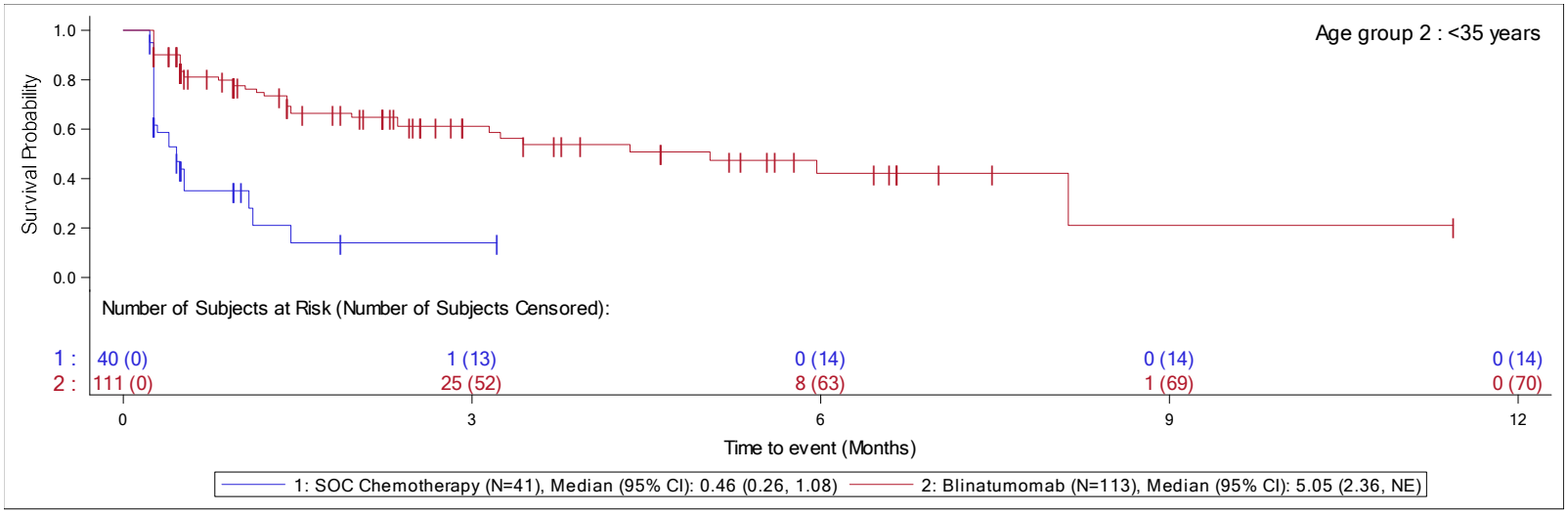
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

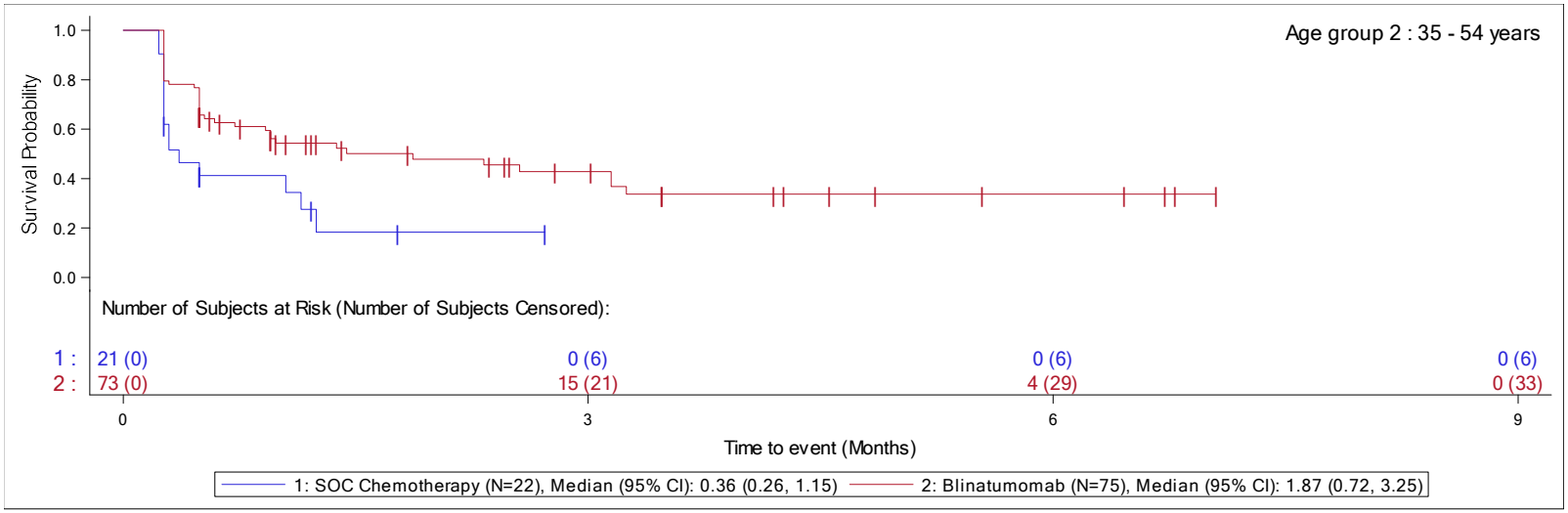
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

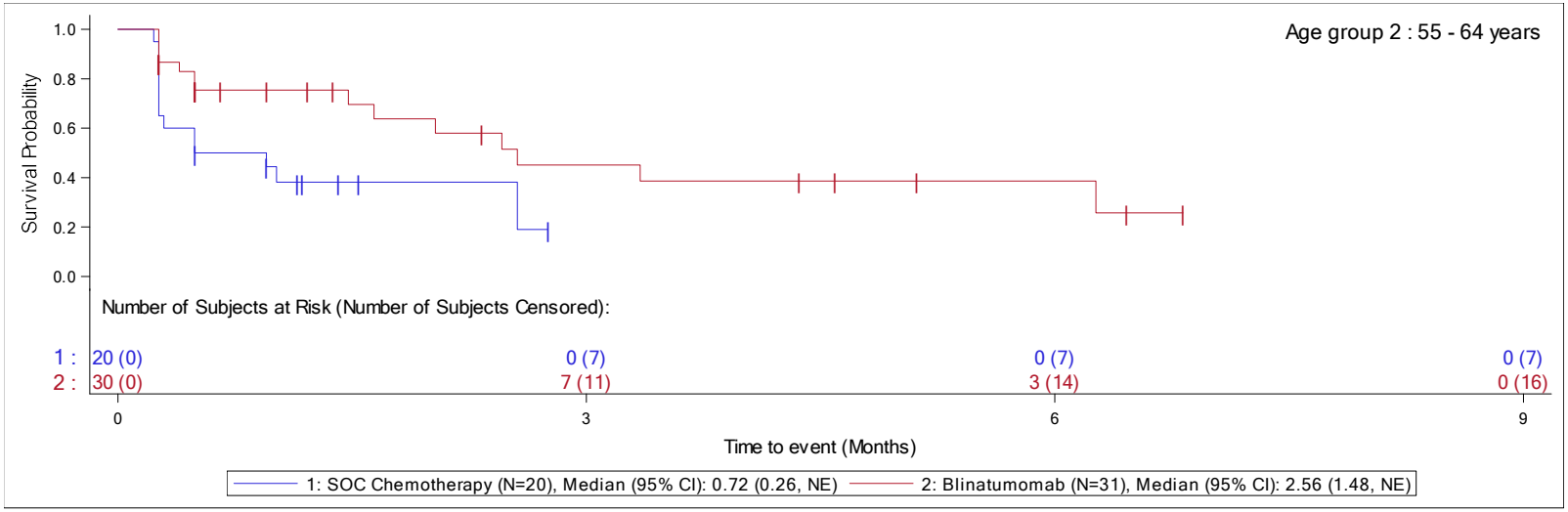
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

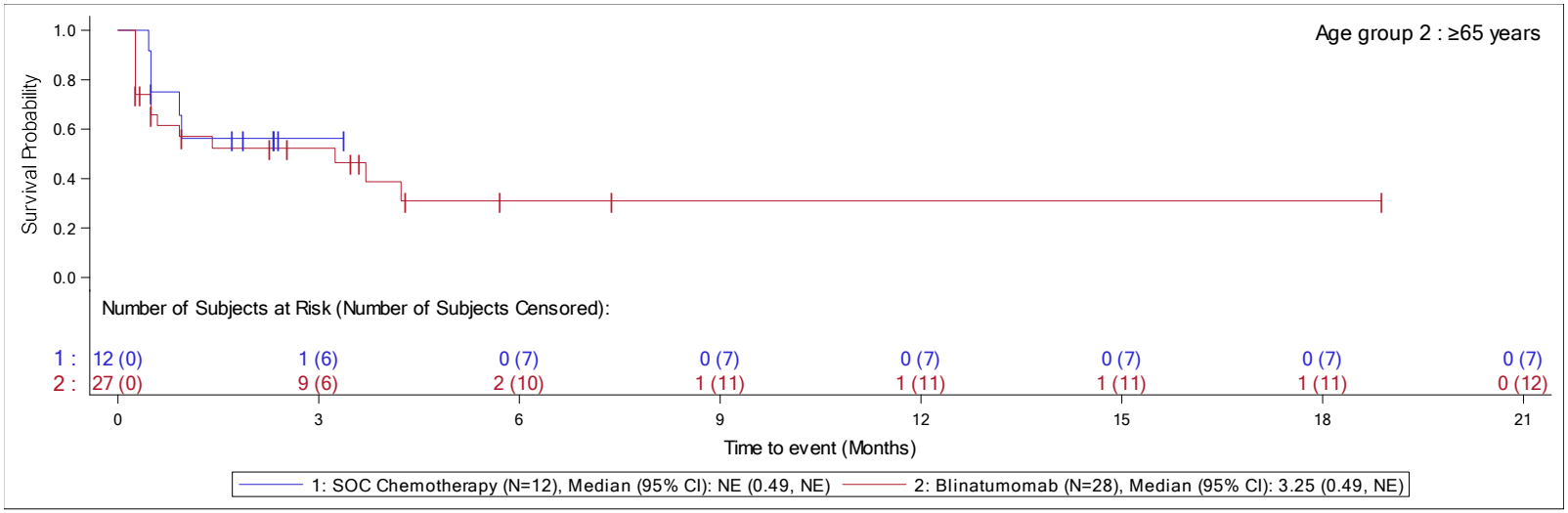
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

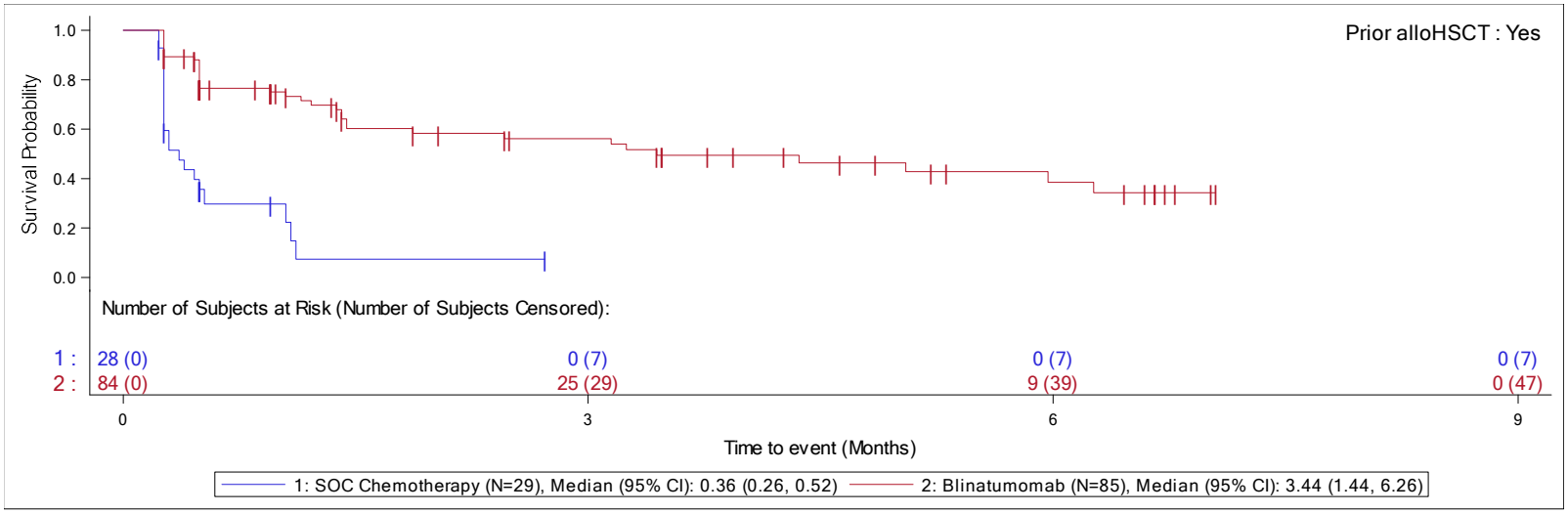
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

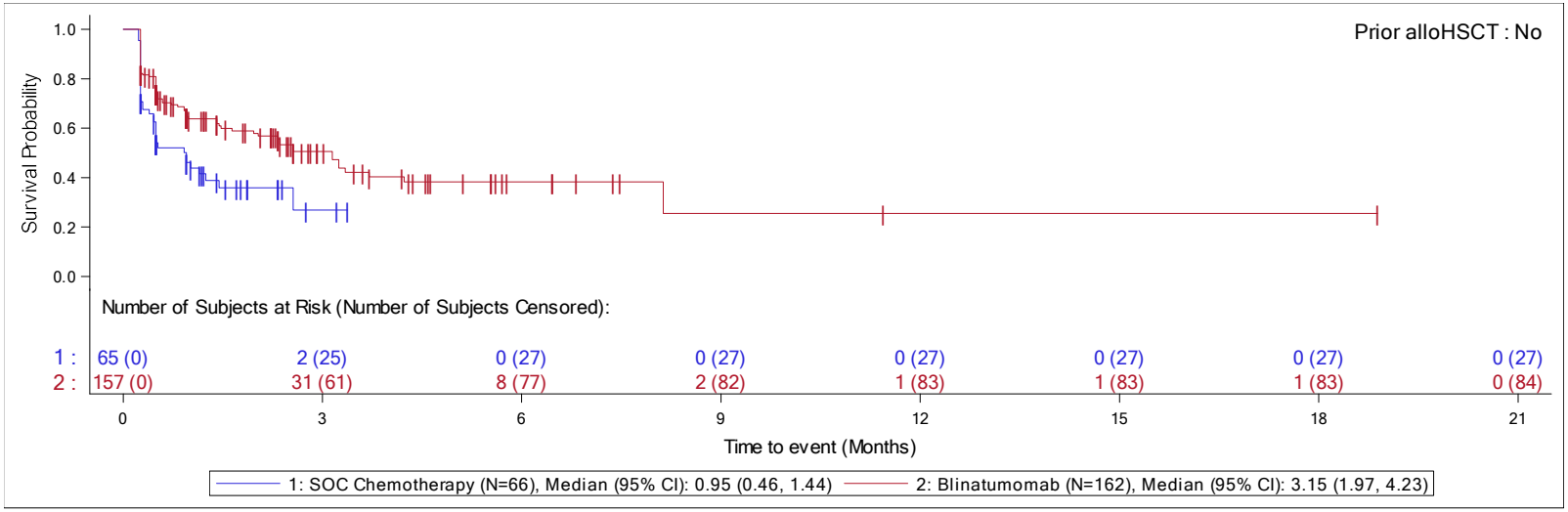
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

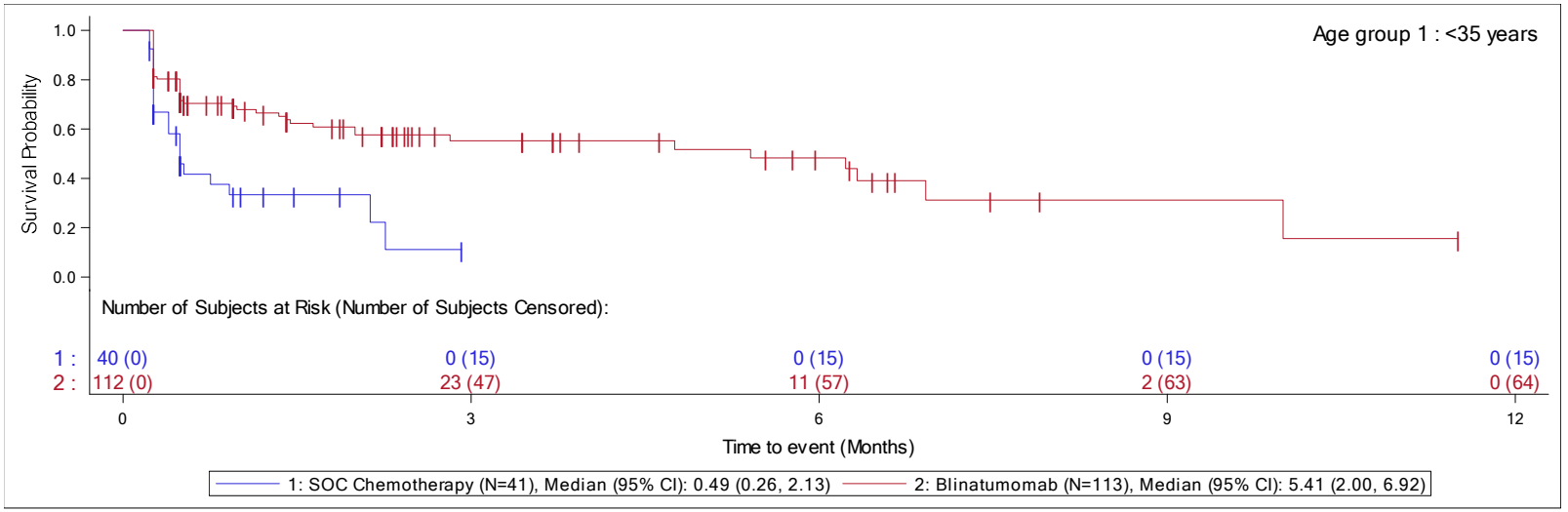
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

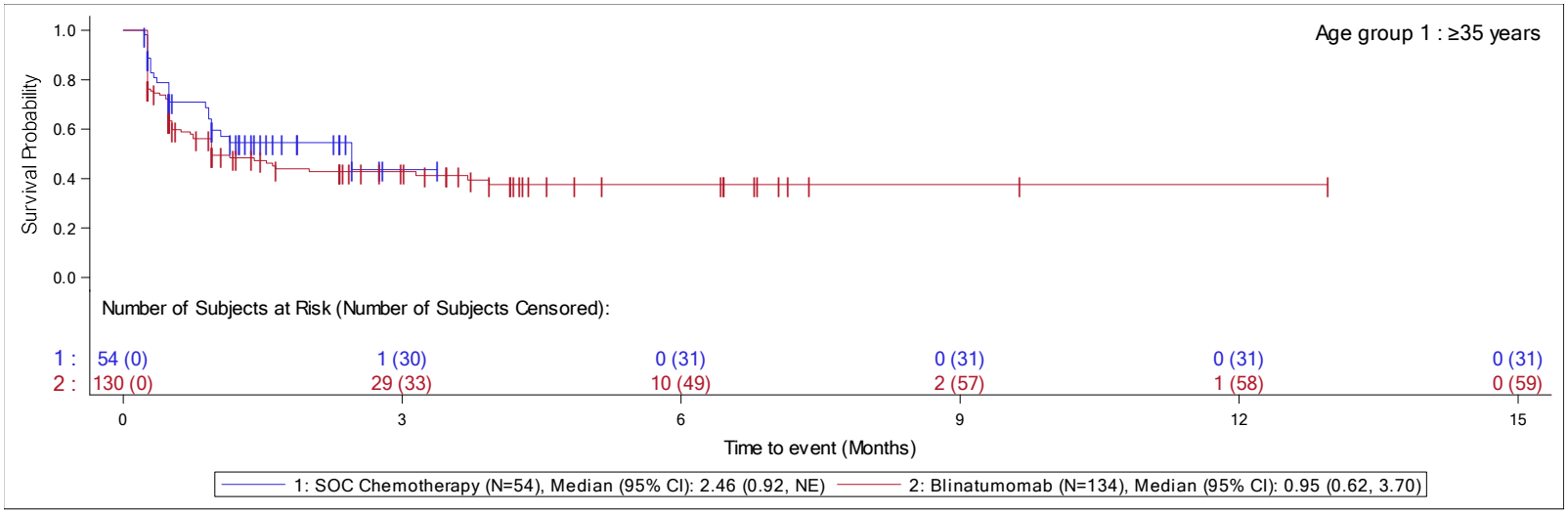
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

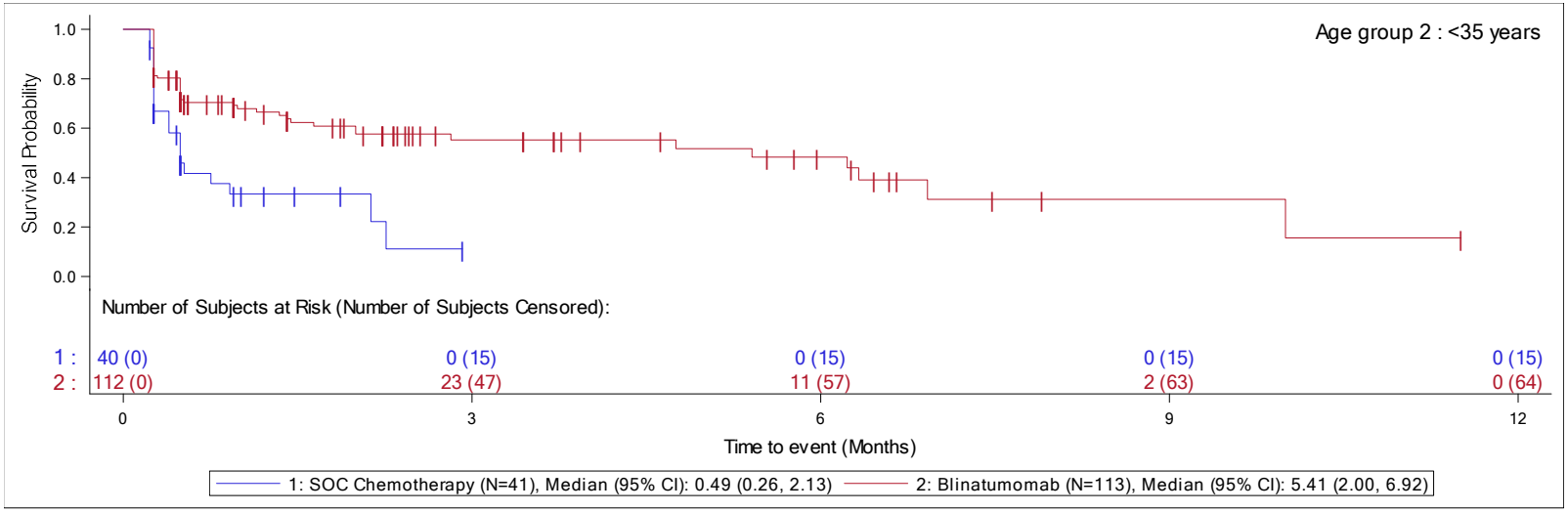
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

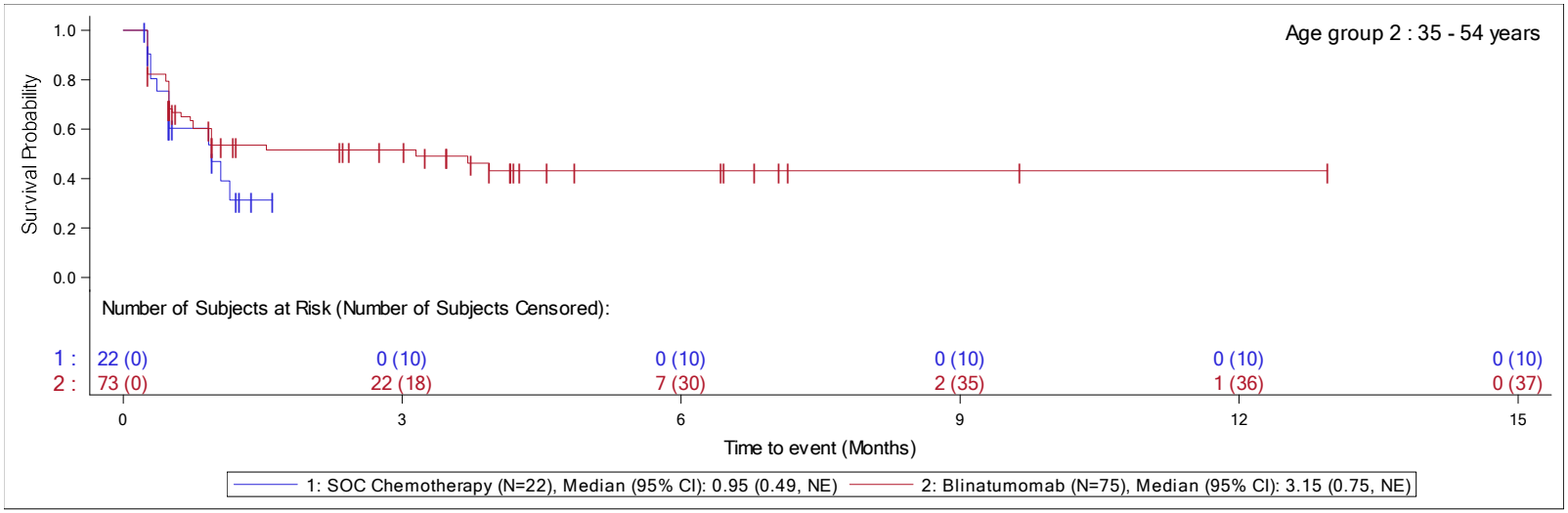
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

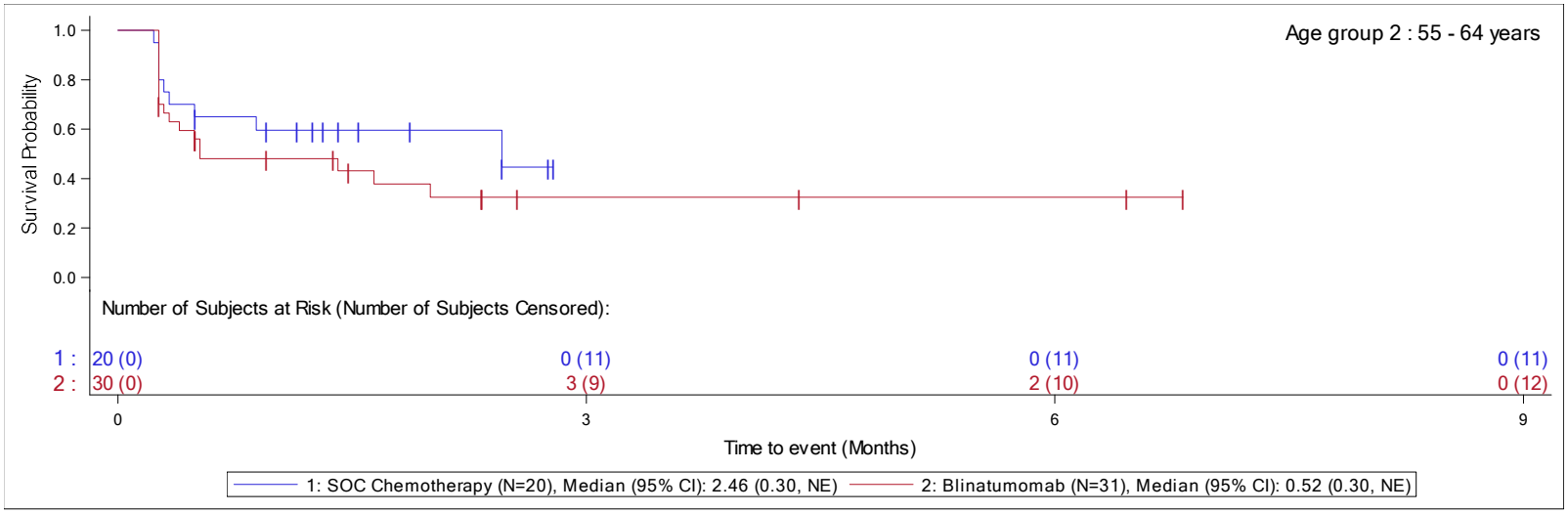
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

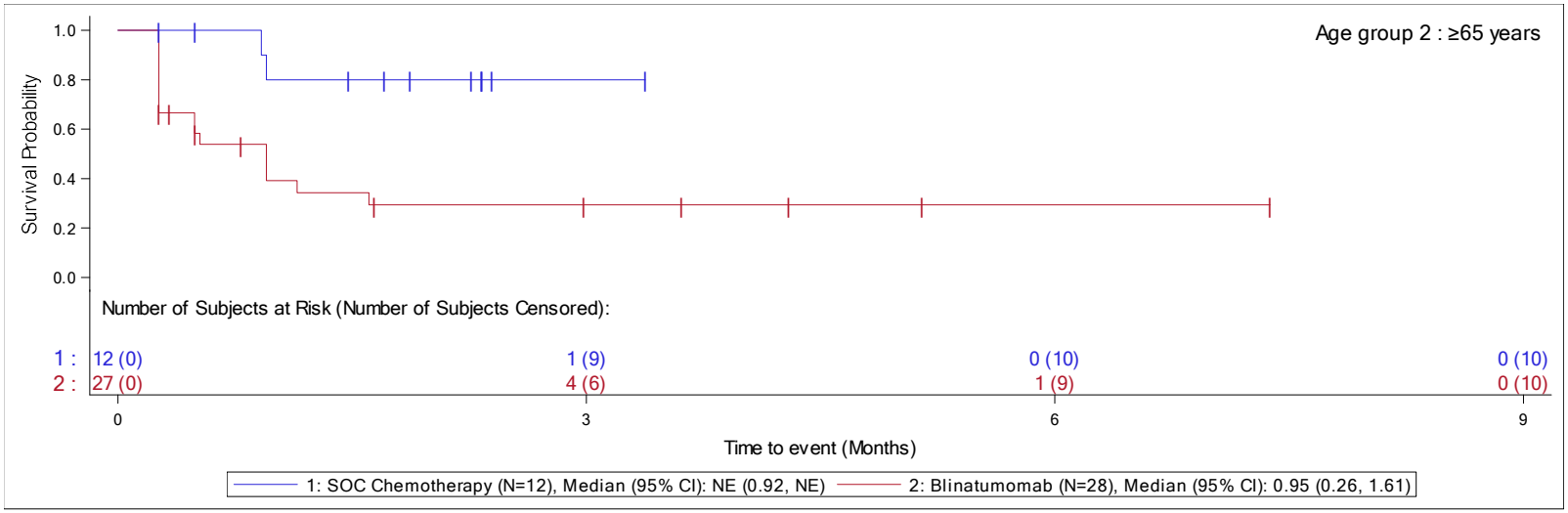
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

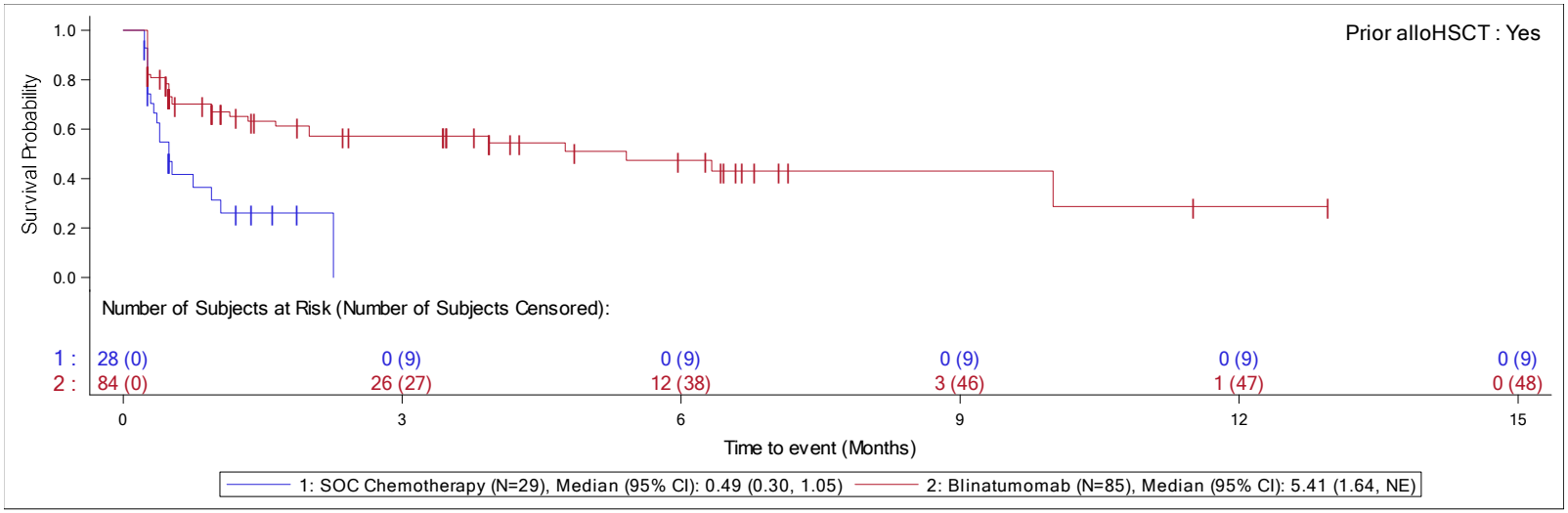
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

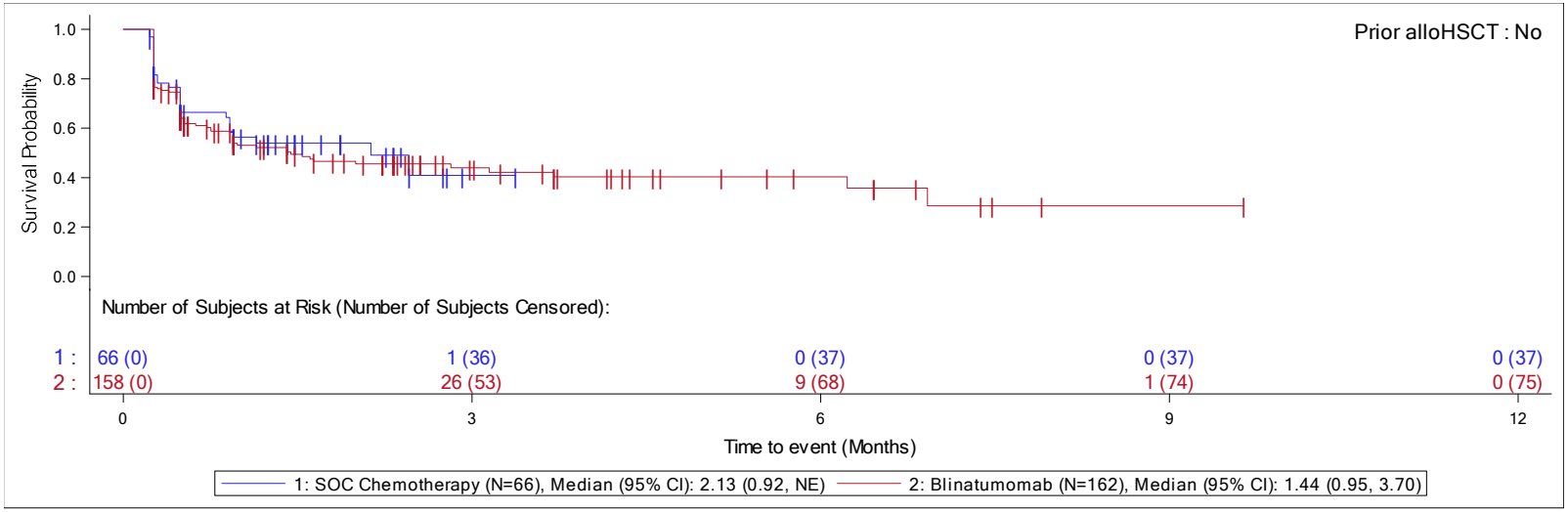
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

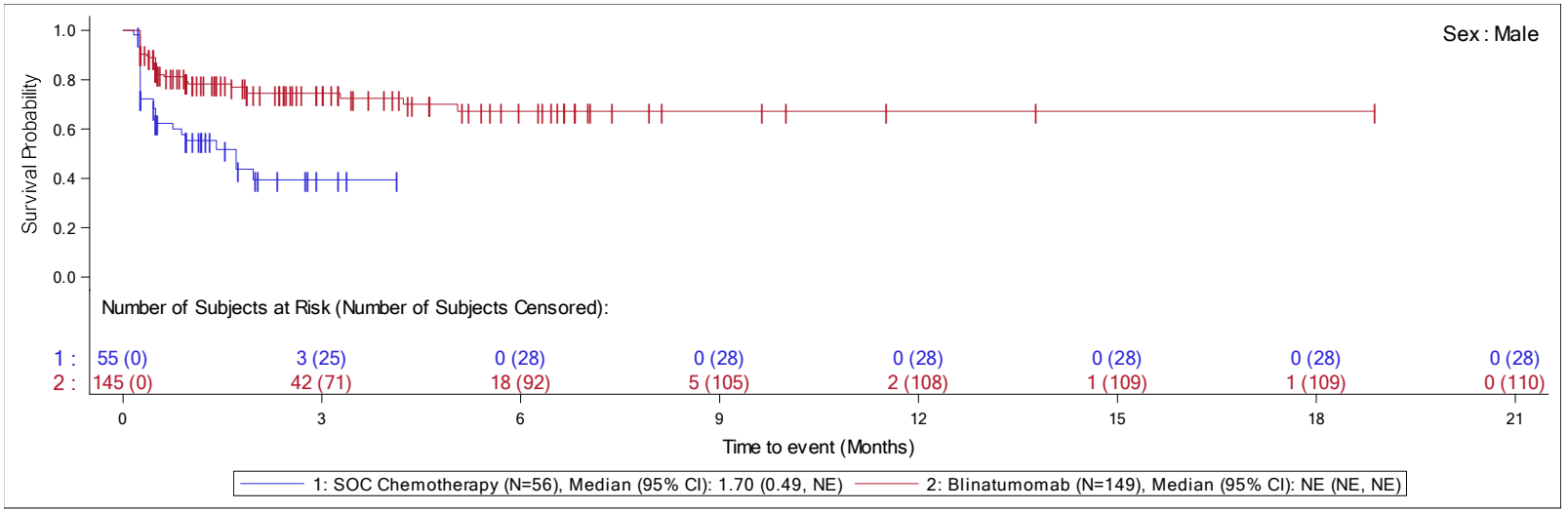
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

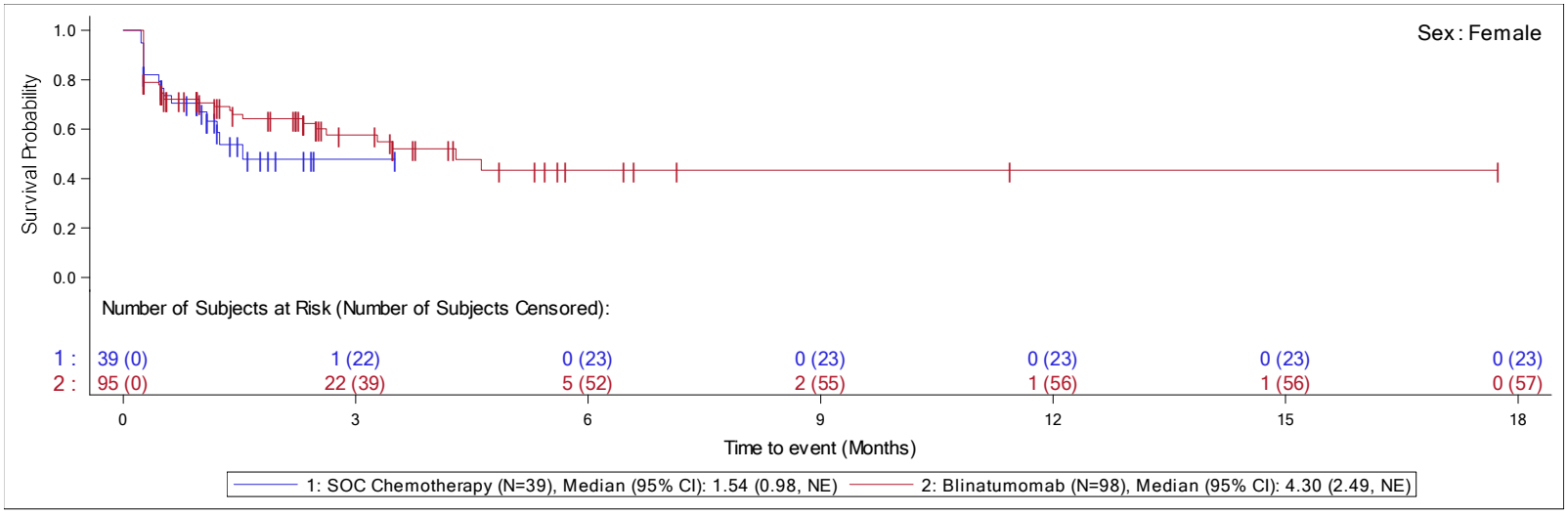
Figure 14-4.4.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-cos-eqcas.sas
Output: f14-04-004-014-km-sub-de-eortc-cos-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Figure 14-4.4.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-cos-eqcas.sas
Output: f14-04-004-014-km-sub-de-eortc-cos-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Anhang 4-G3.5.2: Subgruppenanalyse zu ALLSS-Gesamtscore (Subgruppenanalysen)

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4489
<35 years	21/37 (56.8)	1.21 (0.49, 2.03)	37/107 (34.6)	8.13 (1.54, NE)	0.42 (0.25, 0.73)	0.0014	
≥35 years	30/49 (61.2)	1.05 (0.52, 1.48)	56/115 (48.7)	2.00 (1.41, 4.59)	0.55 (0.35, 0.87)	0.0074	
Age group 2							0.1006
<35 years	21/37 (56.8)	1.21 (0.49, 2.03)	37/107 (34.6)	8.13 (1.54, NE)	0.42 (0.25, 0.73)	0.0014	
35 - 54 years	13/20 (65.0)	1.05 (0.46, 1.48)	33/66 (50.0)	1.44 (0.95, NE)	0.53 (0.28, 1.03)	0.0433	
55 - 64 years	9/20 (45.0)	1.15 (0.46, NE)	14/23 (60.9)	2.00 (0.49, 3.25)	1.02 (0.42, 2.45)	0.9666	
≥65 years	8/9 (88.9)	0.95 (0.26, 1.48)	9/26 (34.6)	NE (1.41, NE)	0.24 (0.09, 0.65)	0.0024	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam.adtteqs

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3513
Male	30/50 (60.0)	0.95 (0.49, 2.03)	54/140 (38.6)	4.59 (1.64, NE)	0.44 (0.28, 0.69)	0.0002	
Female	21/36 (58.3)	1.21 (0.89, 1.54)	39/82 (47.6)	1.87 (0.98, 4.39)	0.60 (0.35, 1.03)	0.0544	
Region							0.5976
USA	6/10 (60.0)	0.89 (0.26, NE)	7/25 (28.0)	NE (1.11, NE)	0.36 (0.12, 1.07)	0.0605	
Europe	29/53 (54.7)	1.15 (0.92, 2.03)	61/145 (42.1)	2.56 (1.51, NE)	0.55 (0.35, 0.86)	0.0059	
Rest of the world	16/23 (69.6)	1.05 (0.49, 1.48)	25/52 (48.1)	2.46 (0.95, NE)	0.44 (0.23, 0.86)	0.0122	
Prior salvage therapy							0.0325
Yes	25/48 (52.1)	1.21 (0.92, 1.77)	58/133 (43.6)	1.54 (1.18, NE)	0.71 (0.44, 1.15)	0.1386	
No	26/38 (68.4)	0.95 (0.49, 1.48)	35/89 (39.3)	4.39 (2.46, NE)	0.31 (0.18, 0.52)	<0.0001	

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam.adtteqs

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.2002
0	29/45 (64.4)	0.95 (0.49, 1.48)	41/98 (41.8)	3.25 (2.46, NE)	0.33 (0.20, 0.54)	<0.0001	
1	14/27 (51.9)	1.15 (0.52, NE)	32/73 (43.8)	1.67 (0.95, NE)	0.70 (0.37, 1.32)	0.2323	
≥2	8/14 (57.1)	1.21 (0.49, NE)	20/51 (39.2)	2.79 (0.95, NE)	0.71 (0.31, 1.63)	0.3961	
Prior alloHSCT							0.4703
Yes	16/28 (57.1)	1.05 (0.49, 2.03)	28/75 (37.3)	13.77 (1.51, NE)	0.44 (0.23, 0.83)	0.0074	
No	35/58 (60.3)	1.15 (0.89, 1.48)	65/147 (44.2)	2.46 (1.41, 4.59)	0.52 (0.34, 0.80)	0.0019	
Race							0.5343
Caucasian	42/70 (60.0)	1.15 (0.52, 1.54)	81/189 (42.9)	2.56 (1.54, 13.77)	0.51 (0.35, 0.75)	0.0004	
Others	9/16 (56.3)	0.95 (0.26, 1.21)	12/33 (36.4)	2.82 (1.41, NE)	0.34 (0.14, 0.86)	0.0175	

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam.adtteqs

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4242
<50%	15/23 (65.2)	0.89 (0.46, 2.39)	29/62 (46.8)	3.25 (1.18, NE)	0.40 (0.21, 0.76)	0.0030	
≥50%	36/61 (59.0)	1.15 (0.92, 1.48)	54/138 (39.1)	2.46 (1.44, NE)	0.50 (0.32, 0.77)	0.0011	

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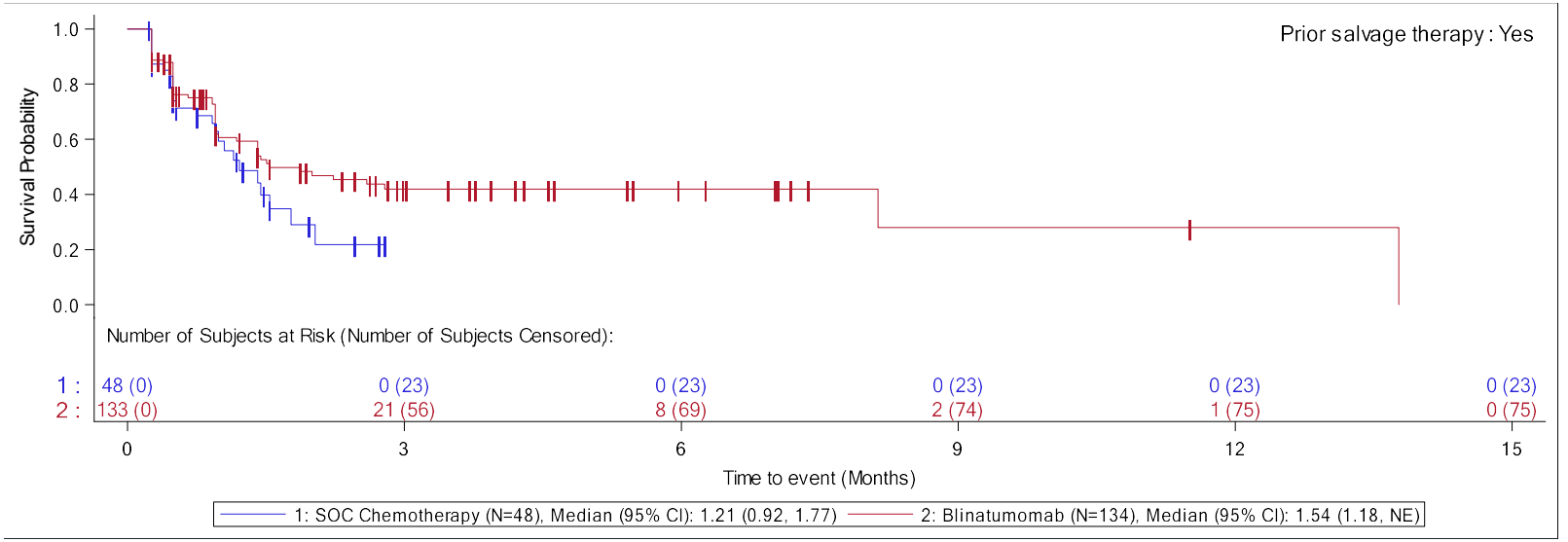
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam.adtteqs

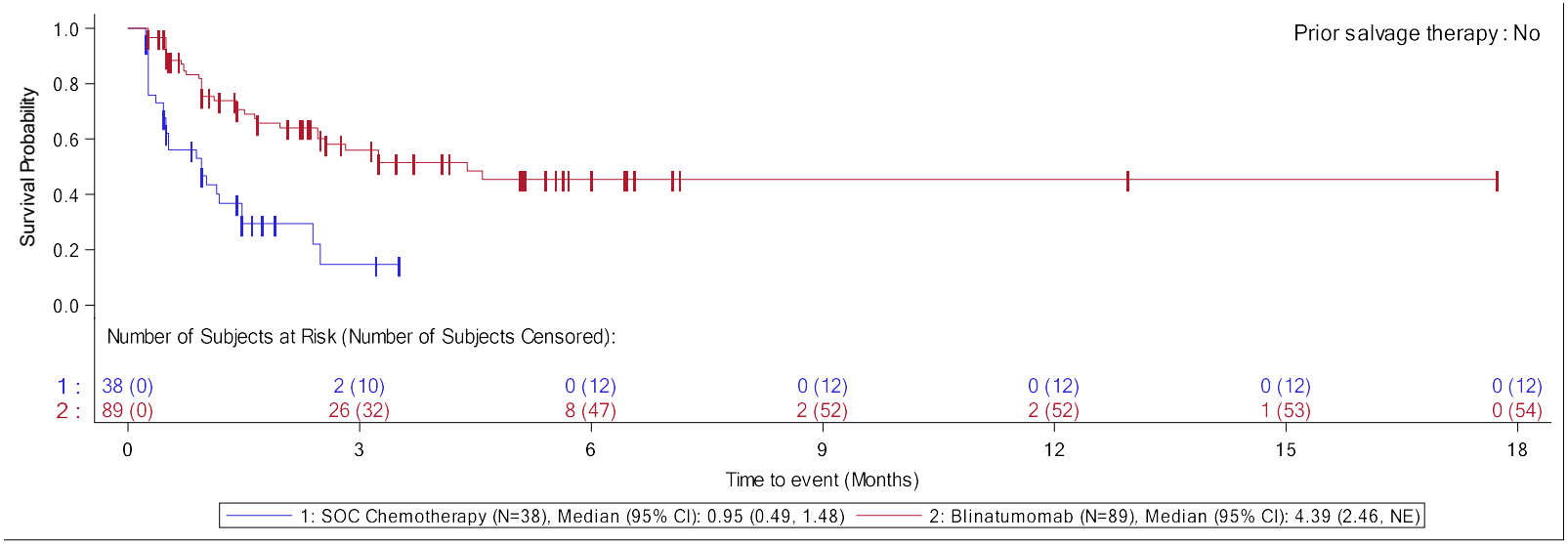
Figure 14-4.4.1. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-allss-ts-allas.sas
Output: f14-04-004-001-km-sub-de-allss-ts-allas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam.adtteqs

Figure 14-4.4.1. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-allss-ts-allas.sas
Output: f14-04-004-001-km-sub-de-allss-ts-allas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam.adtteqs

Anhang 4-G3.6: Subgruppenanalysen zu patientenberichtete gesundheitsbezogene Lebensqualität

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4532
<35 years	20/41 (48.8)	1.38 (0.39, NE)	40/110 (36.4)	8.13 (2.82, NE)	0.49 (0.28, 0.84)	0.0092	
≥35 years	30/54 (55.6)	0.98 (0.49, 2.46)	59/130 (45.4)	3.80 (0.95, NE)	0.67 (0.43, 1.05)	0.0527	
Age group 2							0.0564
<35 years	20/41 (48.8)	1.38 (0.39, NE)	40/110 (36.4)	8.13 (2.82, NE)	0.49 (0.28, 0.84)	0.0092	
35 - 54 years	12/22 (54.5)	0.49 (0.30, NE)	34/74 (45.9)	3.80 (0.72, NE)	0.65 (0.33, 1.26)	0.1488	
55 - 64 years	13/20 (65.0)	0.49 (0.26, NE)	9/30 (30.0)	NE (2.00, NE)	0.29 (0.12, 0.72)	0.0040	
≥65 years	5/12 (41.7)	NE (0.92, NE)	16/26 (61.5)	0.69 (0.49, 4.23)	2.04 (0.74, 5.64)	0.1816	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 05JUN2025:02:43) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2837
Male	28/56 (50.0)	1.25 (0.49, NE)	64/146 (43.8)	3.80 (1.48, NE)	0.65 (0.42, 1.03)	0.0563	
Female	22/39 (56.4)	0.98 (0.36, 1.77)	35/94 (37.2)	NE (1.41, NE)	0.49 (0.29, 0.85)	0.0063	
Region							0.9404
USA	8/12 (66.7)	0.39 (0.26, NE)	11/26 (42.3)	NE (0.36, NE)	0.54 (0.21, 1.33)	0.1765	
Europe	31/59 (52.5)	1.25 (0.49, 2.46)	64/157 (40.8)	8.13 (2.00, NE)	0.57 (0.37, 0.88)	0.0071	
Rest of the world	11/24 (45.8)	1.48 (0.26, NE)	24/57 (42.1)	3.80 (0.95, NE)	0.64 (0.31, 1.33)	0.2292	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 05JUN2025:02:43) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.3276
Yes	24/54 (44.4)	1.48 (0.52, NE)	55/143 (38.5)	8.13 (2.00, NE)	0.69 (0.42, 1.12)	0.1103	
No	26/41 (63.4)	0.46 (0.30, 1.48)	44/97 (45.4)	4.23 (1.41, NE)	0.48 (0.29, 0.79)	0.0026	
Number of salvage therapies							0.9576
0	29/49 (59.2)	0.92 (0.36, 1.77)	52/105 (49.5)	2.95 (0.95, NE)	0.59 (0.37, 0.94)	0.0206	
1	13/29 (44.8)	2.46 (0.49, NE)	28/79 (35.4)	NE (2.00, NE)	0.63 (0.33, 1.23)	0.1540	
≥2	8/17 (47.1)	1.48 (0.26, NE)	19/56 (33.9)	NE (1.21, NE)	0.54 (0.23, 1.24)	0.1420	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 05JUN2025:02:43) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0814
Yes	17/29 (58.6)	0.49 (0.30, 1.38)	28/82 (34.1)	NE (3.61, NE)	0.38 (0.21, 0.71)	0.0013	
No	33/66 (50.0)	1.48 (0.49, NE)	71/158 (44.9)	3.80 (1.41, NE)	0.71 (0.46, 1.07)	0.0862	
Race							0.0353
Caucasian	45/78 (57.7)	0.92 (0.46, 1.48)	81/203 (39.9)	8.13 (2.95, NE)	0.48 (0.33, 0.69)	<0.0001	
Others	5/17 (29.4)	NE (0.52, NE)	18/37 (48.6)	1.54 (0.49, NE)	1.66 (0.61, 4.46)	0.3055	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 05JUN2025:02:43) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4472
<50%	14/25 (56.0)	0.98 (0.36, NE)	24/66 (36.4)	NE (3.80, NE)	0.52 (0.26, 1.01)	0.0317	
≥50%	34/67 (50.7)	1.25 (0.49, NE)	65/151 (43.0)	3.61 (1.41, NE)	0.62 (0.40, 0.94)	0.0213	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 05JUN2025:02:43) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0233
<35 years	26/41 (63.4)	0.49 (0.30, 0.75)	49/111 (44.1)	11.51 (1.34, NE)	0.47 (0.29, 0.77)	0.0013	
≥35 years	33/53 (62.3)	0.95 (0.49, 1.25)	77/130 (59.2)	0.98 (0.69, 1.87)	0.86 (0.57, 1.30)	0.4135	
Age group 2							0.0396
<35 years	26/41 (63.4)	0.49 (0.30, 0.75)	49/111 (44.1)	11.51 (1.34, NE)	0.47 (0.29, 0.77)	0.0013	
35 - 54 years	13/22 (59.1)	0.95 (0.36, 1.25)	46/73 (63.0)	0.98 (0.69, 1.87)	0.77 (0.41, 1.44)	0.3619	
55 - 64 years	12/19 (63.2)	0.98 (0.33, NE)	11/30 (36.7)	NE (1.48, NE)	0.46 (0.20, 1.07)	0.0591	
≥65 years	8/12 (66.7)	0.97 (0.49, NE)	20/27 (74.1)	0.49 (0.26, 2.79)	1.58 (0.68, 3.64)	0.3234	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7950
Male	36/56 (64.3)	0.75 (0.46, 0.95)	80/145 (55.2)	1.34 (0.56, 3.15)	0.68 (0.46, 1.02)	0.0440	
Female	23/38 (60.5)	1.05 (0.49, 2.46)	46/96 (47.9)	3.02 (0.95, NE)	0.61 (0.36, 1.01)	0.0391	
Region							0.1346
USA	5/12 (41.7)	NE (0.26, NE)	15/26 (57.7)	0.95 (0.52, 3.25)	1.86 (0.67, 5.16)	0.2136	
Europe	34/58 (58.6)	0.92 (0.49, 1.38)	78/158 (49.4)	1.87 (0.95, NE)	0.63 (0.42, 0.95)	0.0192	
Rest of the world	20/24 (83.3)	0.49 (0.33, 0.98)	33/57 (57.9)	1.25 (0.49, 3.15)	0.51 (0.29, 0.91)	0.0104	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.7479
Yes	33/54 (61.1)	0.92 (0.49, 1.05)	75/145 (51.7)	1.44 (0.52, NE)	0.70 (0.46, 1.06)	0.0599	
No	26/40 (65.0)	0.52 (0.46, 1.48)	51/96 (53.1)	1.87 (0.95, NE)	0.60 (0.37, 0.97)	0.0299	
Number of salvage therapies							0.8446
0	29/48 (60.4)	0.52 (0.46, 1.48)	57/104 (54.8)	1.87 (0.95, 4.23)	0.66 (0.42, 1.03)	0.0590	
1	18/29 (62.1)	0.98 (0.52, 1.25)	40/82 (48.8)	1.87 (0.95, NE)	0.68 (0.38, 1.19)	0.1292	
≥2	12/17 (70.6)	0.39 (0.26, NE)	29/55 (52.7)	0.95 (0.49, NE)	0.59 (0.30, 1.15)	0.0905	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0072
Yes	22/29 (75.9)	0.49 (0.33, 0.75)	36/84 (42.9)	NE (0.95, NE)	0.39 (0.23, 0.66)	0.0001	
No	37/65 (56.9)	0.98 (0.49, 1.48)	90/157 (57.3)	1.48 (0.72, 2.79)	0.85 (0.57, 1.25)	0.3516	
Race							0.1803
Caucasian	50/77 (64.9)	0.52 (0.49, 0.98)	104/204 (51.0)	1.87 (0.95, 4.23)	0.61 (0.43, 0.86)	0.0022	
Others	9/17 (52.9)	0.95 (0.46, NE)	22/37 (59.5)	0.98 (0.49, 3.02)	1.01 (0.46, 2.20)	0.9842	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4643
<50%	13/25 (52.0)	0.98 (0.49, NE)	32/64 (50.0)	3.05 (0.95, NE)	0.79 (0.41, 1.52)	0.4682	
≥50%	45/66 (68.2)	0.52 (0.46, 0.95)	80/153 (52.3)	1.48 (0.72, 3.15)	0.58 (0.40, 0.83)	0.0017	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.3794
<35 years	28/40 (70.0)	0.26 (0.26, 0.49)	65/112 (58.0)	1.41 (0.52, 2.23)	0.51 (0.32, 0.80)	0.0031	
≥35 years	38/51 (74.5)	0.95 (0.30, 1.25)	74/129 (57.4)	0.95 (0.49, 2.30)	0.66 (0.44, 0.99)	0.0284	
Age group 2							0.2526
<35 years	28/40 (70.0)	0.26 (0.26, 0.49)	65/112 (58.0)	1.41 (0.52, 2.23)	0.51 (0.32, 0.80)	0.0031	
35 - 54 years	14/21 (66.7)	0.95 (0.26, 1.25)	44/73 (60.3)	0.92 (0.49, 0.98)	0.81 (0.44, 1.49)	0.4184	
55 - 64 years	15/19 (78.9)	0.30 (0.26, 1.48)	12/29 (41.4)	2.03 (0.52, NE)	0.35 (0.16, 0.78)	0.0075	
≥65 years	9/11 (81.8)	0.98 (0.26, 1.97)	18/27 (66.7)	0.49 (0.26, 3.31)	0.88 (0.38, 2.03)	0.6642	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1956
Male	36/54 (66.7)	0.49 (0.26, 0.98)	89/145 (61.4)	0.95 (0.49, 1.48)	0.69 (0.47, 1.03)	0.0615	
Female	30/37 (81.1)	0.39 (0.26, 1.05)	50/96 (52.1)	1.41 (0.52, 4.62)	0.46 (0.29, 0.73)	0.0004	
Region							0.9671
USA	9/12 (75.0)	0.26 (0.26, NE)	15/26 (57.7)	0.95 (0.52, 3.25)	0.50 (0.21, 1.18)	0.1402	
Europe	39/56 (69.6)	0.49 (0.26, 1.08)	91/157 (58.0)	0.98 (0.56, 2.03)	0.61 (0.42, 0.89)	0.0066	
Rest of the world	18/23 (78.3)	0.52 (0.26, 1.18)	33/58 (56.9)	0.98 (0.49, 11.51)	0.61 (0.34, 1.09)	0.0726	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4935
Yes	35/53 (66.0)	0.49 (0.26, 0.98)	80/145 (55.2)	0.95 (0.49, 2.03)	0.67 (0.45, 1.00)	0.0369	
No	31/38 (81.6)	0.30 (0.26, 1.08)	59/96 (61.5)	1.02 (0.52, 2.33)	0.50 (0.32, 0.78)	0.0016	
Number of salvage therapies							0.3151
0	38/46 (82.6)	0.30 (0.26, 0.52)	60/103 (58.3)	1.11 (0.72, 2.92)	0.45 (0.29, 0.68)	0.0001	
1	17/28 (60.7)	0.98 (0.26, 1.41)	47/82 (57.3)	0.95 (0.49, 2.03)	0.79 (0.45, 1.39)	0.3561	
≥2	11/17 (64.7)	0.26 (0.26, NE)	32/56 (57.1)	0.72 (0.49, 4.36)	0.68 (0.34, 1.35)	0.2910	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.3437
Yes	22/28 (78.6)	0.39 (0.26, 0.95)	46/84 (54.8)	0.95 (0.49, 4.13)	0.50 (0.30, 0.84)	0.0049	
No	44/63 (69.8)	0.49 (0.26, 1.25)	93/157 (59.2)	1.02 (0.52, 2.03)	0.62 (0.43, 0.90)	0.0088	
Race							0.7951
Caucasian	55/75 (73.3)	0.49 (0.26, 0.98)	119/203 (58.6)	0.95 (0.52, 1.87)	0.59 (0.43, 0.82)	0.0009	
Others	11/16 (68.8)	0.57 (0.26, 1.18)	20/38 (52.6)	0.98 (0.49, NE)	0.54 (0.26, 1.14)	0.1081	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7204
<50%	16/24 (66.7)	0.98 (0.26, 1.84)	34/65 (52.3)	1.87 (0.49, NE)	0.69 (0.38, 1.26)	0.1638	
≥50%	47/64 (73.4)	0.39 (0.26, 0.95)	90/152 (59.2)	0.95 (0.52, 1.41)	0.58 (0.40, 0.82)	0.0020	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.1694
<35 years	22/41 (53.7)	1.21 (0.39, 2.13)	44/111 (39.6)	5.15 (1.87, NE)	0.50 (0.30, 0.85)	0.0075	
≥35 years	36/54 (66.7)	0.92 (0.49, 1.48)	82/131 (62.6)	1.41 (0.52, 2.36)	0.72 (0.48, 1.08)	0.0745	
Age group 2							0.4721
<35 years	22/41 (53.7)	1.21 (0.39, 2.13)	44/111 (39.6)	5.15 (1.87, NE)	0.50 (0.30, 0.85)	0.0075	
35 - 54 years	13/22 (59.1)	1.08 (0.49, 1.77)	46/73 (63.0)	1.41 (0.49, 2.82)	0.78 (0.42, 1.48)	0.3311	
55 - 64 years	15/20 (75.0)	0.49 (0.30, 1.48)	18/30 (60.0)	1.41 (0.49, 4.39)	0.55 (0.27, 1.11)	0.0838	
≥65 years	8/12 (66.7)	0.95 (0.26, NE)	18/28 (64.3)	0.95 (0.33, 3.70)	0.87 (0.37, 2.05)	0.7598	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1878
Male	35/56 (62.5)	0.49 (0.39, 1.38)	72/147 (49.0)	2.75 (1.48, 4.66)	0.51 (0.33, 0.77)	0.0007	
Female	23/39 (59.0)	1.18 (0.49, 1.77)	54/95 (56.8)	1.41 (0.52, 2.98)	0.83 (0.50, 1.36)	0.3774	
Region							0.1867
USA	7/12 (58.3)	0.95 (0.26, NE)	9/26 (34.6)	NE (0.98, NE)	0.50 (0.18, 1.33)	0.1607	
Europe	38/59 (64.4)	0.49 (0.39, 1.25)	79/157 (50.3)	2.36 (1.34, 5.21)	0.54 (0.36, 0.80)	0.0009	
Rest of the world	13/24 (54.2)	1.48 (0.46, 2.13)	38/59 (64.4)	1.21 (0.49, 2.36)	0.89 (0.46, 1.71)	0.6763	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.3302
Yes	30/54 (55.6)	0.92 (0.33, 2.13)	78/145 (53.8)	1.54 (0.95, 4.20)	0.70 (0.46, 1.08)	0.0838	
No	28/41 (68.3)	0.95 (0.49, 1.41)	48/97 (49.5)	2.75 (1.41, NE)	0.51 (0.32, 0.83)	0.0039	
Number of salvage therapies							0.2826
0	34/49 (69.4)	0.95 (0.49, 1.41)	56/105 (53.3)	2.36 (1.41, 3.70)	0.51 (0.33, 0.78)	0.0015	
1	14/29 (48.3)	1.25 (0.49, NE)	43/81 (53.1)	1.48 (0.82, 4.39)	0.91 (0.49, 1.68)	0.6306	
≥2	10/17 (58.8)	0.28 (0.26, NE)	27/56 (48.2)	2.36 (0.49, NE)	0.51 (0.25, 1.08)	0.0842	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0260
Yes	19/29 (65.5)	0.49 (0.30, 1.38)	35/83 (42.2)	4.39 (1.57, NE)	0.36 (0.20, 0.65)	0.0003	
No	39/66 (59.1)	1.08 (0.49, 1.48)	91/159 (57.2)	1.41 (0.82, 2.75)	0.79 (0.54, 1.15)	0.1581	
Race							0.2061
Caucasian	51/78 (65.4)	0.49 (0.46, 1.25)	108/204 (52.9)	2.00 (0.98, 3.25)	0.57 (0.40, 0.80)	0.0006	
Others	7/17 (41.2)	2.13 (0.95, NE)	18/38 (47.4)	2.36 (1.41, NE)	0.94 (0.39, 2.28)	0.8239	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3141
<50%	17/25 (68.0)	0.46 (0.26, 1.70)	35/66 (53.0)	2.36 (1.08, NE)	0.45 (0.25, 0.82)	0.0080	
≥50%	40/67 (59.7)	1.08 (0.49, 1.41)	74/152 (48.7)	2.75 (0.98, 4.36)	0.63 (0.43, 0.94)	0.0121	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4512
<35 years	16/41 (39.0)	2.79 (0.95, NE)	30/111 (27.0)	8.13 (4.43, NE)	0.44 (0.24, 0.83)	0.0088	
≥35 years	19/53 (35.8)	NE (1.18, NE)	43/130 (33.1)	NE (4.36, NE)	0.71 (0.41, 1.24)	0.2240	
Age group 2							0.4629
<35 years	16/41 (39.0)	2.79 (0.95, NE)	30/111 (27.0)	8.13 (4.43, NE)	0.44 (0.24, 0.83)	0.0088	
35 - 54 years	9/21 (42.9)	1.77 (0.49, NE)	23/72 (31.9)	NE (2.36, NE)	0.49 (0.22, 1.08)	0.0674	
55 - 64 years	7/20 (35.0)	NE (0.95, NE)	9/30 (30.0)	4.36 (3.02, NE)	0.48 (0.16, 1.46)	0.1863	
≥65 years	3/12 (25.0)	NE (0.46, NE)	11/28 (39.3)	NE (0.95, NE)	1.56 (0.43, 5.59)	0.4912	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1022
Male	17/55 (30.9)	NE (1.84, NE)	46/147 (31.3)	8.13 (4.36, NE)	0.76 (0.43, 1.33)	0.3197	
Female	18/39 (46.2)	1.77 (0.49, NE)	27/94 (28.7)	11.51 (11.51, NE)	0.41 (0.22, 0.76)	0.0035	
Region							0.2268
USA	4/11 (36.4)	NE (0.46, NE)	10/26 (38.5)	3.80 (0.95, NE)	1.09 (0.33, 3.54)	0.8846	
Europe	18/59 (30.5)	NE (1.77, NE)	44/156 (28.2)	8.13 (6.66, NE)	0.63 (0.36, 1.11)	0.1023	
Rest of the world	13/24 (54.2)	0.95 (0.39, NE)	19/59 (32.2)	11.51 (2.82, NE)	0.39 (0.18, 0.81)	0.0077	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.6271
Yes	17/53 (32.1)	NE (1.05, NE)	40/145 (27.6)	11.51 (8.13, NE)	0.66 (0.37, 1.18)	0.1578	
No	18/41 (43.9)	2.30 (1.18, NE)	33/96 (34.4)	NE (3.02, NE)	0.49 (0.27, 0.88)	0.0153	
Number of salvage therapies							0.6794
0	19/49 (38.8)	2.79 (1.77, NE)	40/104 (38.5)	6.66 (2.82, NE)	0.63 (0.36, 1.10)	0.0992	
1	8/28 (28.6)	NE (1.05, NE)	16/81 (19.8)	NE (11.51, NE)	0.55 (0.23, 1.30)	0.1561	
≥2	8/17 (47.1)	NE (0.26, NE)	17/56 (30.4)	NE (1.51, NE)	0.50 (0.21, 1.17)	0.0963	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0519
Yes	13/29 (44.8)	2.30 (0.49, NE)	21/82 (25.6)	NE (6.66, NE)	0.34 (0.16, 0.71)	0.0022	
No	22/65 (33.8)	NE (1.54, NE)	52/159 (32.7)	8.13 (3.80, NE)	0.74 (0.45, 1.23)	0.2439	
Race							0.7825
Caucasian	29/77 (37.7)	2.79 (1.54, NE)	61/203 (30.0)	NE (6.66, NE)	0.56 (0.36, 0.88)	0.0106	
Others	6/17 (35.3)	NE (0.95, NE)	12/38 (31.6)	11.51 (1.87, NE)	0.64 (0.23, 1.78)	0.3889	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7249
<50%	6/25 (24.0)	NE (NE, NE)	19/66 (28.8)	NE (4.43, NE)	0.63 (0.24, 1.64)	0.3366	
≥50%	27/66 (40.9)	1.84 (1.15, NE)	48/152 (31.6)	8.13 (3.80, NE)	0.62 (0.38, 1.00)	0.0421	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0487
<35 years	24/41 (58.5)	0.49 (0.26, NE)	54/111 (48.6)	1.41 (0.95, NE)	0.58 (0.35, 0.94)	0.0238	
≥35 years	29/53 (54.7)	1.15 (0.92, 1.84)	80/131 (61.1)	0.95 (0.56, 2.00)	1.00 (0.65, 1.54)	0.8897	
Age group 2							0.1414
<35 years	24/41 (58.5)	0.49 (0.26, NE)	54/111 (48.6)	1.41 (0.95, NE)	0.58 (0.35, 0.94)	0.0238	
35 - 54 years	10/21 (47.6)	1.15 (0.52, NE)	44/74 (59.5)	0.95 (0.52, 2.75)	1.11 (0.55, 2.23)	0.8567	
55 - 64 years	14/20 (70.0)	0.95 (0.30, 1.84)	18/30 (60.0)	1.54 (0.49, 5.31)	0.70 (0.34, 1.43)	0.3048	
≥65 years	5/12 (41.7)	NE (0.26, NE)	18/27 (66.7)	0.95 (0.26, 3.25)	1.56 (0.57, 4.22)	0.3793	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2751
Male	29/55 (52.7)	0.98 (0.49, NE)	85/147 (57.8)	0.95 (0.52, 1.80)	0.93 (0.61, 1.42)	0.6989	
Female	24/39 (61.5)	0.95 (0.46, 1.48)	49/95 (51.6)	2.10 (0.95, 5.31)	0.61 (0.37, 1.01)	0.0374	
Region							0.4513
USA	6/11 (54.5)	0.85 (0.26, NE)	11/26 (42.3)	5.31 (0.56, NE)	0.47 (0.17, 1.34)	0.1673	
Europe	29/59 (49.2)	1.25 (0.92, NE)	87/158 (55.1)	1.34 (0.95, 2.33)	0.94 (0.62, 1.44)	0.7346	
Rest of the world	18/24 (75.0)	0.52 (0.39, 0.95)	36/58 (62.1)	0.56 (0.49, 2.10)	0.64 (0.36, 1.14)	0.0923	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.9794
Yes	30/53 (56.6)	0.95 (0.49, 1.77)	77/145 (53.1)	1.05 (0.92, 2.00)	0.80 (0.52, 1.22)	0.2603	
No	23/41 (56.1)	1.08 (0.30, 1.90)	57/97 (58.8)	1.34 (0.56, 3.25)	0.78 (0.47, 1.28)	0.2797	
Number of salvage therapies							0.8982
0	27/49 (55.1)	1.08 (0.46, 1.90)	63/105 (60.0)	1.11 (0.75, 2.75)	0.83 (0.52, 1.31)	0.4034	
1	16/28 (57.1)	0.95 (0.39, 2.46)	45/80 (56.3)	0.95 (0.56, 2.10)	0.79 (0.44, 1.40)	0.3632	
≥2	10/17 (58.8)	0.59 (0.26, NE)	26/57 (45.6)	5.31 (0.49, NE)	0.68 (0.32, 1.41)	0.2646	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1548
Yes	19/29 (65.5)	0.59 (0.26, 1.48)	42/83 (50.6)	1.05 (0.49, NE)	0.65 (0.38, 1.12)	0.0788	
No	34/65 (52.3)	1.15 (0.49, 2.46)	92/159 (57.9)	1.15 (0.95, 2.10)	0.89 (0.60, 1.32)	0.5372	
Race							0.9907
Caucasian	43/77 (55.8)	1.05 (0.49, 1.77)	112/204 (54.9)	1.21 (0.95, 2.10)	0.79 (0.56, 1.13)	0.1568	
Others	10/17 (58.8)	0.95 (0.26, NE)	22/38 (57.9)	0.95 (0.49, 5.77)	0.82 (0.38, 1.73)	0.6187	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0711
<50%	6/25 (24.0)	NE (1.84, NE)	30/66 (45.5)	5.77 (0.95, NE)	1.71 (0.70, 4.13)	0.2433	
≥50%	44/66 (66.7)	0.59 (0.39, 1.08)	90/152 (59.2)	0.95 (0.52, 1.54)	0.69 (0.48, 1.00)	0.0341	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 05JUN2025:02:30) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0488
<35 years	16/41 (39.0)	NE (0.49, NE)	30/108 (27.8)	17.74 (2.95, NE)	0.47 (0.25, 0.88)	0.0155	
≥35 years	15/53 (28.3)	2.46 (2.03, NE)	48/130 (36.9)	NE (2.75, NE)	1.18 (0.66, 2.12)	0.6298	
Age group 2							0.0682
<35 years	16/41 (39.0)	NE (0.49, NE)	30/108 (27.8)	17.74 (2.95, NE)	0.47 (0.25, 0.88)	0.0155	
35 - 54 years	7/21 (33.3)	NE (1.05, NE)	26/74 (35.1)	NE (2.75, NE)	0.82 (0.35, 1.90)	0.5867	
55 - 64 years	3/20 (15.0)	NE (2.30, NE)	13/30 (43.3)	3.02 (0.49, NE)	3.00 (0.84, 10.69)	0.0814	
≥65 years	5/12 (41.7)	2.03 (0.26, NE)	9/26 (34.6)	NE (0.79, NE)	0.77 (0.26, 2.31)	0.6333	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 05JUN2025:02:48) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9679
Male	19/55 (34.5)	2.46 (1.70, NE)	48/143 (33.6)	NE (2.95, NE)	0.77 (0.45, 1.32)	0.3036	
Female	12/39 (30.8)	NE (1.08, NE)	30/95 (31.6)	17.74 (NE, NE)	0.86 (0.44, 1.69)	0.6513	
Region							0.9421
USA	4/11 (36.4)	1.70 (0.26, NE)	7/26 (26.9)	NE (2.75, NE)	0.62 (0.18, 2.15)	0.4304	
Europe	20/59 (33.9)	2.46 (1.80, NE)	53/155 (34.2)	17.74 (4.39, NE)	0.80 (0.48, 1.35)	0.3899	
Rest of the world	7/24 (29.2)	NE (1.05, NE)	18/57 (31.6)	NE (2.82, NE)	0.89 (0.36, 2.18)	0.7569	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 05JUN2025:02:48) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4113
Yes	15/53 (28.3)	NE (2.03, NE)	45/141 (31.9)	NE (2.95, NE)	0.96 (0.54, 1.74)	0.8898	
No	16/41 (39.0)	2.30 (1.08, NE)	33/97 (34.0)	17.74 (3.02, NE)	0.64 (0.35, 1.18)	0.1322	
Number of salvage therapies							0.6439
0	17/49 (34.7)	NE (1.70, NE)	35/104 (33.7)	17.74 (3.02, NE)	0.70 (0.39, 1.27)	0.2265	
1	7/28 (25.0)	2.46 (2.03, NE)	24/80 (30.0)	NE (NE, NE)	1.14 (0.49, 2.66)	0.8105	
≥2	7/17 (41.2)	NE (0.26, NE)	19/54 (35.2)	4.39 (1.38, NE)	0.60 (0.25, 1.45)	0.2717	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 05JUN2025:02:48) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6378
Yes	10/29 (34.5)	NE (0.85, NE)	32/82 (39.0)	17.74 (2.00, NE)	0.92 (0.45, 1.90)	0.7969	
No	21/65 (32.3)	2.46 (1.70, NE)	46/156 (29.5)	NE (NE, NE)	0.73 (0.43, 1.24)	0.2237	
Race							0.8923
Caucasian	26/77 (33.8)	2.46 (1.80, NE)	66/200 (33.0)	17.74 (3.25, NE)	0.77 (0.49, 1.23)	0.2448	
Others	5/17 (29.4)	NE (0.26, NE)	12/38 (31.6)	NE (1.41, NE)	0.99 (0.35, 2.81)	0.9929	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 05JUN2025:02:48) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6711
<50%	11/25 (44.0)	2.30 (0.49, NE)	26/65 (40.0)	17.74 (2.82, NE)	0.59 (0.29, 1.24)	0.1539	
≥50%	20/66 (30.3)	NE (1.80, NE)	43/149 (28.9)	NE (4.39, NE)	0.82 (0.48, 1.39)	0.4293	

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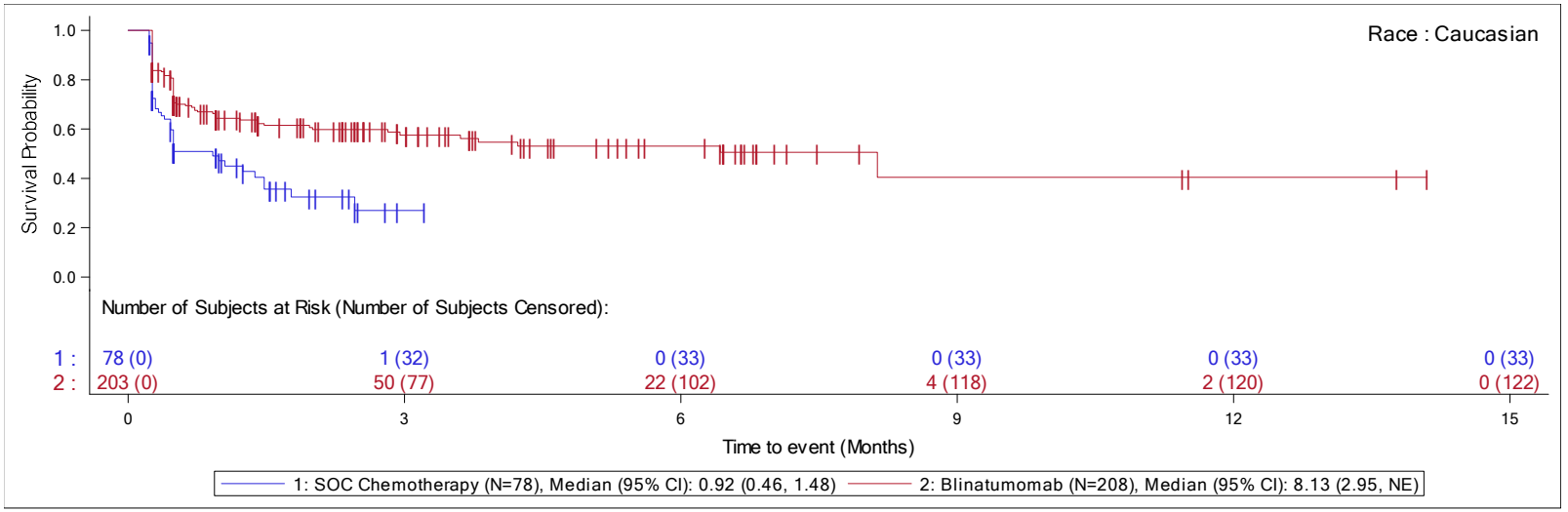
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 05JUN2025:02:48) Source data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

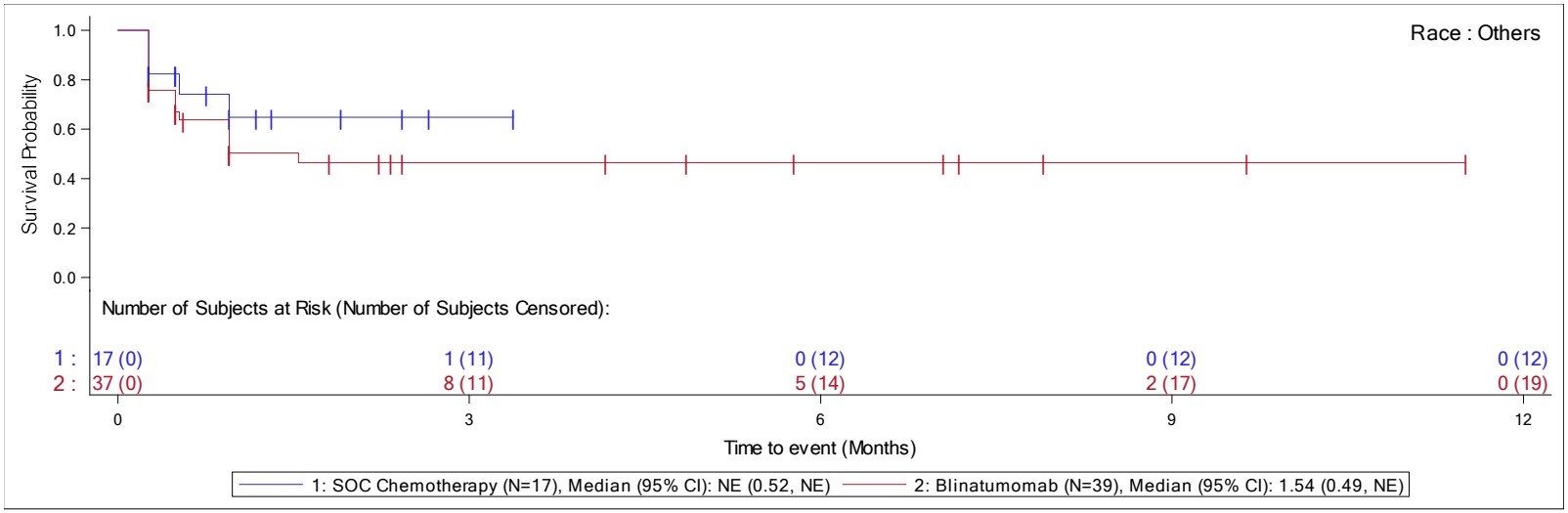
Figure 14-4.4.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-ghs-eqcas.sas
Output: f14-04-004-002-km-sub-de-eortc-ghs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

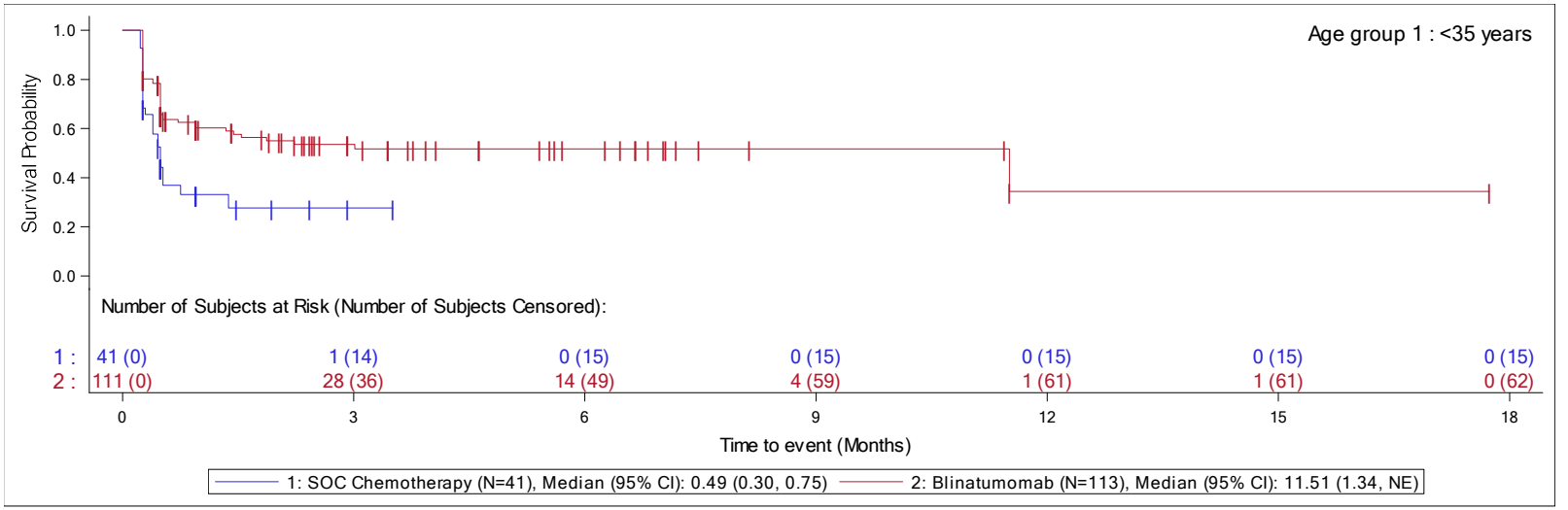
Figure 14-4.4.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-ghs-eqcas.sas
Output: f14-04-004-002-km-sub-de-eortc-ghs-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

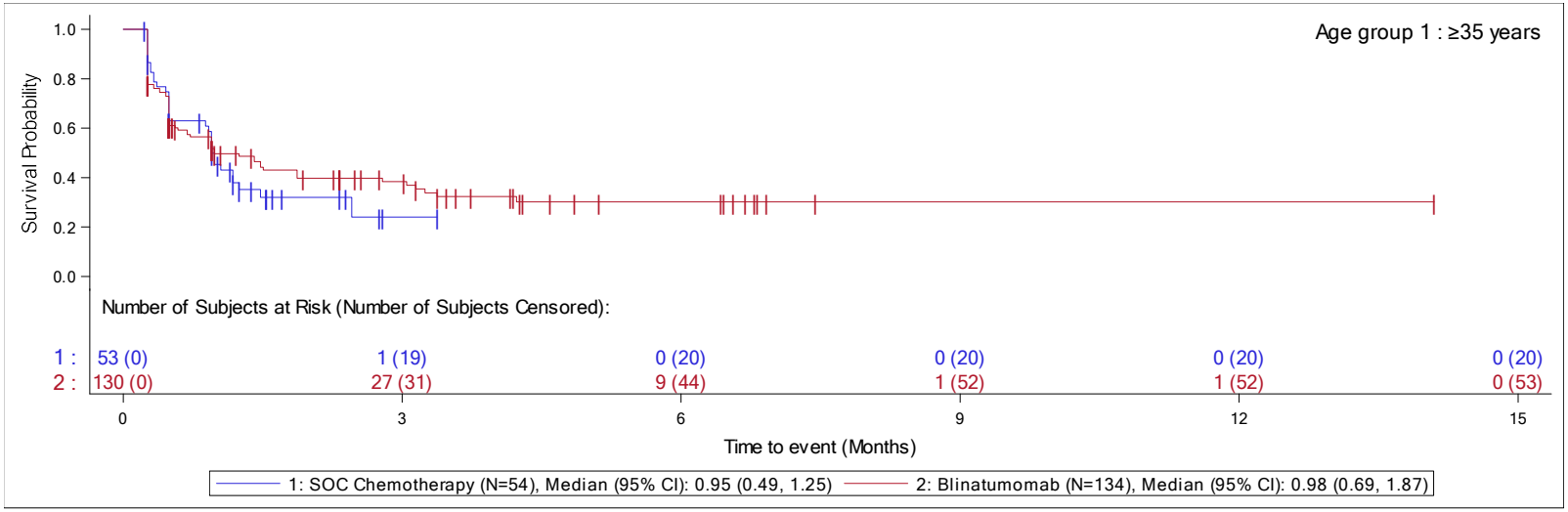
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

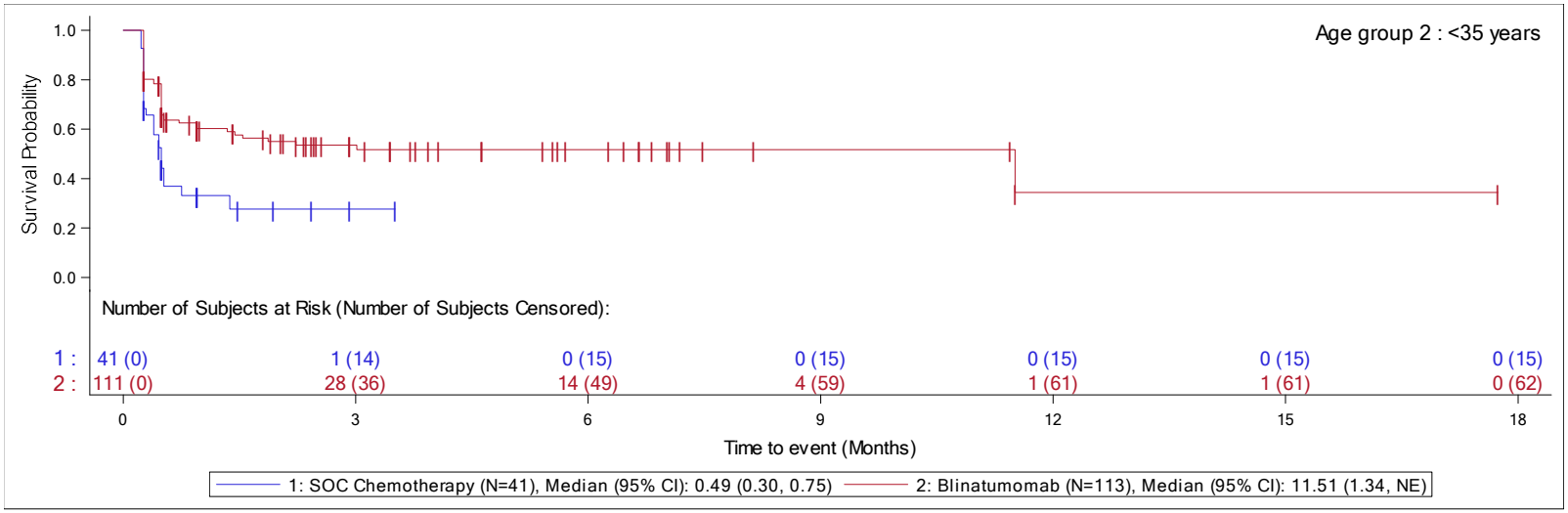
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

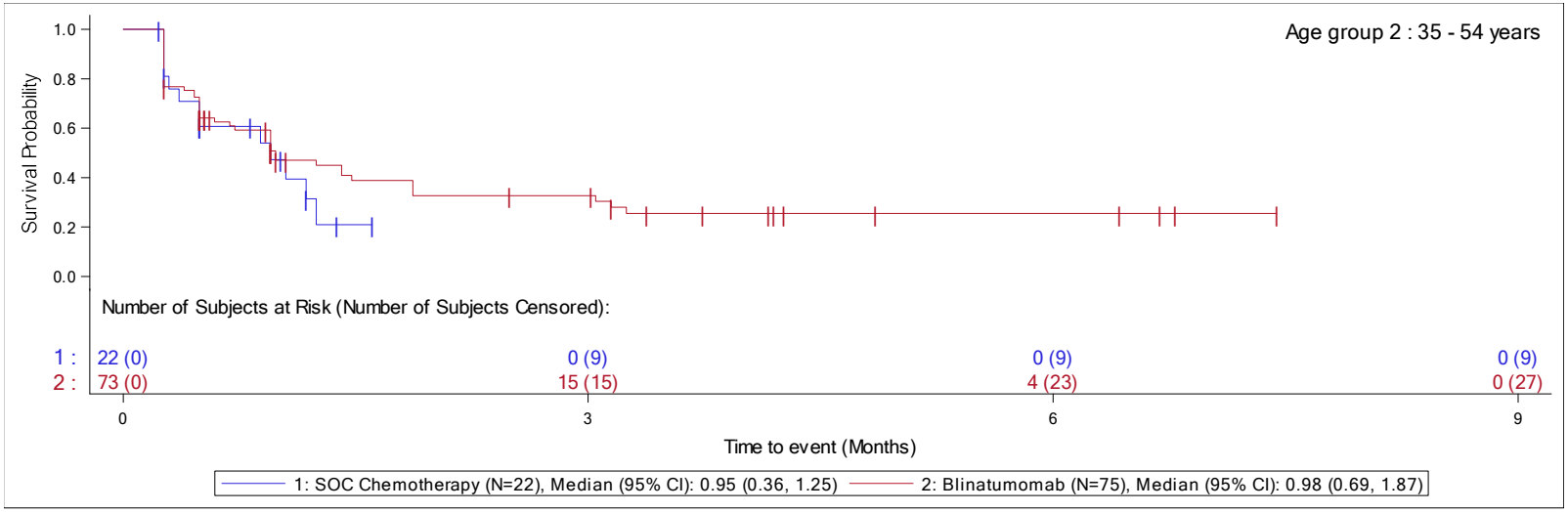
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

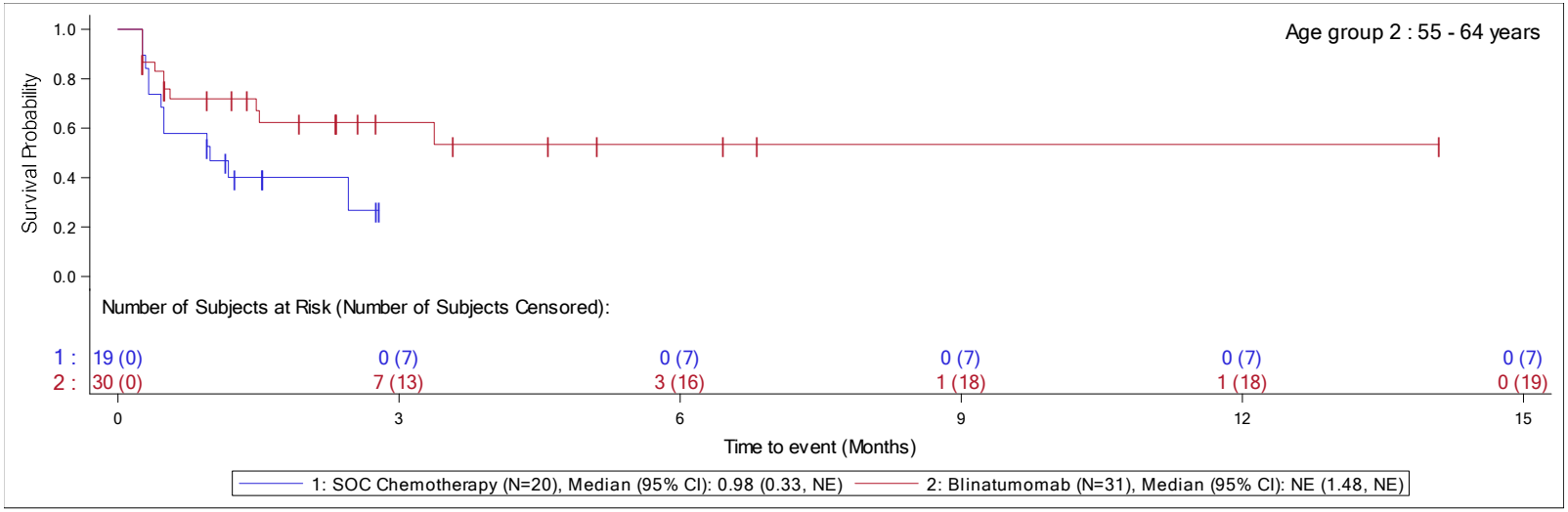
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

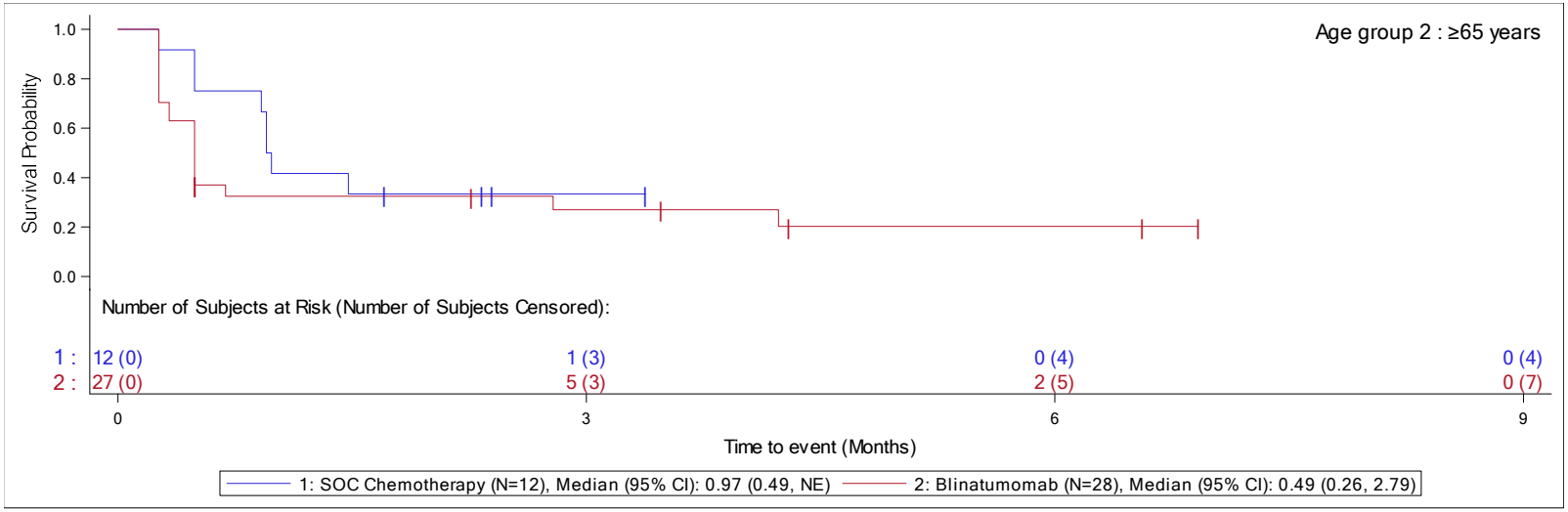
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

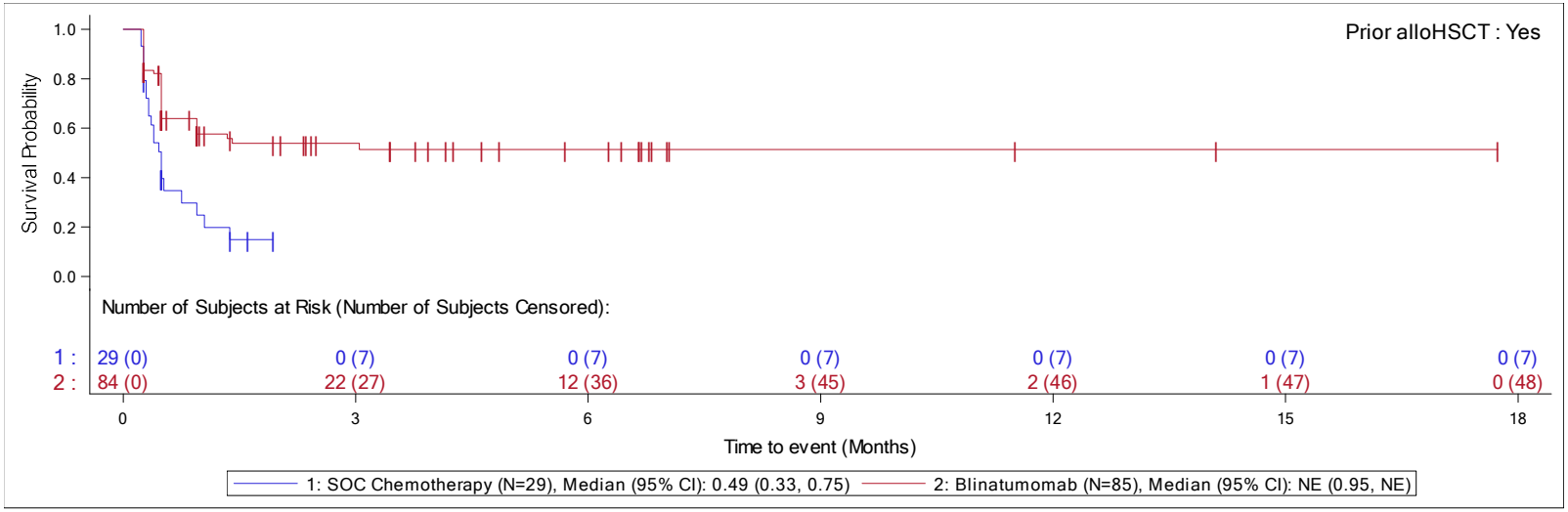
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

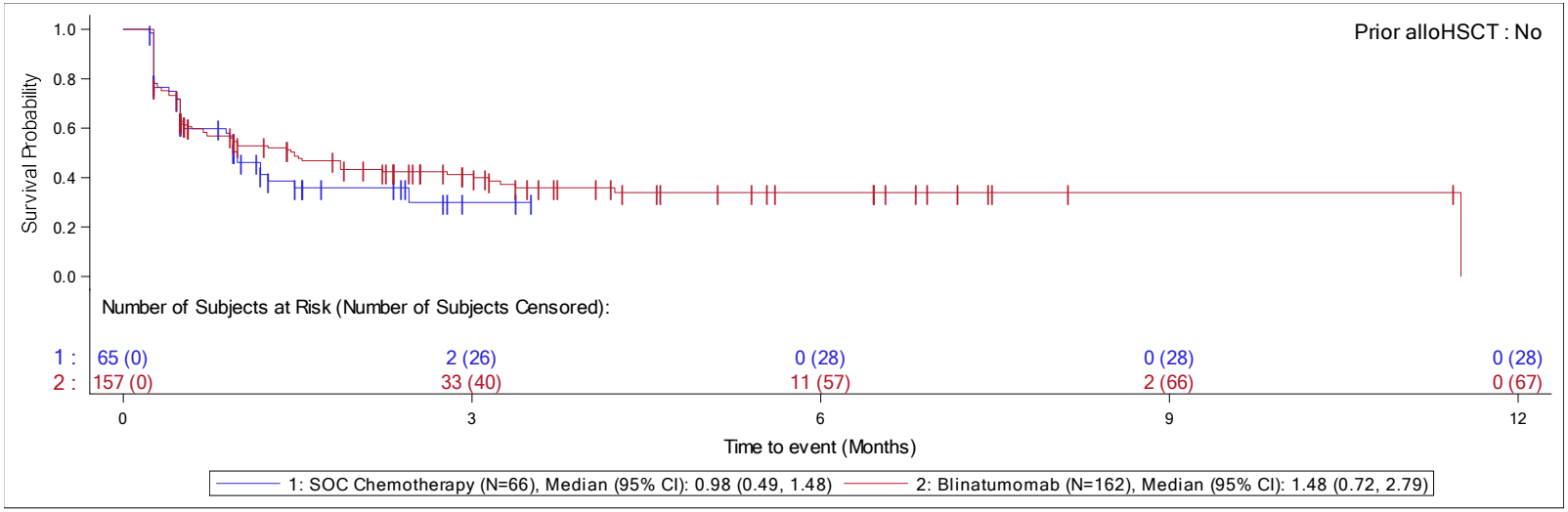
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

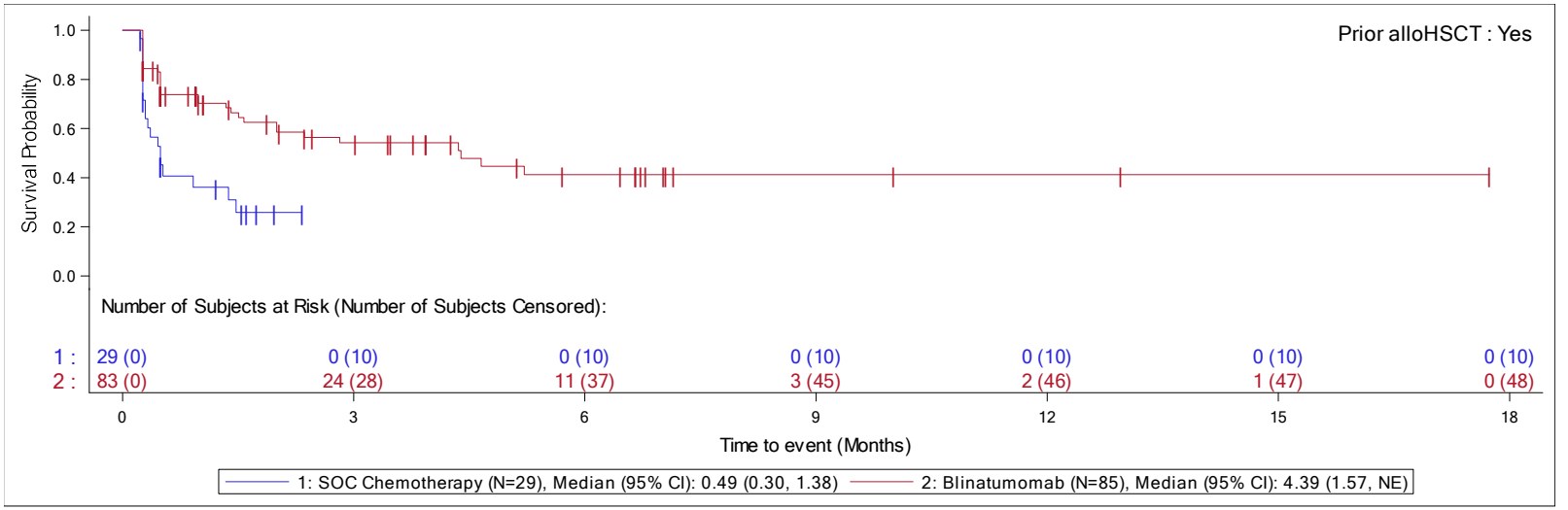
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

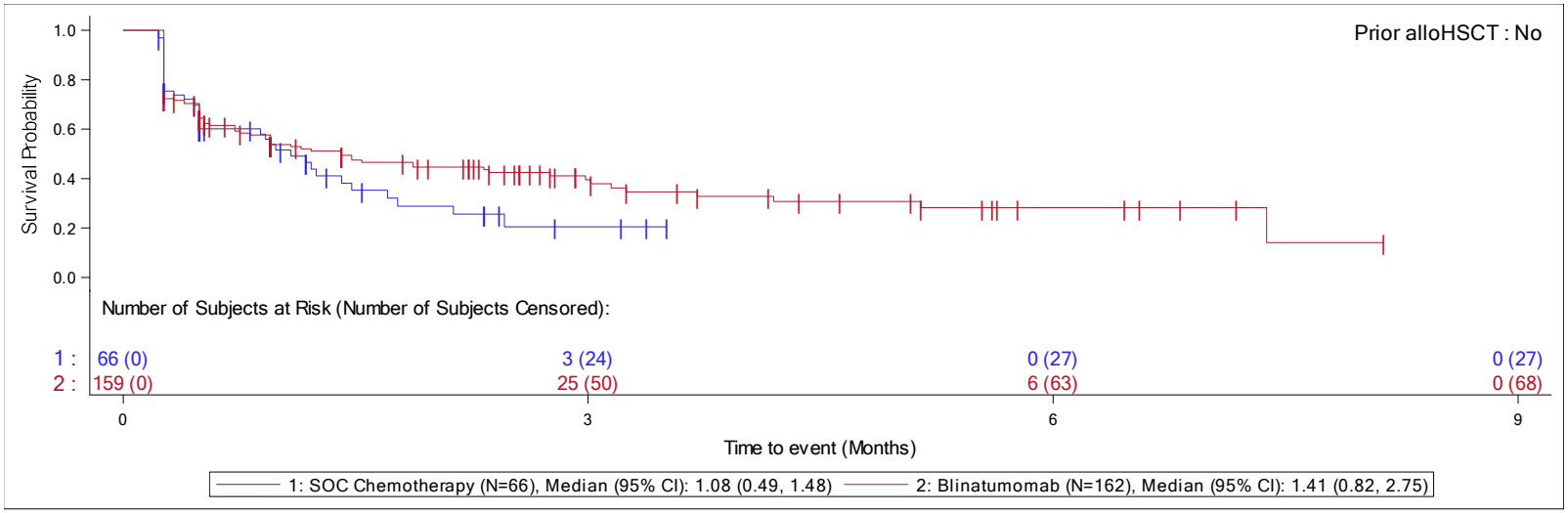
Figure 14-4.4.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-cf-eqcas.sas
Output: f14-04-004-005-km-sub-de-eortc-cf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

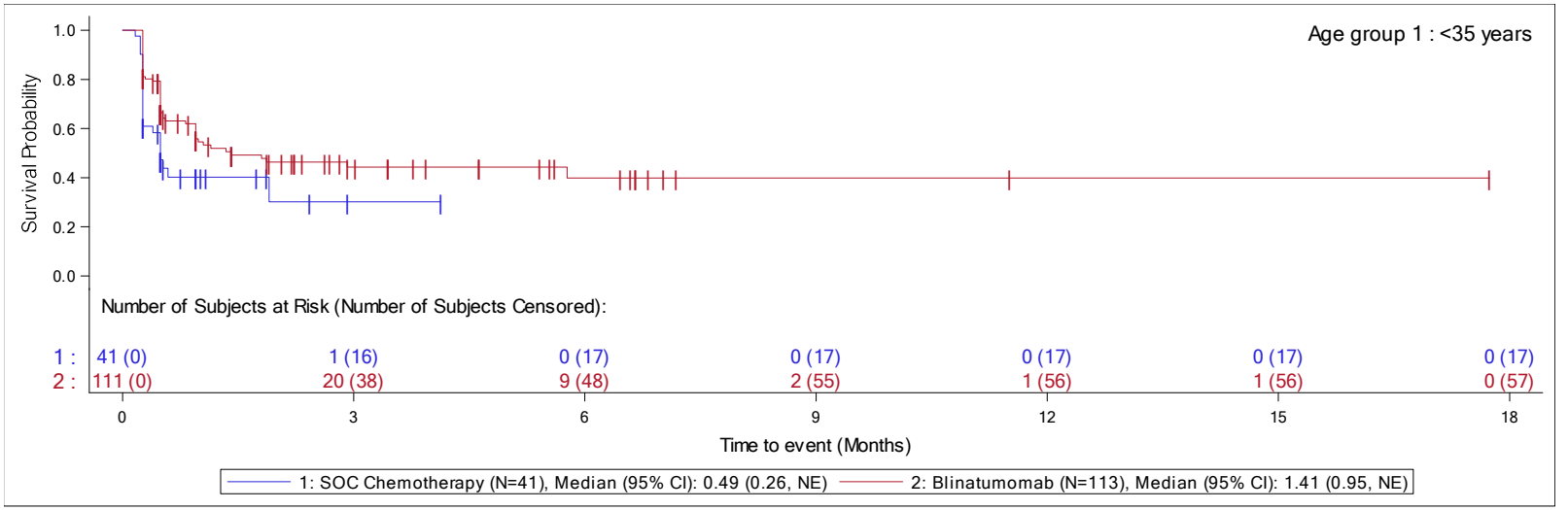
Figure 14-4.4.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-cf-eqcas.sas
Output: f14-04-004-005-km-sub-de-eortc-cf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

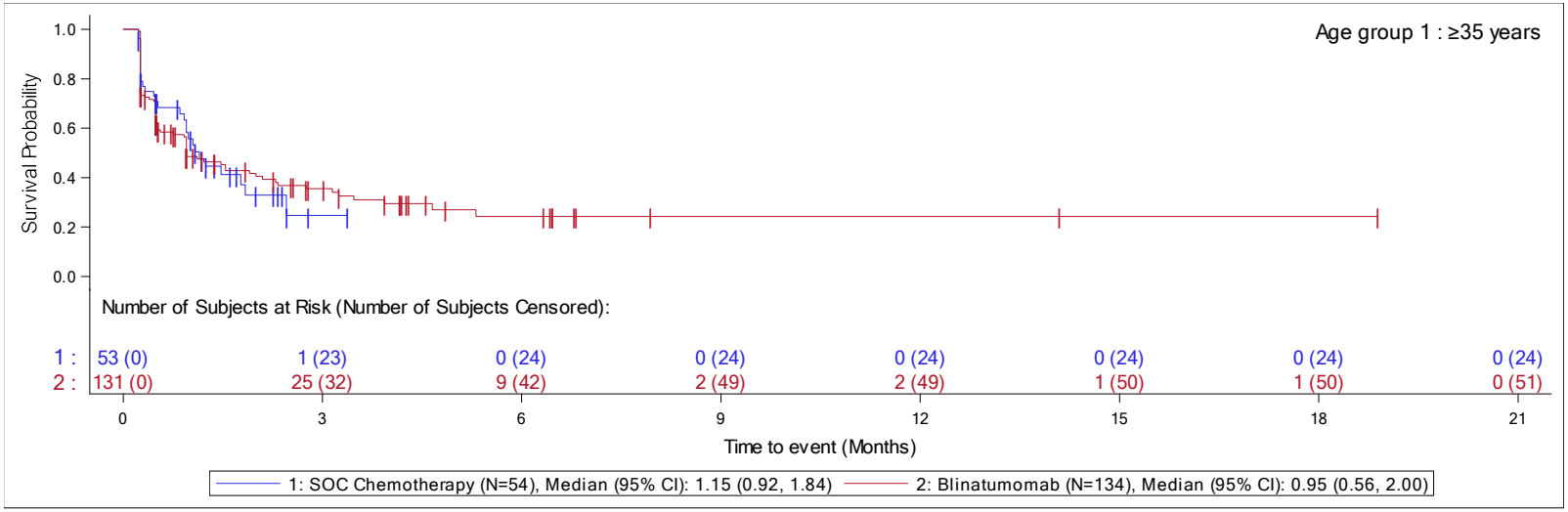
Figure 14-4.4.7. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sf-eqcas.sas
Output: f14-04-004-007-km-sub-de-eortc-sf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

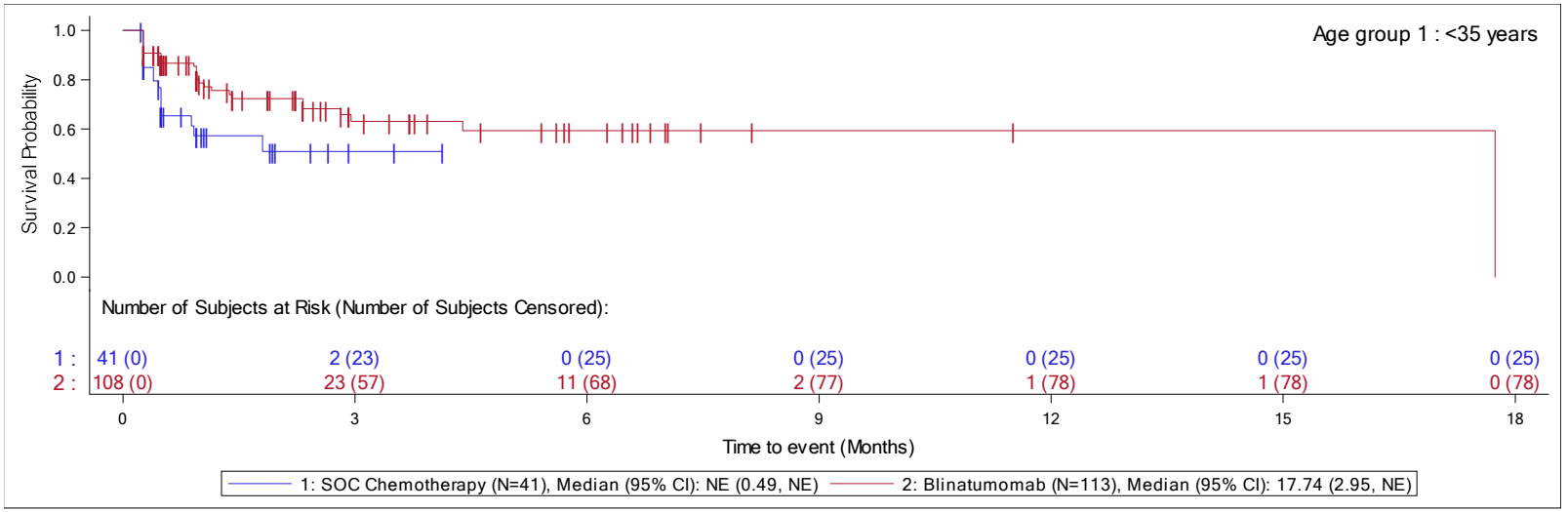
Figure 14-4.4.7. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-sf-eqcas.sas
Output: f14-04-004-007-km-sub-de-eortc-sf-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

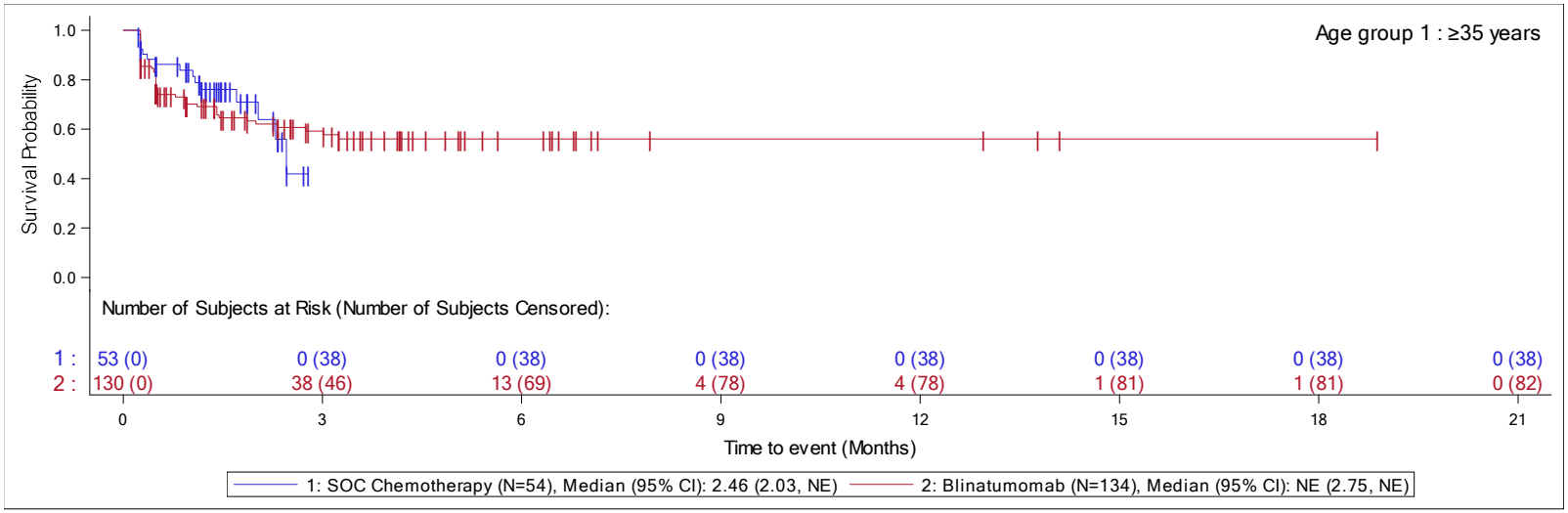
Figure 14-4.4.16. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fis-eqcas.sas
Output: f14-04-004-016-km-sub-de-eortc-fis-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Figure 14-4.4.16. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-de-eortc-fis-eqcas.sas
Output: f14-04-004-016-km-sub-de-eortc-fis-eqcas.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam_pa.adqs, adam_pa.adtteqs

Anhang 4-G3.7: Subgruppenanalysen zu Sicherheitsrelevanten Endpunkten

Anhang 4-G3.7.1: Subgruppenanalysen zu Gesamtraten UE

Table 14-6.2.1. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.5405
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	123/123 (100.0)	0.07 (NE, NE)	0.95 (0.68, 1.33)	0.7170	
≥35 years	59/59 (100.0)	0.07 (NE, NE)	140/144 (97.2)	0.07 (0.03, 0.07)	1.10 (0.81, 1.50)	0.7176	
Age group 2							0.9306
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	124/124 (100.0)	0.07 (NE, NE)	0.96 (0.69, 1.34)	0.7466	
35 - 54 years	25/25 (100.0)	0.07 (0.03, 0.10)	76/77 (98.7)	0.07 (0.03, 0.07)	1.13 (0.72, 1.79)	0.7694	
55 - 64 years	22/22 (100.0)	0.07 (0.03, 0.10)	32/33 (97.0)	0.03 (0.03, 0.07)	1.09 (0.63, 1.90)	0.8594	
≥65 years	12/12 (100.0)	0.05 (0.03, 0.20)	31/33 (93.9)	0.07 (0.03, 0.07)	0.96 (0.49, 1.88)	0.7941	
Sex							0.2834
Male	63/64 (98.4)	0.07 (0.03, 0.07)	156/159 (98.1)	0.07 (NE, NE)	0.93 (0.69, 1.25)	0.5348	
Female	45/45 (100.0)	0.07 (NE, NE)	107/108 (99.1)	0.07 (0.03, 0.07)	1.24 (0.87, 1.77)	0.2883	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-saf.sas
Output: t14-06-002-001-tte-sub-teae-saf.rtf (Date generated: 28MAY2025:04:47) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.1. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.4096
USA	12/13 (92.3)	0.07 (0.03, 0.16)	30/30 (100.0)	0.07 (0.03, 0.07)	1.54 (0.78, 3.03)	0.1887	
Europe	68/68 (100.0)	0.07 (0.03, 0.07)	174/177 (98.3)	0.07 (NE, NE)	0.95 (0.71, 1.26)	0.5281	
Rest of the world	28/28 (100.0)	0.07 (0.03, 0.07)	59/60 (98.3)	0.05 (0.03, 0.07)	1.09 (0.69, 1.72)	0.7975	
Prior salvage therapy							0.1520
Yes	62/63 (98.4)	0.07 (0.07, 0.10)	159/161 (98.8)	0.07 (NE, NE)	1.16 (0.86, 1.56)	0.4166	
No	46/46 (100.0)	0.07 (0.03, 0.07)	104/106 (98.1)	0.07 (NE, NE)	0.86 (0.61, 1.22)	0.3185	
Number of salvage therapies							0.1224
0	55/55 (100.0)	0.03 (0.03, 0.07)	110/112 (98.2)	0.07 (NE, NE)	0.82 (0.59, 1.14)	0.1678	
1	33/34 (97.1)	0.07 (0.07, 0.10)	89/91 (97.8)	0.07 (0.03, 0.07)	1.13 (0.76, 1.69)	0.5886	
≥2	20/20 (100.0)	0.10 (0.07, 0.16)	64/64 (100.0)	0.07 (0.03, 0.07)	1.47 (0.88, 2.47)	0.1655	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-saf.sas
Output: t14-06-002-001-tte-sub-teae-saf.rtf (Date generated: 28MAY2025:04:47) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.1. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.7714
Yes	35/35 (100.0)	0.07 (0.03, 0.07)	92/93 (98.9)	0.07 (0.03, 0.07)	0.95 (0.64, 1.42)	0.5578	
No	73/74 (98.6)	0.07 (NE, NE)	171/174 (98.3)	0.07 (NE, NE)	1.04 (0.79, 1.37)	0.8761	
Race							0.8995
Caucasian	90/90 (100.0)	0.07 (NE, NE)	222/226 (98.2)	0.07 (NE, NE)	1.02 (0.79, 1.30)	0.8392	
Others	18/19 (94.7)	0.07 (0.03, 0.07)	41/41 (100.0)	0.07 (0.03, 0.07)	1.04 (0.59, 1.81)	0.7449	
Central laboratory baseline bone marrow blasts							0.3123
<50%	27/27 (100.0)	0.07 (0.03, 0.07)	70/73 (95.9)	0.07 (0.03, 0.07)	0.96 (0.61, 1.50)	0.7252	
≥50%	76/77 (98.7)	0.07 (NE, NE)	168/168 (100.0)	0.07 (NE, NE)	1.18 (0.90, 1.55)	0.2759	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-saf.sas
Output: t14-06-002-001-tte-sub-teae-saf.rtf (Date generated: 28MAY2025:04:47) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6694
<35 years	20/50 (40.0)	2.82 (1.02, NE)	72/123 (58.5)	1.54 (1.02, 3.93)	1.18 (0.72, 1.95)	0.5103	
≥35 years	28/59 (47.5)	1.84 (0.69, NE)	93/144 (64.6)	1.57 (1.15, 2.46)	0.98 (0.63, 1.51)	0.9307	
Age group 2							0.4069
<35 years	20/50 (40.0)	2.82 (1.02, NE)	73/124 (58.9)	1.48 (1.02, 3.87)	1.20 (0.73, 1.98)	0.4729	
35 - 54 years	12/25 (48.0)	1.87 (0.39, NE)	41/77 (53.2)	1.87 (1.15, 5.41)	0.66 (0.34, 1.28)	0.2160	
55 - 64 years	10/22 (45.5)	1.57 (0.43, NE)	26/33 (78.8)	1.51 (0.95, 3.70)	1.03 (0.48, 2.23)	0.9365	
≥65 years	6/12 (50.0)	1.85 (0.20, NE)	25/33 (75.8)	0.49 (0.23, 2.36)	1.49 (0.60, 3.72)	0.4021	
Sex							0.4328
Male	27/64 (42.2)	2.82 (1.11, NE)	99/159 (62.3)	1.48 (1.08, 3.08)	1.17 (0.76, 1.80)	0.4802	
Female	21/45 (46.7)	1.28 (0.52, NE)	66/108 (61.1)	1.64 (1.15, 2.59)	0.93 (0.56, 1.55)	0.7975	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-saf.sas
Output: t14-06-002-002-tte-sub-ser-teae-saf.rtf (Date generated: 28MAY2025:04:53) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.2114
USA	4/13 (30.8)	1.84 (0.89, NE)	22/30 (73.3)	1.08 (0.46, 2.92)	2.36 (0.80, 6.91)	0.1102	
Europe	27/68 (39.7)	2.82 (1.57, NE)	97/177 (54.8)	2.52 (1.51, 4.59)	1.01 (0.65, 1.56)	0.9713	
Rest of the world	17/28 (60.7)	0.46 (0.33, NE)	46/60 (76.7)	0.92 (0.56, 1.31)	0.94 (0.53, 1.65)	0.8316	
Prior salvage therapy							0.1572
Yes	26/63 (41.3)	1.84 (1.02, NE)	104/161 (64.6)	1.28 (0.95, 1.64)	1.31 (0.85, 2.02)	0.2262	
No	22/46 (47.8)	1.87 (0.52, NE)	61/106 (57.5)	2.56 (1.44, 5.54)	0.78 (0.47, 1.29)	0.3337	
Number of salvage therapies							0.6701
0	24/55 (43.6)	2.82 (0.75, NE)	62/112 (55.4)	3.70 (1.48, 5.54)	0.91 (0.56, 1.48)	0.6961	
1	15/34 (44.1)	1.57 (0.62, NE)	60/91 (65.9)	1.15 (0.75, 1.64)	1.14 (0.64, 2.03)	0.6526	
≥2	9/20 (45.0)	1.84 (0.39, NE)	43/64 (67.2)	1.28 (0.95, 2.52)	1.15 (0.56, 2.39)	0.7038	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-saf.sas
Output: t14-06-002-002-tte-sub-ser-teae-saf.rtf (Date generated: 28MAY2025:04:53) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0069
Yes	22/35 (62.9)	0.92 (0.39, 2.82)	58/93 (62.4)	1.74 (1.18, 3.93)	0.57 (0.34, 0.95)	0.0289	
No	26/74 (35.1)	NE (1.84, NE)	107/174 (61.5)	1.48 (1.05, 2.46)	1.49 (0.97, 2.30)	0.0697	
Race							0.7096
Caucasian	39/90 (43.3)	1.87 (1.02, NE)	138/226 (61.1)	1.64 (1.34, 2.59)	1.05 (0.73, 1.50)	0.8016	
Others	9/19 (47.4)	1.84 (0.43, NE)	27/41 (65.9)	1.05 (0.72, 2.56)	1.28 (0.59, 2.74)	0.5329	
Central laboratory baseline bone marrow blasts							0.1773
<50%	14/27 (51.9)	1.87 (0.52, NE)	43/73 (58.9)	3.28 (1.44, 5.54)	0.63 (0.33, 1.19)	0.1515	
≥50%	32/77 (41.6)	2.82 (1.11, NE)	106/168 (63.1)	1.41 (1.05, 1.87)	1.25 (0.84, 1.87)	0.2677	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-saf.sas
Output: t14-06-002-002-tte-sub-ser-teae-saf.rtf (Date generated: 28MAY2025:04:53) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6369
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	102/123 (82.9)	0.36 (0.23, 0.59)	0.63 (0.44, 0.90)	0.0093	
≥35 years	55/59 (93.2)	0.23 (0.16, 0.26)	129/144 (89.6)	0.16 (0.10, 0.33)	0.73 (0.52, 1.01)	0.0425	
Age group 2							0.8384
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	103/124 (83.1)	0.34 (0.20, 0.59)	0.63 (0.44, 0.90)	0.0106	
35 - 54 years	24/25 (96.0)	0.23 (0.13, 0.26)	69/77 (89.6)	0.26 (0.10, 0.43)	0.62 (0.38, 1.01)	0.0444	
55 - 64 years	21/22 (95.5)	0.21 (0.10, 0.26)	29/33 (87.9)	0.10 (0.07, 0.46)	0.69 (0.38, 1.26)	0.1814	
≥65 years	10/12 (83.3)	0.23 (0.03, 0.56)	30/33 (90.9)	0.13 (0.07, 0.33)	0.97 (0.47, 2.02)	0.9315	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 28MAY2025:05:02) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8242
Male	56/64 (87.5)	0.21 (0.13, 0.30)	135/159 (84.9)	0.33 (0.23, 0.46)	0.68 (0.50, 0.94)	0.0162	
Female	44/45 (97.8)	0.23 (0.16, 0.26)	96/108 (88.9)	0.13 (0.10, 0.30)	0.69 (0.47, 1.00)	0.0332	
Region							0.0953
USA	10/13 (76.9)	0.26 (0.07, 0.89)	28/30 (93.3)	0.13 (0.07, 0.33)	1.42 (0.69, 2.94)	0.3534	
Europe	63/68 (92.6)	0.23 (0.16, 0.26)	147/177 (83.1)	0.30 (0.16, 0.39)	0.64 (0.48, 0.87)	0.0031	
Rest of the world	27/28 (96.4)	0.16 (0.07, 0.26)	56/60 (93.3)	0.38 (0.13, 0.56)	0.55 (0.34, 0.89)	0.0130	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 28MAY2025:05:02) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4525
Yes	58/63 (92.1)	0.23 (0.16, 0.26)	143/161 (88.8)	0.30 (0.16, 0.39)	0.70 (0.51, 0.96)	0.0206	
No	42/46 (91.3)	0.23 (0.10, 0.26)	88/106 (83.0)	0.26 (0.13, 0.43)	0.65 (0.45, 0.95)	0.0238	
Number of salvage therapies							0.7264
0	50/55 (90.9)	0.23 (0.13, 0.26)	92/112 (82.1)	0.26 (0.13, 0.39)	0.68 (0.48, 0.97)	0.0307	
1	31/34 (91.2)	0.20 (0.10, 0.26)	81/91 (89.0)	0.33 (0.16, 0.46)	0.60 (0.39, 0.93)	0.0184	
≥2	19/20 (95.0)	0.25 (0.10, 0.43)	58/64 (90.6)	0.23 (0.07, 0.36)	0.75 (0.44, 1.29)	0.2124	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 28MAY2025:05:02) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6161
Yes	35/35 (100.0)	0.23 (0.16, 0.26)	81/93 (87.1)	0.20 (0.13, 0.36)	0.60 (0.40, 0.92)	0.0113	
No	65/74 (87.8)	0.21 (0.13, 0.26)	150/174 (86.2)	0.33 (0.16, 0.43)	0.71 (0.53, 0.96)	0.0227	
Race							0.3117
Caucasian	83/90 (92.2)	0.21 (0.16, 0.26)	194/226 (85.8)	0.26 (0.16, 0.36)	0.66 (0.51, 0.86)	0.0014	
Others	17/19 (89.5)	0.26 (0.10, 0.43)	37/41 (90.2)	0.39 (0.10, 0.59)	0.80 (0.44, 1.43)	0.4404	
Central laboratory baseline bone marrow blasts							0.0534
<50%	24/27 (88.9)	0.23 (0.10, 0.26)	58/73 (79.5)	0.66 (0.33, 1.44)	0.46 (0.28, 0.76)	0.0018	
≥50%	71/77 (92.2)	0.20 (0.16, 0.26)	151/168 (89.9)	0.18 (0.10, 0.33)	0.81 (0.61, 1.08)	0.1257	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 28MAY2025:05:02) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.2488
<35 years	1/50 (2.0)	NE (NE, NE)	10/123 (8.1)	NE (NE, NE)	3.28 (0.42, 25.80)	0.2315	
≥35 years	8/59 (13.6)	NE (NE, NE)	23/144 (16.0)	NE (13.15, NE)	0.89 (0.39, 2.03)	0.7870	
Age group 2							0.6789
<35 years	1/50 (2.0)	NE (NE, NE)	11/124 (8.9)	NE (NE, NE)	3.67 (0.47, 28.62)	0.1833	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	10/77 (13.0)	NE (NE, NE)	1.01 (0.22, 4.75)	0.9850	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	7/33 (21.2)	13.15 (3.70, NE)	0.74 (0.20, 2.77)	0.6571	
≥65 years	2/12 (16.7)	NE (0.75, NE)	5/33 (15.2)	NE (NE, NE)	0.96 (0.19, 4.95)	0.9585	
Sex							0.8718
Male	6/64 (9.4)	NE (NE, NE)	23/159 (14.5)	NE (NE, NE)	1.15 (0.46, 2.85)	0.7647	
Female	3/45 (6.7)	NE (NE, NE)	10/108 (9.3)	NE (13.15, NE)	1.17 (0.31, 4.32)	0.8186	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-trt-disc-saf.sas
Output: t14-06-002-004-tte-sub-teae-trt-disc-saf.rtf (Date generated: 28MAY2025:05:10) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.8162
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (3.02, NE)	NE (NE, NE)	0.0986	
Europe	6/68 (8.8)	NE (NE, NE)	20/177 (11.3)	NE (13.15, NE)	0.96 (0.38, 2.43)	0.9288	
Rest of the world	3/28 (10.7)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.77 (0.19, 3.09)	0.7087	
Prior salvage therapy							0.9870
Yes	9/63 (14.3)	NE (NE, NE)	25/161 (15.5)	13.15 (13.15, NE)	0.81 (0.38, 1.76)	0.6014	
No	0/46 (0.0)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	NE (NE, NE)	0.0978	
Number of salvage therapies							0.4782
0	2/55 (3.6)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)	1.76 (0.37, 8.27)	0.4677	
1	6/34 (17.6)	NE (NE, NE)	16/91 (17.6)	13.15 (13.15, NE)	0.73 (0.28, 1.88)	0.5066	
≥2	1/20 (5.0)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)	2.02 (0.25, 16.42)	0.4994	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-trt-disc-saf.sas
Output: t14-06-002-004-tte-sub-teae-trt-disc-saf.rtf (Date generated: 28MAY2025:05:10) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.3257
Yes	4/35 (11.4)	NE (NE, NE)	11/93 (11.8)	NE (13.15, NE)	0.61 (0.18, 2.01)	0.4064	
No	5/74 (6.8)	NE (NE, NE)	22/174 (12.6)	NE (NE, NE)	1.64 (0.62, 4.34)	0.3188	
Race							0.6038
Caucasian	7/90 (7.8)	NE (NE, NE)	28/226 (12.4)	NE (13.15, NE)	1.27 (0.55, 2.94)	0.5749	
Others	2/19 (10.5)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	0.80 (0.15, 4.29)	0.7990	
Central laboratory baseline bone marrow blasts							0.0206
<50%	5/27 (18.5)	NE (NE, NE)	7/73 (9.6)	13.15 (13.15, NE)	0.35 (0.10, 1.18)	0.0764	
≥50%	3/77 (3.9)	NE (NE, NE)	20/168 (11.9)	NE (NE, NE)	2.43 (0.72, 8.25)	0.1420	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-trt-disc-saf.sas
Output: t14-06-002-004-tte-sub-teae-trt-disc-saf.rtf (Date generated: 28MAY2025:05:10) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.5405
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	123/123 (100.0)	0.07 (NE, NE)	0.95 (0.68, 1.33)	0.7170	
≥35 years	59/59 (100.0)	0.07 (NE, NE)	140/144 (97.2)	0.07 (0.03, 0.07)	1.10 (0.81, 1.50)	0.7176	
Age group 2							0.9306
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	124/124 (100.0)	0.07 (NE, NE)	0.96 (0.69, 1.34)	0.7466	
35 - 54 years	25/25 (100.0)	0.07 (0.03, 0.10)	76/77 (98.7)	0.07 (0.03, 0.07)	1.13 (0.72, 1.79)	0.7694	
55 - 64 years	22/22 (100.0)	0.07 (0.03, 0.10)	32/33 (97.0)	0.03 (0.03, 0.07)	1.09 (0.63, 1.90)	0.8594	
≥65 years	12/12 (100.0)	0.05 (0.03, 0.20)	31/33 (93.9)	0.07 (0.03, 0.07)	0.96 (0.49, 1.88)	0.7941	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 28MAY2025:04:52) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2834
Male	63/64 (98.4)	0.07 (0.03, 0.07)	156/159 (98.1)	0.07 (NE, NE)	0.93 (0.69, 1.25)	0.5348	
Female	45/45 (100.0)	0.07 (NE, NE)	107/108 (99.1)	0.07 (0.03, 0.07)	1.24 (0.87, 1.77)	0.2883	
Region							0.4096
USA	12/13 (92.3)	0.07 (0.03, 0.16)	30/30 (100.0)	0.07 (0.03, 0.07)	1.54 (0.78, 3.03)	0.1887	
Europe	68/68 (100.0)	0.07 (0.03, 0.07)	174/177 (98.3)	0.07 (NE, NE)	0.95 (0.71, 1.26)	0.5281	
Rest of the world	28/28 (100.0)	0.07 (0.03, 0.07)	59/60 (98.3)	0.05 (0.03, 0.07)	1.09 (0.69, 1.72)	0.7975	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 28MAY2025:04:52) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1520
Yes	62/63 (98.4)	0.07 (0.07, 0.10)	159/161 (98.8)	0.07 (NE, NE)	1.16 (0.86, 1.56)	0.4166	
No	46/46 (100.0)	0.07 (0.03, 0.07)	104/106 (98.1)	0.07 (NE, NE)	0.86 (0.61, 1.22)	0.3185	
Number of salvage therapies							0.1224
0	55/55 (100.0)	0.03 (0.03, 0.07)	110/112 (98.2)	0.07 (NE, NE)	0.82 (0.59, 1.14)	0.1678	
1	33/34 (97.1)	0.07 (0.07, 0.10)	89/91 (97.8)	0.07 (0.03, 0.07)	1.13 (0.76, 1.69)	0.5886	
≥2	20/20 (100.0)	0.10 (0.07, 0.16)	64/64 (100.0)	0.07 (0.03, 0.07)	1.47 (0.88, 2.47)	0.1655	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 28MAY2025:04:52) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.7714
Yes	35/35 (100.0)	0.07 (0.03, 0.07)	92/93 (98.9)	0.07 (0.03, 0.07)	0.95 (0.64, 1.42)	0.5578	
No	73/74 (98.6)	0.07 (NE, NE)	171/174 (98.3)	0.07 (NE, NE)	1.04 (0.79, 1.37)	0.8761	
Race							0.8995
Caucasian	90/90 (100.0)	0.07 (NE, NE)	222/226 (98.2)	0.07 (NE, NE)	1.02 (0.79, 1.30)	0.8392	
Others	18/19 (94.7)	0.07 (0.03, 0.07)	41/41 (100.0)	0.07 (0.03, 0.07)	1.04 (0.59, 1.81)	0.7449	
Central laboratory baseline bone marrow blasts							0.3123
<50%	27/27 (100.0)	0.07 (0.03, 0.07)	70/73 (95.9)	0.07 (0.03, 0.07)	0.96 (0.61, 1.50)	0.7252	
≥50%	76/77 (98.7)	0.07 (NE, NE)	168/168 (100.0)	0.07 (NE, NE)	1.18 (0.90, 1.55)	0.2759	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 28MAY2025:04:52) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6466
<35 years	20/50 (40.0)	2.82 (1.02, NE)	72/123 (58.5)	1.54 (1.02, 3.93)	1.18 (0.72, 1.95)	0.5103	
≥35 years	28/59 (47.5)	1.84 (0.69, NE)	92/144 (63.9)	1.57 (1.18, 2.56)	0.97 (0.62, 1.49)	0.8820	
Age group 2							0.3780
<35 years	20/50 (40.0)	2.82 (1.02, NE)	73/124 (58.9)	1.48 (1.02, 3.87)	1.20 (0.73, 1.98)	0.4729	
35 - 54 years	12/25 (48.0)	1.87 (0.39, NE)	40/77 (51.9)	2.56 (1.38, 5.41)	0.64 (0.33, 1.24)	0.1891	
55 - 64 years	10/22 (45.5)	1.57 (0.43, NE)	26/33 (78.8)	1.51 (0.95, 3.70)	1.03 (0.48, 2.23)	0.9365	
≥65 years	6/12 (50.0)	1.85 (0.20, NE)	25/33 (75.8)	0.49 (0.23, 2.36)	1.49 (0.60, 3.72)	0.4021	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 28MAY2025:04:59) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4054
Male	27/64 (42.2)	2.82 (1.11, NE)	99/159 (62.3)	1.48 (1.08, 3.08)	1.17 (0.76, 1.80)	0.4802	
Female	21/45 (46.7)	1.28 (0.52, NE)	65/108 (60.2)	1.70 (1.18, 2.92)	0.92 (0.55, 1.52)	0.7390	
Region							0.2100
USA	4/13 (30.8)	1.84 (0.89, NE)	22/30 (73.3)	1.08 (0.46, 2.92)	2.36 (0.80, 6.91)	0.1102	
Europe	27/68 (39.7)	2.82 (1.57, NE)	96/177 (54.2)	2.59 (1.51, 4.59)	0.99 (0.64, 1.54)	0.9800	
Rest of the world	17/28 (60.7)	0.46 (0.33, NE)	46/60 (76.7)	0.92 (0.56, 1.31)	0.94 (0.53, 1.65)	0.8316	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 28MAY2025:04:59) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1658
Yes	26/63 (41.3)	1.84 (1.02, NE)	103/161 (64.0)	1.31 (0.98, 1.64)	1.29 (0.84, 2.00)	0.2475	
No	22/46 (47.8)	1.87 (0.52, NE)	61/106 (57.5)	2.56 (1.44, 5.54)	0.78 (0.47, 1.29)	0.3337	
Number of salvage therapies							0.6881
0	24/55 (43.6)	2.82 (0.75, NE)	62/112 (55.4)	3.70 (1.48, 5.54)	0.91 (0.56, 1.48)	0.6961	
1	15/34 (44.1)	1.57 (0.62, NE)	60/91 (65.9)	1.15 (0.75, 1.64)	1.14 (0.64, 2.03)	0.6526	
≥2	9/20 (45.0)	1.84 (0.39, NE)	42/64 (65.6)	1.28 (0.98, 2.52)	1.12 (0.54, 2.32)	0.7673	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 28MAY2025:04:59) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0059
Yes	22/35 (62.9)	0.92 (0.39, 2.82)	57/93 (61.3)	1.74 (1.18, 4.59)	0.56 (0.33, 0.93)	0.0233	
No	26/74 (35.1)	NE (1.84, NE)	107/174 (61.5)	1.48 (1.05, 2.46)	1.49 (0.97, 2.30)	0.0697	
Race							0.6957
Caucasian	39/90 (43.3)	1.87 (1.02, NE)	137/226 (60.6)	1.70 (1.38, 2.92)	1.04 (0.72, 1.49)	0.8405	
Others	9/19 (47.4)	1.84 (0.43, NE)	27/41 (65.9)	1.05 (0.72, 2.56)	1.28 (0.59, 2.74)	0.5329	
Central laboratory baseline bone marrow blasts							0.1855
<50%	14/27 (51.9)	1.87 (0.52, NE)	43/73 (58.9)	3.28 (1.44, 5.54)	0.63 (0.33, 1.19)	0.1515	
≥50%	32/77 (41.6)	2.82 (1.11, NE)	105/168 (62.5)	1.41 (1.05, 1.87)	1.24 (0.83, 1.85)	0.2929	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 28MAY2025:04:59) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6369
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	102/123 (82.9)	0.36 (0.23, 0.59)	0.63 (0.44, 0.90)	0.0093	
≥35 years	55/59 (93.2)	0.23 (0.16, 0.26)	129/144 (89.6)	0.16 (0.10, 0.33)	0.73 (0.52, 1.01)	0.0425	
Age group 2							0.8384
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	103/124 (83.1)	0.34 (0.20, 0.59)	0.63 (0.44, 0.90)	0.0106	
35 - 54 years	24/25 (96.0)	0.23 (0.13, 0.26)	69/77 (89.6)	0.26 (0.10, 0.43)	0.62 (0.38, 1.01)	0.0444	
55 - 64 years	21/22 (95.5)	0.21 (0.10, 0.26)	29/33 (87.9)	0.10 (0.07, 0.46)	0.69 (0.38, 1.26)	0.1814	
≥65 years	10/12 (83.3)	0.23 (0.03, 0.56)	30/33 (90.9)	0.13 (0.07, 0.33)	0.97 (0.47, 2.02)	0.9315	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 28MAY2025:06:08) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8242
Male	56/64 (87.5)	0.21 (0.13, 0.30)	135/159 (84.9)	0.33 (0.23, 0.46)	0.68 (0.50, 0.94)	0.0162	
Female	44/45 (97.8)	0.23 (0.16, 0.26)	96/108 (88.9)	0.13 (0.10, 0.30)	0.69 (0.47, 1.00)	0.0332	
Region							0.0953
USA	10/13 (76.9)	0.26 (0.07, 0.89)	28/30 (93.3)	0.13 (0.07, 0.33)	1.42 (0.69, 2.94)	0.3534	
Europe	63/68 (92.6)	0.23 (0.16, 0.26)	147/177 (83.1)	0.30 (0.16, 0.39)	0.64 (0.48, 0.87)	0.0031	
Rest of the world	27/28 (96.4)	0.16 (0.07, 0.26)	56/60 (93.3)	0.38 (0.13, 0.56)	0.55 (0.34, 0.89)	0.0130	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 28MAY2025:06:08) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4525
Yes	58/63 (92.1)	0.23 (0.16, 0.26)	143/161 (88.8)	0.30 (0.16, 0.39)	0.70 (0.51, 0.96)	0.0206	
No	42/46 (91.3)	0.23 (0.10, 0.26)	88/106 (83.0)	0.26 (0.13, 0.43)	0.65 (0.45, 0.95)	0.0238	
Number of salvage therapies							0.7264
0	50/55 (90.9)	0.23 (0.13, 0.26)	92/112 (82.1)	0.26 (0.13, 0.39)	0.68 (0.48, 0.97)	0.0307	
1	31/34 (91.2)	0.20 (0.10, 0.26)	81/91 (89.0)	0.33 (0.16, 0.46)	0.60 (0.39, 0.93)	0.0184	
≥2	19/20 (95.0)	0.25 (0.10, 0.43)	58/64 (90.6)	0.23 (0.07, 0.36)	0.75 (0.44, 1.29)	0.2124	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 28MAY2025:06:08) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6161
Yes	35/35 (100.0)	0.23 (0.16, 0.26)	81/93 (87.1)	0.20 (0.13, 0.36)	0.60 (0.40, 0.92)	0.0113	
No	65/74 (87.8)	0.21 (0.13, 0.26)	150/174 (86.2)	0.33 (0.16, 0.43)	0.71 (0.53, 0.96)	0.0227	
Race							0.3117
Caucasian	83/90 (92.2)	0.21 (0.16, 0.26)	194/226 (85.8)	0.26 (0.16, 0.36)	0.66 (0.51, 0.86)	0.0014	
Others	17/19 (89.5)	0.26 (0.10, 0.43)	37/41 (90.2)	0.39 (0.10, 0.59)	0.80 (0.44, 1.43)	0.4404	
Central laboratory baseline bone marrow blasts							0.0534
<50%	24/27 (88.9)	0.23 (0.10, 0.26)	58/73 (79.5)	0.66 (0.33, 1.44)	0.46 (0.28, 0.76)	0.0018	
≥50%	71/77 (92.2)	0.20 (0.16, 0.26)	151/168 (89.9)	0.18 (0.10, 0.33)	0.81 (0.61, 1.08)	0.1257	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 28MAY2025:06:08) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.14. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.2932
<35 years	1/50 (2.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	2.87 (0.36, 22.85)	0.2969	
≥35 years	8/59 (13.6)	NE (NE, NE)	23/144 (16.0)	NE (13.15, NE)	0.89 (0.39, 2.03)	0.7870	
Age group 2							0.7292
<35 years	1/50 (2.0)	NE (NE, NE)	10/124 (8.1)	NE (NE, NE)	3.26 (0.41, 25.62)	0.2345	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	10/77 (13.0)	NE (NE, NE)	1.01 (0.22, 4.75)	0.9850	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	7/33 (21.2)	13.15 (3.70, NE)	0.74 (0.20, 2.77)	0.6571	
≥65 years	2/12 (16.7)	NE (0.75, NE)	5/33 (15.2)	NE (NE, NE)	0.96 (0.19, 4.95)	0.9585	
Sex							0.7634
Male	6/64 (9.4)	NE (NE, NE)	23/159 (14.5)	NE (NE, NE)	1.15 (0.46, 2.85)	0.7647	
Female	3/45 (6.7)	NE (NE, NE)	9/108 (8.3)	NE (13.15, NE)	1.02 (0.27, 3.88)	0.9723	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-trt-disc-edp-saf.sas
Output: t14-06-002-014-tte-sub-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:02:33) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.14. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.8480
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (3.02, NE)	NE (NE, NE)	0.0986	
Europe	6/68 (8.8)	NE (NE, NE)	19/177 (10.7)	NE (13.15, NE)	0.89 (0.35, 2.28)	0.8136	
Rest of the world	3/28 (10.7)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.77 (0.19, 3.09)	0.7087	
Prior salvage therapy							0.9871
Yes	9/63 (14.3)	NE (NE, NE)	24/161 (14.9)	13.15 (13.15, NE)	0.77 (0.35, 1.68)	0.5146	
No	0/46 (0.0)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	NE (NE, NE)	0.0978	
Number of salvage therapies							0.4283
0	2/55 (3.6)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)	1.76 (0.37, 8.27)	0.4677	
1	6/34 (17.6)	NE (NE, NE)	15/91 (16.5)	13.15 (13.15, NE)	0.67 (0.25, 1.75)	0.4057	
≥2	1/20 (5.0)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)	2.02 (0.25, 16.42)	0.4994	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-trt-disc-edp-saf.sas
Output: t14-06-002-014-tte-sub-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:02:33) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.14. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.3590
Yes	4/35 (11.4)	NE (NE, NE)	11/93 (11.8)	NE (13.15, NE)	0.61 (0.18, 2.01)	0.4064	
No	5/74 (6.8)	NE (NE, NE)	21/174 (12.1)	NE (NE, NE)	1.55 (0.58, 4.12)	0.3807	
Race							0.6345
Caucasian	7/90 (7.8)	NE (NE, NE)	27/226 (11.9)	NE (13.15, NE)	1.21 (0.52, 2.82)	0.6547	
Others	2/19 (10.5)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	0.80 (0.15, 4.29)	0.7990	
Central laboratory baseline bone marrow blasts							0.0246
<50%	5/27 (18.5)	NE (NE, NE)	7/73 (9.6)	13.15 (13.15, NE)	0.35 (0.10, 1.18)	0.0764	
≥50%	3/77 (3.9)	NE (NE, NE)	19/168 (11.3)	NE (NE, NE)	2.27 (0.66, 7.75)	0.1793	

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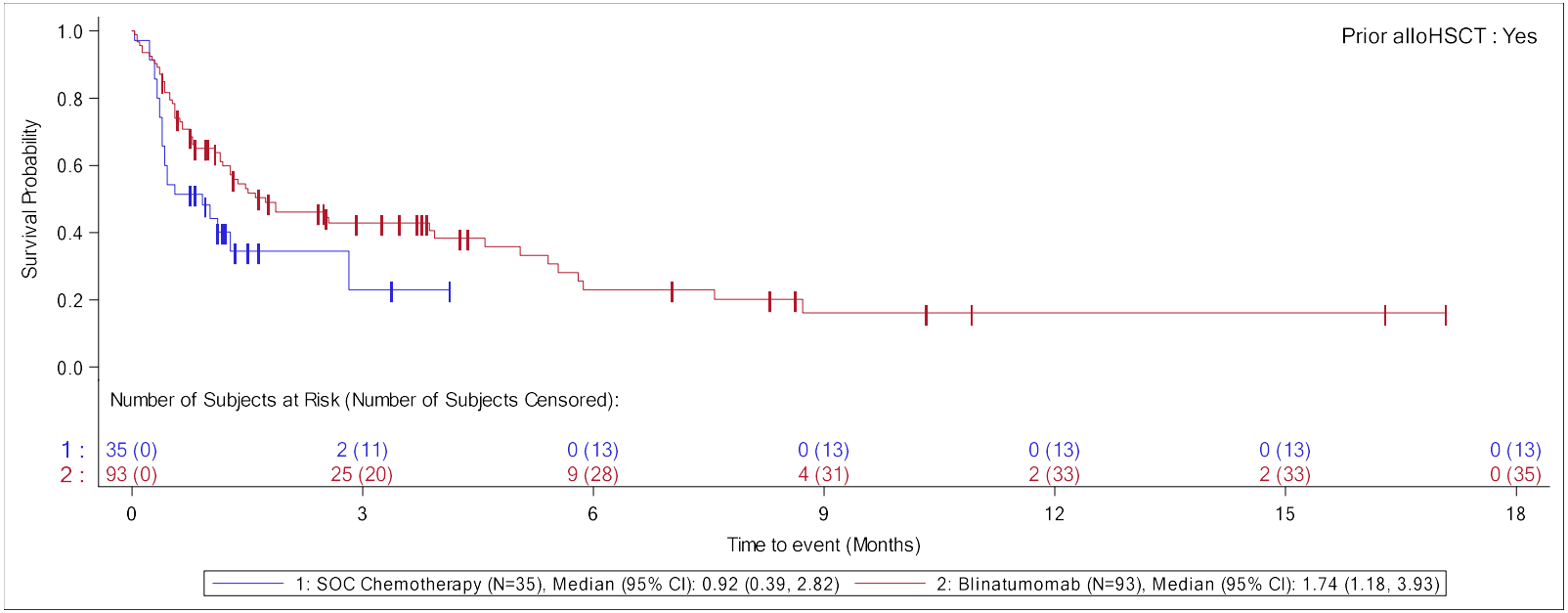
Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-trt-disc-edp-saf.sas
Output: t14-06-002-014-tte-sub-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:02:33) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

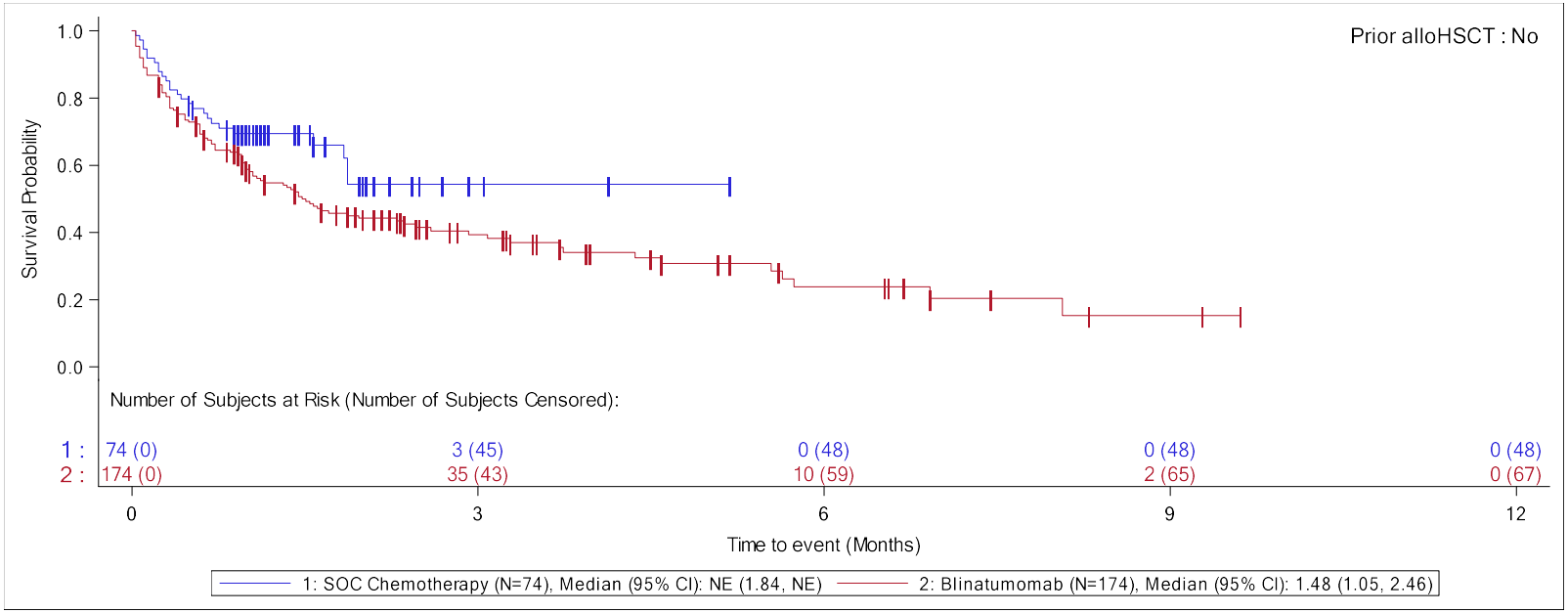
Figure 14-6.2.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-saf.sas
Output: f14-06-002-002-km-sub-ser-teae-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

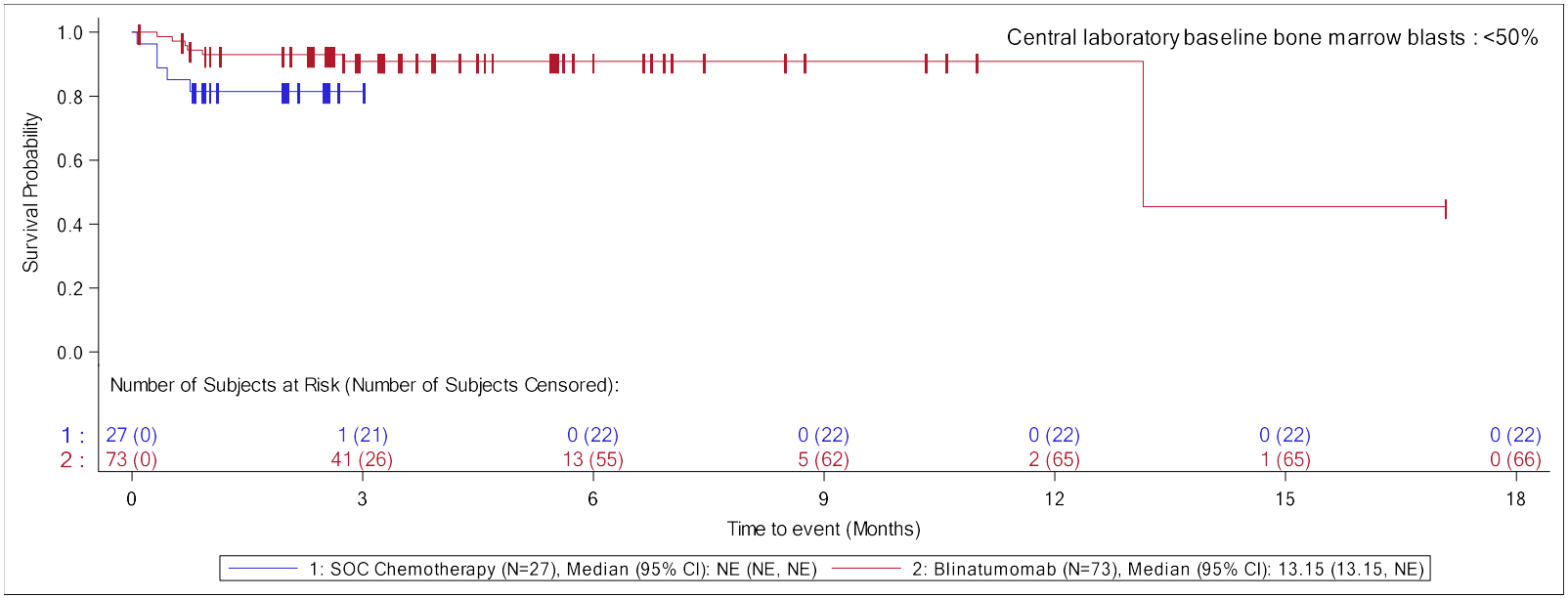
Figure 14-6.2.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-saf.sas
Output: f14-06-002-002-km-sub-ser-teae-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

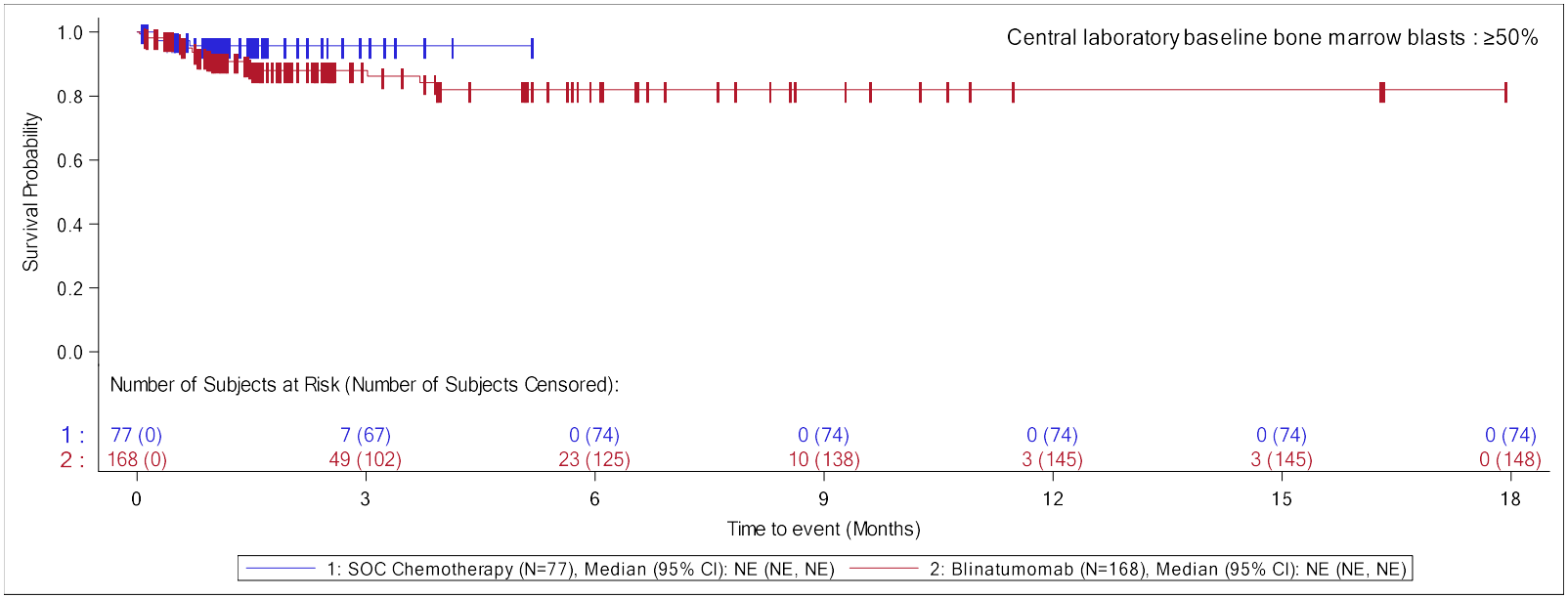
Figure 14-6.2.4. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-trt-disc-saf.sas
Output: f14-06-002-004-km-sub-teae-trt-disc-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

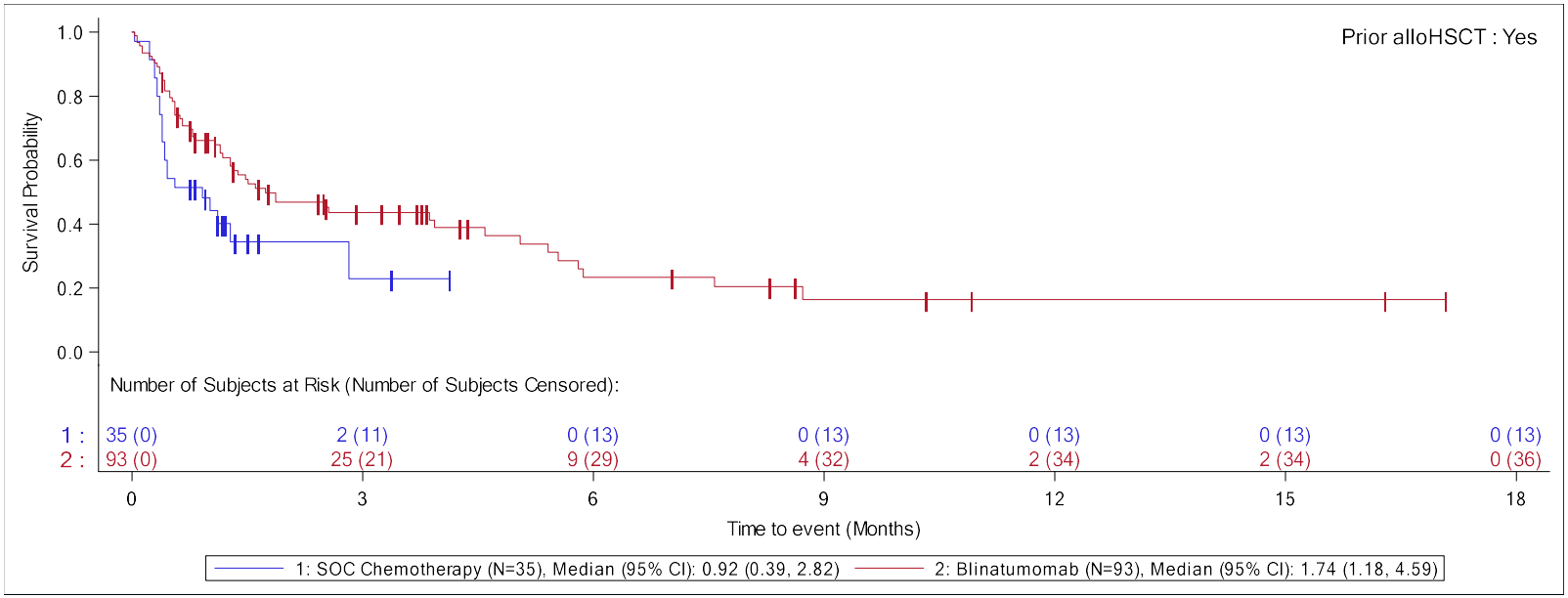
Figure 14-6.2.4. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-trt-disc-saf.sas
Output: f14-06-002-004-km-sub-teae-trt-disc-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

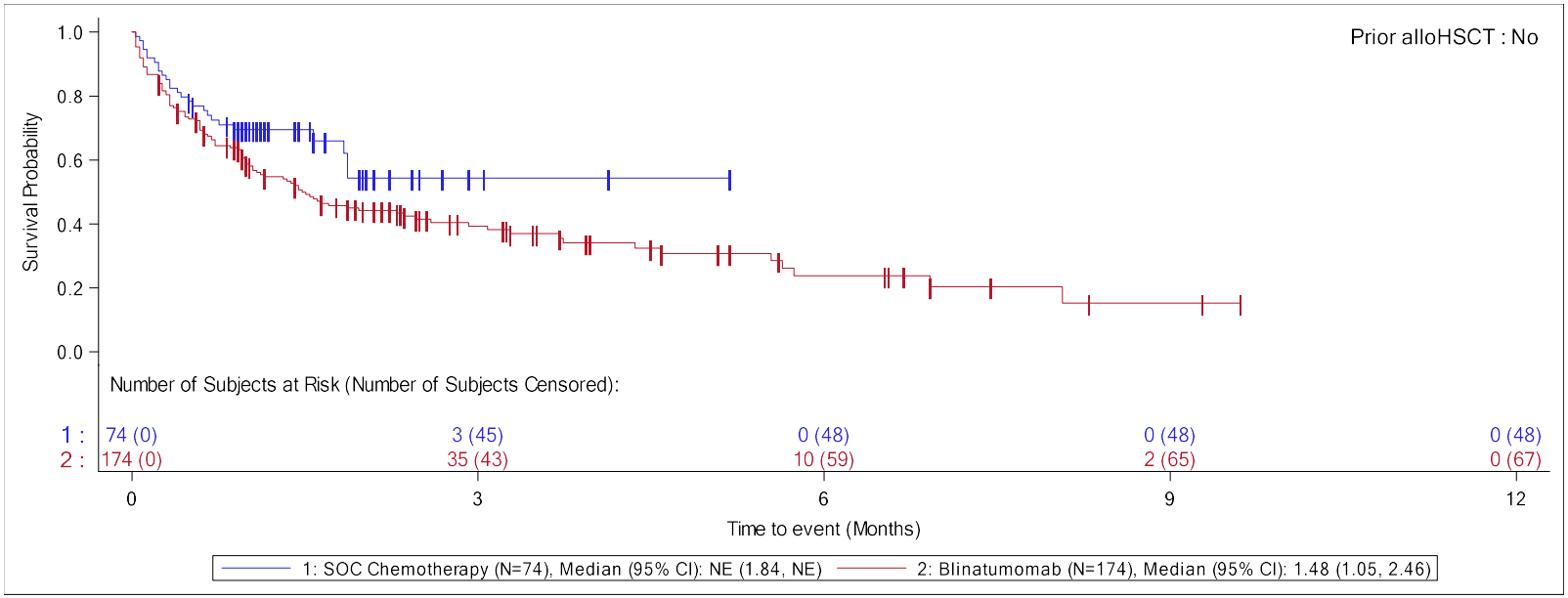
Figure 14-6.2.9. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-edp-saf.sas
Output: f14-06-002-009-km-sub-ser-teae-edp-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

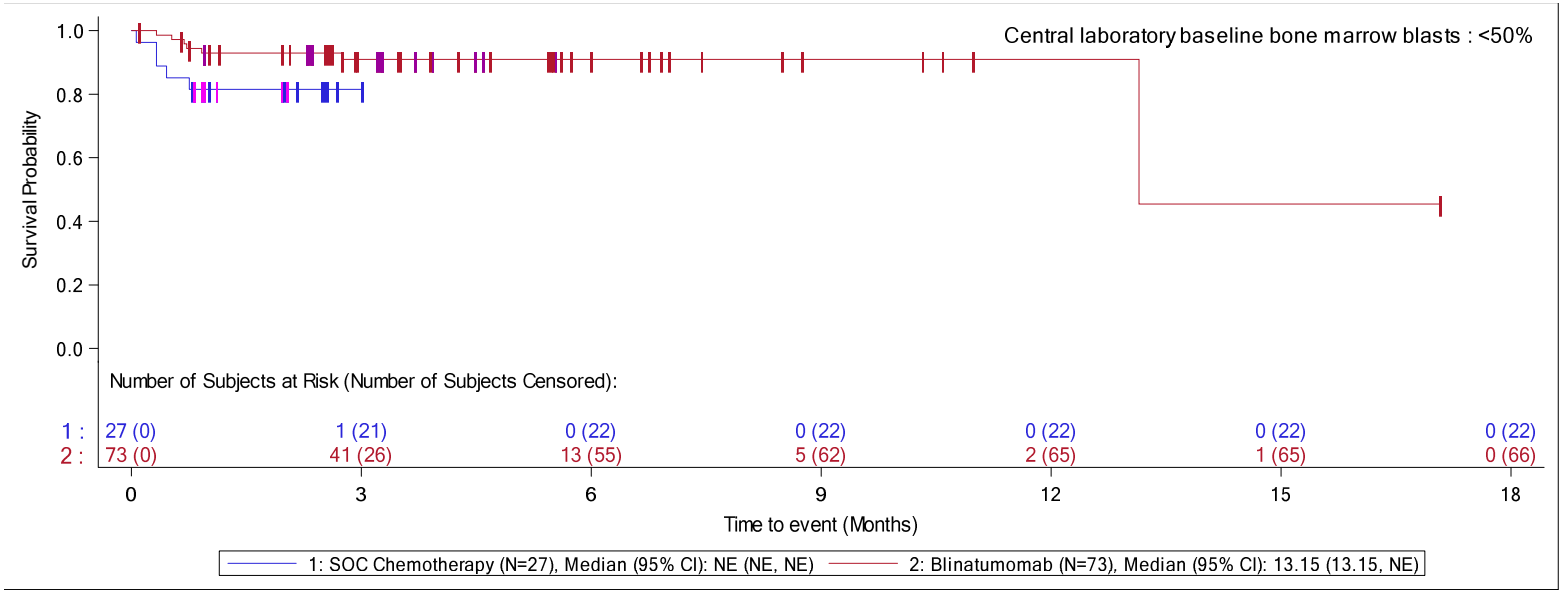
Figure 14-6.2.9. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-edp-saf.sas
Output: f14-06-002-009-km-sub-ser-teae-edp-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

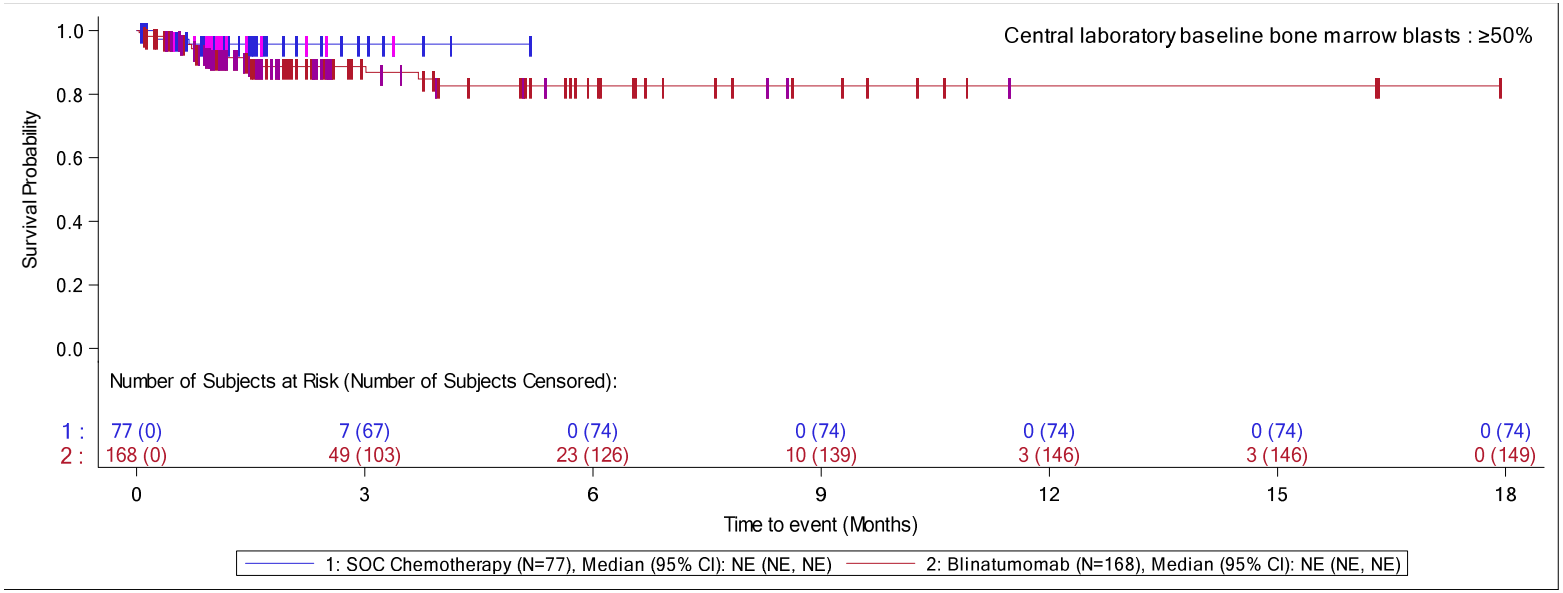
Figure 14-6.2.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-trt-disc-edp-saf.sas
Output: f14-06-002-014-km-sub-teae-trt-disc-edp-saf.rtf (Date Generated: 03DEC25 05:37) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Figure 14-6.2.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-trt-disc-edp-saf.sas
Output: f14-06-002-014-km-sub-teae-trt-disc-edp-saf.rtf (Date Generated: 03DEC25 05:37) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Anhang 4-G3.7.2: Subgruppenanalysen zu UE von besonderem Interesse

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Capillary leak syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow	53/109 (48.6)	1.31 (0.69, NE)	163/267 (61.0)	0.92 (0.52, 1.44)	1.24 (0.91, 1.69)	0.1806	
Age group 1							0.2059
<35 years	25/50 (50.0)	1.11 (0.49, NE)	69/123 (56.1)	1.44 (0.79, 2.85)	0.95 (0.60, 1.51)	0.8222	
≥35 years	28/59 (47.5)	NE (0.49, NE)	94/144 (65.3)	0.52 (0.33, 1.08)	1.53 (1.00, 2.34)	0.0468	
Age group 2							0.5189
<35 years	25/50 (50.0)	1.11 (0.49, NE)	70/124 (56.5)	1.44 (0.79, 2.85)	0.96 (0.61, 1.52)	0.8670	
35 - 54 years	14/25 (56.0)	0.79 (0.30, NE)	56/77 (72.7)	0.46 (0.20, 0.72)	1.37 (0.76, 2.47)	0.2915	
55 - 64 years	10/22 (45.5)	NE (0.26, NE)	17/33 (51.5)	1.90 (0.33, NE)	1.12 (0.51, 2.46)	0.7686	
≥65 years	4/12 (33.3)	NE (0.13, NE)	20/33 (60.6)	0.79 (0.13, 2.79)	2.17 (0.73, 6.38)	0.1522	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6673
Male	28/64 (43.8)	1.41 (0.75, NE)	87/159 (54.7)	1.44 (0.72, 2.85)	1.16 (0.76, 1.79)	0.4876	
Female	25/45 (55.6)	0.72 (0.39, NE)	76/108 (70.4)	0.46 (0.23, 0.92)	1.38 (0.87, 2.17)	0.1675	
Region							0.3712
USA	5/13 (38.5)	NE (0.10, NE)	18/30 (60.0)	0.69 (0.43, NE)	1.65 (0.61, 4.44)	0.3148	
Europe	29/68 (42.6)	NE (0.82, NE)	102/177 (57.6)	1.28 (0.59, 2.10)	1.40 (0.93, 2.12)	0.1107	
Rest of the world	19/28 (67.9)	0.46 (0.10, 1.31)	43/60 (71.7)	0.39 (0.13, 1.28)	0.87 (0.50, 1.51)	0.6068	
Prior salvage therapy							0.6205
Yes	27/63 (42.9)	1.41 (0.72, NE)	92/161 (57.1)	1.08 (0.59, 1.70)	1.34 (0.87, 2.06)	0.1850	
No	26/46 (56.5)	0.84 (0.33, NE)	71/106 (67.0)	0.62 (0.36, 1.44)	1.14 (0.73, 1.79)	0.5634	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4606
0	31/55 (56.4)	0.72 (0.33, NE)	74/112 (66.1)	0.79 (0.43, 1.48)	1.07 (0.70, 1.64)	0.7414	
1	16/34 (47.1)	0.89 (0.49, NE)	54/91 (59.3)	0.95 (0.39, 1.90)	1.35 (0.77, 2.36)	0.3115	
≥2	6/20 (30.0)	NE (1.11, NE)	35/64 (54.7)	1.08 (0.46, 3.02)	1.89 (0.79, 4.50)	0.1475	
Prior alloHSCT							0.3600
Yes	20/35 (57.1)	0.82 (0.26, NE)	58/93 (62.4)	0.75 (0.33, 1.90)	0.96 (0.57, 1.62)	0.8844	
No	33/74 (44.6)	NE (0.56, NE)	105/174 (60.3)	0.92 (0.52, 1.44)	1.38 (0.93, 2.04)	0.1096	
Race							0.8880
Caucasian	43/90 (47.8)	1.41 (0.56, NE)	134/226 (59.3)	0.79 (0.49, 1.48)	1.28 (0.90, 1.80)	0.1677	
Others	10/19 (52.6)	1.11 (0.10, NE)	29/41 (70.7)	1.08 (0.36, 1.44)	1.01 (0.49, 2.10)	0.9936	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0243
<50%	16/27 (59.3)	0.56 (0.13, NE)	39/73 (53.4)	2.85 (0.49, NE)	0.75 (0.42, 1.36)	0.3320	
≥50%	35/77 (45.5)	1.41 (0.82, NE)	112/168 (66.7)	0.62 (0.43, 1.08)	1.59 (1.09, 2.33)	0.0157	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Cytokine release syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	43/267 (16.1)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Age group 1							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/123 (14.6)	NE (NE, NE)	NE (NE, NE)	0.0057	
≥35 years	0/59 (0.0)	NE (NE, NE)	25/144 (17.4)	NE (NE, NE)	NE (NE, NE)	0.0013	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/124 (14.5)	NE (NE, NE)	NE (NE, NE)	0.0059	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	12/77 (15.6)	NE (NE, NE)	NE (NE, NE)	0.0463	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	7/33 (21.2)	NE (NE, NE)	NE (NE, NE)	0.0272	
≥65 years	0/12 (0.0)	NE (NE, NE)	6/33 (18.2)	8.33 (8.33, NE)	NE (NE, NE)	0.1600	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	NE (NE, NE)	23/159 (14.5)	NE (NE, NE)	NE (NE, NE)	0.0018	
Female	0/45 (0.0)	NE (NE, NE)	20/108 (18.5)	NE (NE, NE)	NE (NE, NE)	0.0042	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (NE, NE)	NE (NE, NE)	0.0629	
Europe	0/68 (0.0)	NE (NE, NE)	18/177 (10.2)	NE (NE, NE)	NE (NE, NE)	0.0106	
Rest of the world	0/28 (0.0)	NE (NE, NE)	18/60 (30.0)	NE (NE, NE)	NE (NE, NE)	0.0021	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	NE (NE, NE)	31/161 (19.3)	NE (NE, NE)	NE (NE, NE)	0.0003	
No	0/46 (0.0)	NE (NE, NE)	12/106 (11.3)	NE (NE, NE)	NE (NE, NE)	0.0271	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	NE (NE, NE)	0.0140	
1	0/34 (0.0)	NE (NE, NE)	21/91 (23.1)	NE (NE, NE)	NE (NE, NE)	0.0033	
≥2	0/20 (0.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)	NE (NE, NE)	0.0979	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	NE (NE, NE)	13/93 (14.0)	NE (NE, NE)	NE (NE, NE)	0.0283	
No	0/74 (0.0)	NE (NE, NE)	30/174 (17.2)	NE (8.33, NE)	NE (NE, NE)	0.0003	
Race							0.9997
Caucasian	0/90 (0.0)	NE (NE, NE)	40/226 (17.7)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Others	0/19 (0.0)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	NE (NE, NE)	0.2831	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	NE (NE, NE)	11/73 (15.1)	NE (NE, NE)	NE (NE, NE)	0.0353	
≥50%	0/77 (0.0)	NE (NE, NE)	28/168 (16.7)	NE (NE, NE)	NE (NE, NE)	0.0003	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Decreased immunoglobulins (AMQ) - Narrow	2/109 (1.8)	NE (NE, NE)	26/267 (9.7)	NE (8.30, NE)	2.21 (0.51, 9.66)	0.2810	
Age group 1							0.9915
<35 years	0/50 (0.0)	NE (NE, NE)	11/123 (8.9)	NE (7.18, NE)	NE (NE, NE)	0.1876	
≥35 years	2/59 (3.4)	NE (NE, NE)	15/144 (10.4)	NE (7.74, NE)	1.30 (0.28, 6.12)	0.7416	
Age group 2							0.9305
<35 years	0/50 (0.0)	NE (NE, NE)	11/124 (8.9)	NE (7.18, NE)	NE (NE, NE)	0.1876	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	10/77 (13.0)	NE (8.30, NE)	NE (NE, NE)	0.2819	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	3/33 (9.1)	NE (5.80, NE)	0.64 (0.04, 10.23)	0.7497	
≥65 years	1/12 (8.3)	NE (NE, NE)	2/33 (6.1)	NE (7.74, NE)	0.37 (0.02, 5.95)	0.4645	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9877
Male	2/64 (3.1)	NE (NE, NE)	13/159 (8.2)	NE (7.18, NE)	1.13 (0.24, 5.41)	0.8820	
Female	0/45 (0.0)	NE (NE, NE)	13/108 (12.0)	NE (7.74, NE)	NE (NE, NE)	0.1741	
Region							0.3889
USA	1/13 (7.7)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	0.40 (0.03, 6.45)	0.5052	
Europe	1/68 (1.5)	NE (NE, NE)	19/177 (10.7)	NE (7.74, NE)	2.80 (0.36, 21.94)	0.3068	
Rest of the world	0/28 (0.0)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	NE (NE, NE)	0.3519	
Prior salvage therapy							0.9904
Yes	0/63 (0.0)	NE (NE, NE)	17/161 (10.6)	NE (7.02, NE)	NE (NE, NE)	0.0947	
No	2/46 (4.3)	NE (NE, NE)	9/106 (8.5)	NE (8.30, NE)	0.77 (0.15, 4.01)	0.7512	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9999
0	2/55 (3.6)	NE (NE, NE)	10/112 (8.9)	NE (8.30, NE)	0.76 (0.14, 4.05)	0.7474	
1	0/34 (0.0)	NE (NE, NE)	11/91 (12.1)	NE (5.31, NE)	NE (NE, NE)	0.1851	
≥2	0/20 (0.0)	NE (NE, NE)	5/64 (7.8)	NE (7.18, NE)	NE (NE, NE)	0.4057	
Prior alloHSCT							0.9893
Yes	0/35 (0.0)	NE (NE, NE)	16/93 (17.2)	NE (7.02, NE)	NE (NE, NE)	0.1706	
No	2/74 (2.7)	NE (NE, NE)	10/174 (5.7)	NE (NE, NE)	1.15 (0.24, 5.52)	0.8632	
Race							0.3415
Caucasian	1/90 (1.1)	NE (NE, NE)	21/226 (9.3)	NE (8.30, NE)	3.08 (0.40, 23.79)	0.2566	
Others	1/19 (5.3)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	1.39 (0.16, 12.37)	0.7766	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9902
<50%	0/27 (0.0)	NE (NE, NE)	10/73 (13.7)	NE (7.02, NE)	NE (NE, NE)	0.2799	
≥50%	2/77 (2.6)	NE (NE, NE)	13/168 (7.7)	NE (8.30, NE)	1.43 (0.30, 6.77)	0.6519	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Haematopoietic cytopenias (SMQ) - Narrow	79/109 (72.5)	0.26 (0.23, 0.30)	160/267 (59.9)	1.15 (0.62, 2.10)	0.56 (0.42, 0.73)	<0.0001	
Age group 1							0.9338
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	72/123 (58.5)	1.64 (0.62, 2.59)	0.52 (0.34, 0.80)	0.0024	
≥35 years	45/59 (76.3)	0.26 (0.20, 0.30)	88/144 (61.1)	0.79 (0.46, 2.16)	0.59 (0.41, 0.85)	0.0037	
Age group 2							0.7457
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	73/124 (58.9)	1.64 (0.62, 2.59)	0.53 (0.35, 0.81)	0.0030	
35 - 54 years	18/25 (72.0)	0.26 (0.23, 0.56)	48/77 (62.3)	0.82 (0.33, 2.46)	0.68 (0.39, 1.18)	0.1541	
55 - 64 years	19/22 (86.4)	0.26 (0.10, 0.43)	20/33 (60.6)	0.52 (0.20, NE)	0.44 (0.23, 0.85)	0.0124	
≥65 years	8/12 (66.7)	0.23 (0.03, NE)	19/33 (57.6)	2.36 (0.20, 8.26)	0.63 (0.27, 1.49)	0.2791	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5829
Male	45/64 (70.3)	0.26 (0.20, 0.36)	96/159 (60.4)	1.31 (0.52, 2.03)	0.57 (0.40, 0.82)	0.0021	
Female	34/45 (75.6)	0.26 (0.20, 0.30)	64/108 (59.3)	0.98 (0.49, 3.11)	0.55 (0.36, 0.84)	0.0052	
Region							0.1393
USA	8/13 (61.5)	0.39 (0.20, NE)	23/30 (76.7)	0.48 (0.20, 1.15)	1.01 (0.45, 2.31)	0.9857	
Europe	47/68 (69.1)	0.26 (0.20, 0.33)	98/177 (55.4)	1.64 (0.62, 3.02)	0.59 (0.41, 0.84)	0.0031	
Rest of the world	24/28 (85.7)	0.23 (0.10, 0.30)	39/60 (65.0)	1.54 (0.33, 2.36)	0.32 (0.18, 0.57)	<0.0001	
Prior salvage therapy							0.0492
Yes	43/63 (68.3)	0.30 (0.23, 0.43)	101/161 (62.7)	1.08 (0.59, 1.93)	0.64 (0.44, 0.92)	0.0128	
No	36/46 (78.3)	0.23 (0.13, 0.26)	59/106 (55.7)	2.03 (0.39, 6.62)	0.46 (0.30, 0.71)	0.0003	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3370
0	42/55 (76.4)	0.26 (0.16, 0.26)	66/112 (58.9)	0.85 (0.39, 2.82)	0.51 (0.34, 0.75)	0.0007	
1	24/34 (70.6)	0.28 (0.20, 0.56)	55/91 (60.4)	1.64 (0.62, 2.89)	0.51 (0.31, 0.86)	0.0075	
≥2	13/20 (65.0)	0.39 (0.20, NE)	39/64 (60.9)	0.62 (0.33, 2.10)	0.76 (0.40, 1.43)	0.3722	
Prior alloHSCT							0.3470
Yes	29/35 (82.9)	0.26 (0.16, 0.36)	56/93 (60.2)	2.03 (0.26, 2.69)	0.45 (0.28, 0.73)	0.0006	
No	50/74 (67.6)	0.26 (0.20, 0.36)	104/174 (59.8)	0.98 (0.59, 1.97)	0.62 (0.44, 0.87)	0.0056	
Race							0.9393
Caucasian	64/90 (71.1)	0.26 (0.20, 0.30)	133/226 (58.8)	1.31 (0.59, 2.36)	0.58 (0.43, 0.79)	0.0004	
Others	15/19 (78.9)	0.26 (0.10, 0.43)	27/41 (65.9)	0.98 (0.39, 1.93)	0.42 (0.21, 0.82)	0.0101	

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(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1810
<50%	20/27 (74.1)	0.26 (0.16, 0.36)	41/73 (56.2)	2.52 (1.15, 6.62)	0.39 (0.22, 0.69)	0.0009	
≥50%	56/77 (72.7)	0.26 (0.20, 0.36)	103/168 (61.3)	0.62 (0.39, 1.64)	0.64 (0.46, 0.89)	0.0062	

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(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infections and infestations (SOC)	79/109 (72.5)	0.49 (0.39, 0.62)	171/267 (64.0)	1.31 (1.05, 1.90)	0.50 (0.38, 0.66)	<0.0001	
Age group 1							0.1421
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/123 (61.0)	1.28 (1.02, 2.72)	0.62 (0.40, 0.95)	0.0265	
≥35 years	48/59 (81.4)	0.43 (0.33, 0.56)	96/144 (66.7)	1.31 (0.75, 1.90)	0.42 (0.29, 0.61)	<0.0001	
Age group 2							0.2777
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/124 (60.5)	1.28 (1.02, 2.72)	0.62 (0.40, 0.95)	0.0261	
35 - 54 years	20/25 (80.0)	0.43 (0.30, 0.62)	53/77 (68.8)	1.08 (0.69, 2.49)	0.37 (0.21, 0.65)	0.0003	
55 - 64 years	17/22 (77.3)	0.41 (0.30, 0.79)	25/33 (75.8)	1.15 (0.46, 1.84)	0.55 (0.29, 1.08)	0.0778	
≥65 years	11/12 (91.7)	0.41 (0.10, 1.54)	18/33 (54.5)	3.08 (0.56, 5.54)	0.33 (0.15, 0.74)	0.0047	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8457
Male	46/64 (71.9)	0.49 (0.39, 0.72)	100/159 (62.9)	1.28 (0.79, 2.72)	0.51 (0.35, 0.74)	0.0002	
Female	33/45 (73.3)	0.49 (0.33, 0.69)	71/108 (65.7)	1.48 (0.95, 2.52)	0.48 (0.31, 0.74)	0.0008	
Region							0.8360
USA	8/13 (61.5)	1.21 (0.16, NE)	17/30 (56.7)	1.31 (0.72, NE)	0.64 (0.27, 1.52)	0.3130	
Europe	49/68 (72.1)	0.49 (0.36, 0.72)	111/177 (62.7)	1.80 (1.11, 2.69)	0.46 (0.33, 0.66)	<0.0001	
Rest of the world	22/28 (78.6)	0.46 (0.36, 0.49)	43/60 (71.7)	0.79 (0.56, 1.48)	0.48 (0.27, 0.84)	0.0090	
Prior salvage therapy							0.0379
Yes	42/63 (66.7)	0.49 (0.39, 1.11)	109/161 (67.7)	0.95 (0.69, 1.41)	0.66 (0.46, 0.96)	0.0265	
No	37/46 (80.4)	0.49 (0.33, 0.62)	62/106 (58.5)	2.75 (1.31, 3.61)	0.32 (0.21, 0.50)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0601
0	40/55 (72.7)	0.49 (0.36, 0.72)	69/112 (61.6)	2.75 (1.28, 3.64)	0.38 (0.25, 0.58)	<0.0001	
1	27/34 (79.4)	0.46 (0.30, 0.66)	57/91 (62.6)	1.21 (0.69, 1.97)	0.42 (0.26, 0.69)	0.0003	
≥2	12/20 (60.0)	0.49 (0.33, NE)	45/64 (70.3)	0.72 (0.46, 1.28)	0.95 (0.50, 1.82)	0.8630	
Prior alloHSCT							0.5569
Yes	24/35 (68.6)	0.49 (0.36, 1.11)	65/93 (69.9)	1.31 (0.92, 2.00)	0.48 (0.29, 0.81)	0.0049	
No	55/74 (74.3)	0.49 (0.39, 0.62)	106/174 (60.9)	1.28 (0.75, 2.69)	0.49 (0.35, 0.68)	<0.0001	
Race							0.2409
Caucasian	66/90 (73.3)	0.49 (0.39, 0.62)	140/226 (61.9)	1.61 (1.15, 2.52)	0.46 (0.34, 0.63)	<0.0001	
Others	13/19 (68.4)	0.43 (0.20, 1.11)	31/41 (75.6)	0.72 (0.36, 1.02)	0.70 (0.36, 1.38)	0.2942	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0848
<50%	22/27 (81.5)	0.49 (0.33, 1.51)	45/73 (61.6)	3.21 (2.52, 4.10)	0.23 (0.13, 0.42)	<0.0001	
≥50%	54/77 (70.1)	0.49 (0.39, 0.59)	108/168 (64.3)	1.02 (0.69, 1.31)	0.60 (0.43, 0.84)	0.0026	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infusion reaction (AMQ) - Narrow	12/109 (11.0)	NE (NE, NE)	129/267 (48.3)	2.85 (1.41, NE)	5.25 (2.90, 9.49)	<0.0001	
Age group 1							0.3767
<35 years	7/50 (14.0)	NE (NE, NE)	58/123 (47.2)	6.23 (0.07, NE)	4.10 (1.87, 8.99)	<0.0001	
≥35 years	5/59 (8.5)	NE (NE, NE)	71/144 (49.3)	1.67 (0.07, NE)	6.79 (2.74, 16.85)	<0.0001	
Age group 2							0.7911
<35 years	7/50 (14.0)	NE (NE, NE)	58/124 (46.8)	6.23 (0.07, NE)	4.05 (1.85, 8.89)	<0.0001	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	40/77 (51.9)	1.44 (0.07, NE)	7.35 (1.77, 30.47)	0.0010	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	12/33 (36.4)	4.85 (2.92, NE)	7.75 (1.00, 60.32)	0.0198	
≥65 years	2/12 (16.7)	NE (0.07, NE)	19/33 (57.6)	0.07 (0.07, NE)	4.45 (1.03, 19.18)	0.0250	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4050
Male	8/64 (12.5)	NE (NE, NE)	72/159 (45.3)	2.92 (1.41, NE)	4.33 (2.08, 8.99)	<0.0001	
Female	4/45 (8.9)	NE (NE, NE)	57/108 (52.8)	1.44 (0.07, NE)	7.10 (2.57, 19.60)	<0.0001	
Region							0.0914
USA	1/13 (7.7)	NE (NE, NE)	13/30 (43.3)	NE (0.07, NE)	7.06 (0.92, 54.01)	0.0245	
Europe	3/68 (4.4)	NE (NE, NE)	78/177 (44.1)	NE (1.44, NE)	12.09 (3.81, 38.32)	<0.0001	
Rest of the world	8/28 (28.6)	NE (NE, NE)	38/60 (63.3)	0.07 (0.07, 2.82)	2.46 (1.14, 5.31)	0.0144	
Prior salvage therapy							0.4303
Yes	8/63 (12.7)	NE (NE, NE)	74/161 (46.0)	2.85 (1.41, NE)	4.22 (2.03, 8.76)	<0.0001	
No	4/46 (8.7)	NE (NE, NE)	55/106 (51.9)	1.44 (0.07, NE)	7.43 (2.69, 20.52)	<0.0001	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7340
0	7/55 (12.7)	NE (NE, NE)	61/112 (54.5)	1.41 (0.07, NE)	5.40 (2.47, 11.82)	<0.0001	
1	3/34 (8.8)	NE (NE, NE)	47/91 (51.6)	2.82 (0.07, 6.23)	7.10 (2.20, 22.88)	<0.0001	
≥2	2/20 (10.0)	NE (NE, NE)	21/64 (32.8)	NE (2.85, NE)	3.51 (0.82, 14.99)	0.0646	
Prior alloHSCT							0.4866
Yes	5/35 (14.3)	NE (NE, NE)	44/93 (47.3)	4.85 (0.07, NE)	3.94 (1.56, 9.96)	0.0013	
No	7/74 (9.5)	NE (NE, NE)	85/174 (48.9)	2.82 (0.07, NE)	6.18 (2.85, 13.36)	<0.0001	
Race							0.0421
Caucasian	6/90 (6.7)	NE (NE, NE)	102/226 (45.1)	4.85 (1.44, NE)	8.27 (3.63, 18.84)	<0.0001	
Others	6/19 (31.6)	NE (0.07, NE)	27/41 (65.9)	0.07 (0.07, 2.82)	2.22 (0.91, 5.42)	0.0596	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4563
<50%	3/27 (11.1)	NE (NE, NE)	45/73 (61.6)	0.07 (0.07, 2.85)	7.40 (2.29, 23.89)	<0.0001	
≥50%	9/77 (11.7)	NE (NE, NE)	76/168 (45.2)	2.92 (1.41, NE)	4.47 (2.24, 8.93)	<0.0001	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow	27/109 (24.8)	NE (3.02, NE)	58/267 (21.7)	NE (NE, NE)	0.80 (0.51, 1.27)	0.3398	
Age group 1							0.6778
<35 years	13/50 (26.0)	3.02 (3.02, NE)	26/123 (21.1)	NE (NE, NE)	0.72 (0.37, 1.41)	0.3274	
≥35 years	14/59 (23.7)	NE (NE, NE)	32/144 (22.2)	NE (NE, NE)	0.88 (0.47, 1.66)	0.6957	
Age group 2							0.0763
<35 years	13/50 (26.0)	3.02 (3.02, NE)	26/124 (21.0)	NE (NE, NE)	0.71 (0.36, 1.40)	0.3212	
35 - 54 years	5/25 (20.0)	NE (NE, NE)	21/77 (27.3)	NE (5.54, NE)	1.21 (0.45, 3.23)	0.7170	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	9/33 (27.3)	NE (NE, NE)	1.55 (0.48, 5.03)	0.4628	
≥65 years	5/12 (41.7)	NE (0.13, NE)	2/33 (6.1)	NE (NE, NE)	0.15 (0.03, 0.75)	0.0080	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5275
Male	16/64 (25.0)	NE (NE, NE)	39/159 (24.5)	NE (NE, NE)	0.94 (0.53, 1.68)	0.8357	
Female	11/45 (24.4)	NE (3.02, NE)	19/108 (17.6)	NE (NE, NE)	0.55 (0.26, 1.20)	0.1238	
Region							0.7222
USA	7/13 (53.8)	3.02 (0.13, NE)	14/30 (46.7)	1.44 (0.26, NE)	0.76 (0.30, 1.88)	0.5492	
Europe	11/68 (16.2)	NE (NE, NE)	29/177 (16.4)	NE (NE, NE)	1.00 (0.50, 2.02)	0.9989	
Rest of the world	9/28 (32.1)	NE (0.56, NE)	15/60 (25.0)	NE (5.54, NE)	0.59 (0.25, 1.38)	0.2187	
Prior salvage therapy							0.7374
Yes	16/63 (25.4)	NE (NE, NE)	34/161 (21.1)	NE (NE, NE)	0.76 (0.42, 1.37)	0.3505	
No	11/46 (23.9)	NE (3.02, NE)	24/106 (22.6)	NE (NE, NE)	0.86 (0.42, 1.78)	0.6774	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5571
0	10/55 (18.2)	NE (3.02, NE)	22/112 (19.6)	NE (NE, NE)	1.05 (0.49, 2.23)	0.9135	
1	9/34 (26.5)	NE (NE, NE)	18/91 (19.8)	NE (5.54, NE)	0.58 (0.26, 1.32)	0.1902	
≥2	8/20 (40.0)	NE (0.20, NE)	18/64 (28.1)	NE (NE, NE)	0.60 (0.26, 1.38)	0.2151	
Prior alloHSCT							0.4345
Yes	9/35 (25.7)	NE (NE, NE)	26/93 (28.0)	NE (5.67, NE)	1.00 (0.46, 2.15)	0.9615	
No	18/74 (24.3)	NE (3.02, NE)	32/174 (18.4)	NE (NE, NE)	0.70 (0.39, 1.24)	0.2151	
Race							0.4914
Caucasian	24/90 (26.7)	NE (3.02, NE)	49/226 (21.7)	NE (NE, NE)	0.75 (0.46, 1.22)	0.2352	
Others	3/19 (15.8)	NE (NE, NE)	9/41 (22.0)	NE (NE, NE)	1.22 (0.33, 4.55)	0.7614	

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(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2707
<50%	5/27 (18.5)	NE (NE, NE)	20/73 (27.4)	NE (5.54, NE)	1.44 (0.54, 3.87)	0.4647	
≥50%	20/77 (26.0)	NE (NE, NE)	37/168 (22.0)	NE (NE, NE)	0.78 (0.45, 1.35)	0.3619	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Lymphopenia (AMQ) - Narrow	4/109 (3.7)	NE (NE, NE)	5/267 (1.9)	NE (NE, NE)	0.34 (0.08, 1.42)	0.1234	
Age group 1							0.6391
<35 years	1/50 (2.0)	-	2/123 (1.6)	-	-	-	
≥35 years	3/59 (5.1)	-	3/144 (2.1)	-	-	-	
Age group 2							0.9164
<35 years	1/50 (2.0)	-	2/124 (1.6)	-	-	-	
35 - 54 years	2/25 (8.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	1/22 (4.5)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6961
Male	3/64 (4.7)	-	3/159 (1.9)	-	-	-	
Female	1/45 (2.2)	-	2/108 (1.9)	-	-	-	
Region							0.7100
USA	1/13 (7.7)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	3/177 (1.7)	-	-	-	
Rest of the world	3/28 (10.7)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							0.6738
Yes	2/63 (3.2)	-	3/161 (1.9)	-	-	-	
No	2/46 (4.3)	-	2/106 (1.9)	-	-	-	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5246
0	1/55 (1.8)	-	3/112 (2.7)	-	-	-	
1	2/34 (5.9)	-	1/91 (1.1)	-	-	-	
≥2	1/20 (5.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.5526
Yes	2/35 (5.7)	-	2/93 (2.2)	-	-	-	
No	2/74 (2.7)	-	3/174 (1.7)	-	-	-	
Race							0.9943
Caucasian	4/90 (4.4)	-	4/226 (1.8)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4374
<50%	1/27 (3.7)	-	3/73 (4.1)	-	-	-	
≥50%	3/77 (3.9)	-	2/168 (1.2)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Medication errors and product use issues (AMQ) - Broad	0/109 (0.0)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	NE (NE, NE)	0.0355	
Age group 1							0.9999
<35 years	0/50 (0.0)	-	7/123 (5.7)	-	-	-	
≥35 years	0/59 (0.0)	-	5/144 (3.5)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	7/124 (5.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	6/159 (3.8)	-	-	-	
Female	0/45 (0.0)	-	6/108 (5.6)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	7/177 (4.0)	-	-	-	
Rest of the world	0/28 (0.0)	-	5/60 (8.3)	-	-	-	
Prior salvage therapy							0.9999
Yes	0/63 (0.0)	-	5/161 (3.1)	-	-	-	
No	0/46 (0.0)	-	7/106 (6.6)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	9/112 (8.0)	-	-	-	
1	0/34 (0.0)	-	2/91 (2.2)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	3/93 (3.2)	-	-	-	
No	0/74 (0.0)	-	9/174 (5.2)	-	-	-	
Race							0.9998
Caucasian	0/90 (0.0)	-	7/226 (3.1)	-	-	-	
Others	0/19 (0.0)	-	5/41 (12.2)	-	-	-	

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(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9974
<50%	0/27 (0.0)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0242	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Neutropenia (AMQ) - Narrow	70/109 (64.2)	0.36 (0.26, 0.43)	111/267 (41.6)	4.79 (2.59, 6.69)	0.39 (0.28, 0.53)	<0.0001	
Age group 1							0.6759
<35 years	30/50 (60.0)	0.36 (0.26, 2.49)	51/123 (41.5)	5.02 (2.10, NE)	0.41 (0.26, 0.66)	0.0001	
≥35 years	40/59 (67.8)	0.36 (0.26, 0.46)	60/144 (41.7)	4.79 (2.36, 8.26)	0.37 (0.24, 0.56)	<0.0001	
Age group 2							0.9262
<35 years	30/50 (60.0)	0.36 (0.26, 2.49)	52/124 (41.9)	5.02 (2.10, NE)	0.42 (0.26, 0.67)	0.0002	
35 - 54 years	18/25 (72.0)	0.30 (0.23, 0.56)	33/77 (42.9)	4.79 (1.54, NE)	0.35 (0.19, 0.64)	0.0004	
55 - 64 years	16/22 (72.7)	0.38 (0.20, 0.59)	15/33 (45.5)	1.97 (0.49, NE)	0.38 (0.19, 0.79)	0.0083	
≥65 years	6/12 (50.0)	NE (0.10, NE)	11/33 (33.3)	4.95 (2.36, NE)	0.32 (0.10, 0.99)	0.0378	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3122
Male	41/64 (64.1)	0.36 (0.26, 0.59)	71/159 (44.7)	2.89 (1.97, 6.69)	0.41 (0.28, 0.62)	<0.0001	
Female	29/45 (64.4)	0.30 (0.23, 1.05)	40/108 (37.0)	6.69 (3.11, NE)	0.35 (0.21, 0.59)	<0.0001	
Region							0.7279
USA	9/13 (69.2)	0.33 (0.23, NE)	16/30 (53.3)	1.31 (0.39, NE)	0.54 (0.23, 1.25)	0.1408	
Europe	37/68 (54.4)	0.46 (0.30, NE)	59/177 (33.3)	8.26 (4.62, NE)	0.40 (0.26, 0.62)	<0.0001	
Rest of the world	24/28 (85.7)	0.26 (0.20, 0.36)	36/60 (60.0)	1.93 (0.79, 2.89)	0.26 (0.14, 0.47)	<0.0001	
Prior salvage therapy							0.0867
Yes	38/63 (60.3)	0.39 (0.30, 1.05)	70/161 (43.5)	3.02 (1.97, 6.69)	0.46 (0.31, 0.70)	0.0001	
No	32/46 (69.6)	0.26 (0.23, 0.43)	41/106 (38.7)	6.69 (4.79, NE)	0.31 (0.19, 0.50)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6830
0	36/55 (65.5)	0.30 (0.23, 0.43)	46/112 (41.1)	6.69 (2.59, NE)	0.37 (0.23, 0.59)	<0.0001	
1	22/34 (64.7)	0.38 (0.26, 1.05)	40/91 (44.0)	3.11 (1.93, 5.02)	0.37 (0.21, 0.64)	0.0002	
≥2	12/20 (60.0)	0.43 (0.26, NE)	25/64 (39.1)	2.79 (1.97, NE)	0.44 (0.22, 0.88)	0.0162	
Prior alloHSCT							0.0902
Yes	27/35 (77.1)	0.30 (0.23, 0.43)	38/93 (40.9)	4.79 (2.30, NE)	0.26 (0.15, 0.44)	<0.0001	
No	43/74 (58.1)	0.39 (0.30, NE)	73/174 (42.0)	4.62 (2.07, 8.26)	0.47 (0.32, 0.69)	<0.0001	
Race							0.9512
Caucasian	55/90 (61.1)	0.36 (0.30, 0.95)	88/226 (38.9)	6.66 (2.89, NE)	0.39 (0.28, 0.56)	<0.0001	
Others	15/19 (78.9)	0.30 (0.13, 0.43)	23/41 (56.1)	1.41 (0.52, 5.02)	0.33 (0.16, 0.67)	0.0014	

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(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3365
<50%	16/27 (59.3)	0.36 (0.26, NE)	27/73 (37.0)	6.69 (3.02, NE)	0.26 (0.13, 0.52)	<0.0001	
≥50%	51/77 (66.2)	0.33 (0.26, 0.43)	76/168 (45.2)	3.11 (1.64, 6.69)	0.48 (0.34, 0.69)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Tumour lysis syndrome (SMQ) - Narrow	1/109 (0.9)	NE (NE, NE)	10/267 (3.7)	NE (13.87, NE)	3.42 (0.43, 27.05)	0.2142	
Age group 1							0.9932
<35 years	0/50 (0.0)	-	4/123 (3.3)	-	-	-	
≥35 years	1/59 (1.7)	-	6/144 (4.2)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	4/124 (3.2)	-	-	-	
35 - 54 years	1/25 (4.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	0/22 (0.0)	-	3/33 (9.1)	-	-	-	
≥65 years	0/12 (0.0)	-	1/33 (3.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9941
Male	1/64 (1.6)	-	8/159 (5.0)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	5/177 (2.8)	-	-	-	
Rest of the world	1/28 (3.6)	-	3/60 (5.0)	-	-	-	
Prior salvage therapy							0.9932
Yes	1/63 (1.6)	-	6/161 (3.7)	-	-	-	
No	0/46 (0.0)	-	4/106 (3.8)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 28MAY2025:05:43) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	5/112 (4.5)	-	-	-	
1	1/34 (2.9)	-	4/91 (4.4)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.9942
Yes	0/35 (0.0)	-	5/93 (5.4)	-	-	-	
No	1/74 (1.4)	-	5/174 (2.9)	-	-	-	
Race							0.9997
Caucasian	1/90 (1.1)	NE (NE, NE)	10/226 (4.4)	NE (13.87, NE)	3.41 (0.43, 26.94)	0.2156	
Others	0/19 (0.0)	NE (NE, NE)	0/41 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9957
<50%	0/27 (0.0)	-	1/73 (1.4)	-	-	-	
≥50%	1/77 (1.3)	-	5/168 (3.0)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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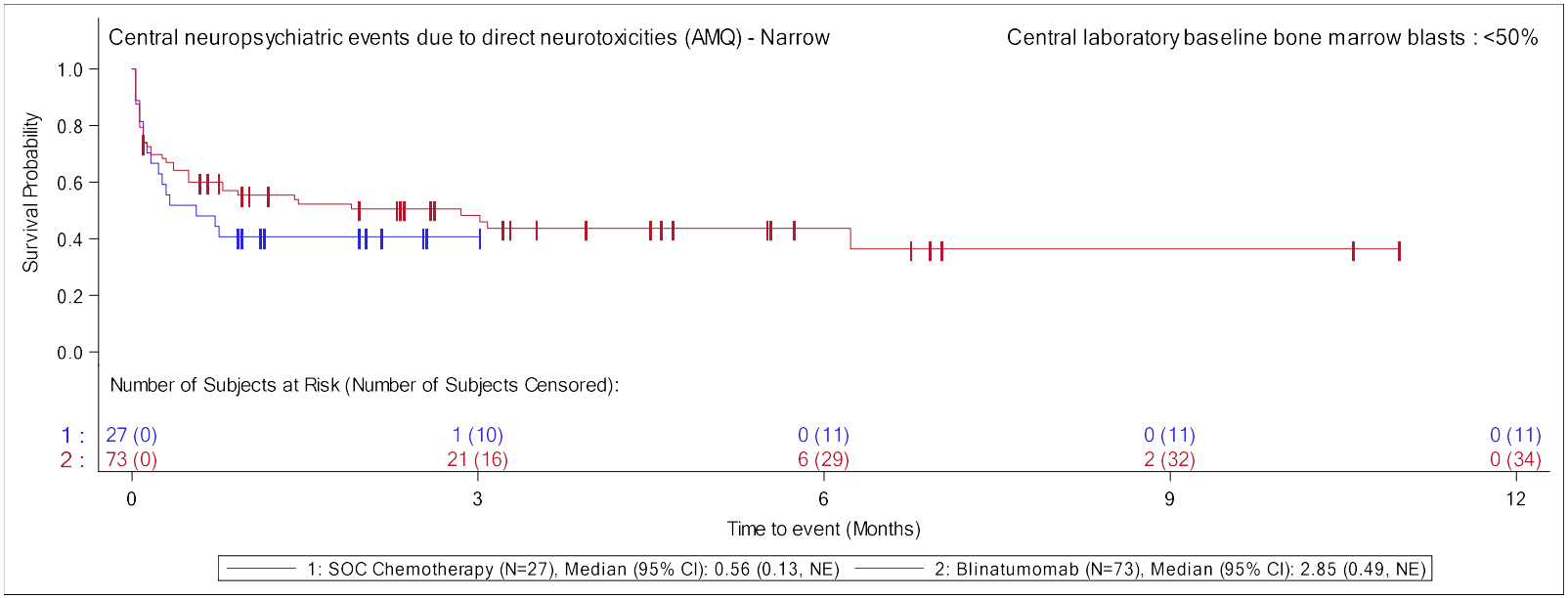
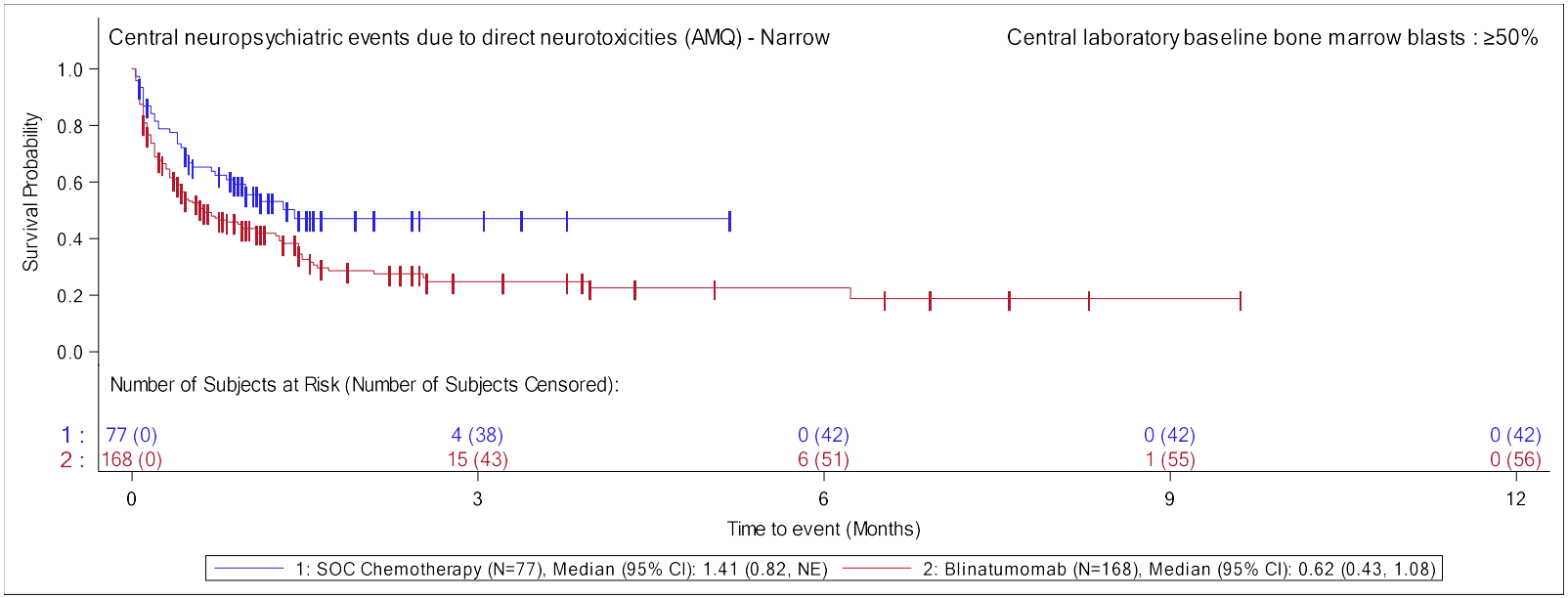
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-aesi-saf.sas
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

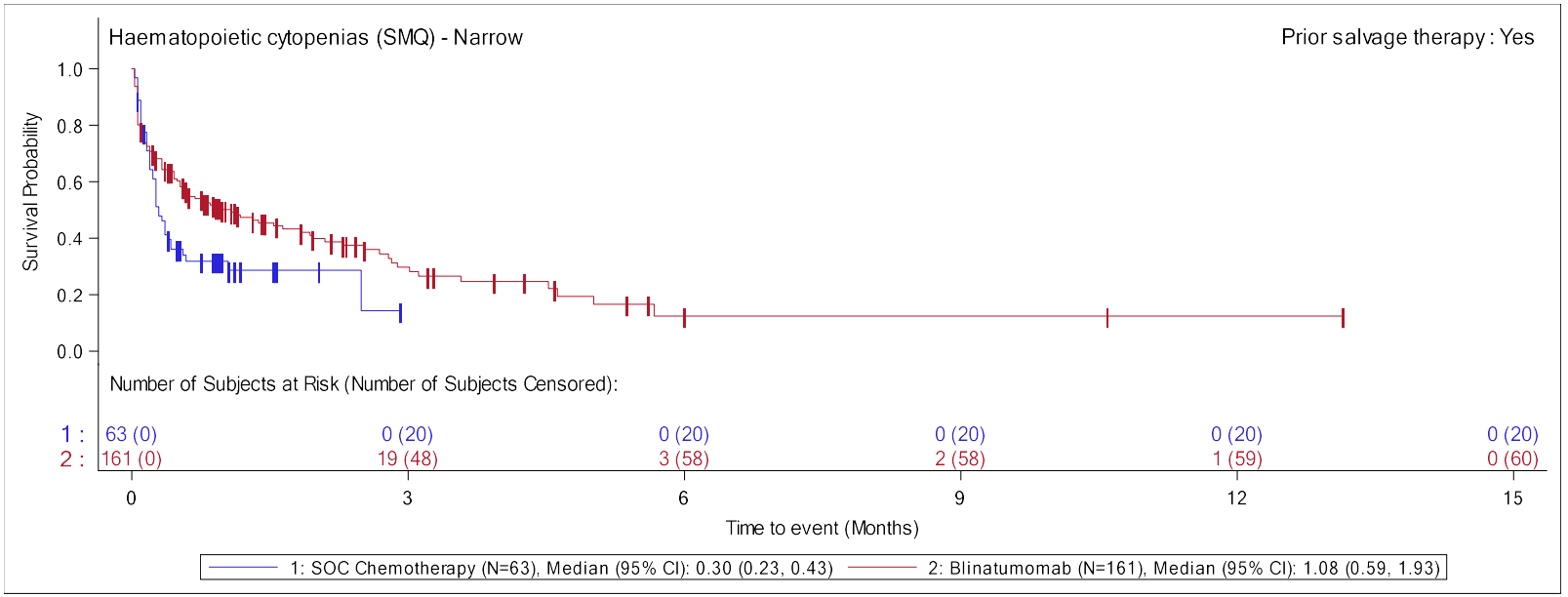
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-aesi-saf.sas
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

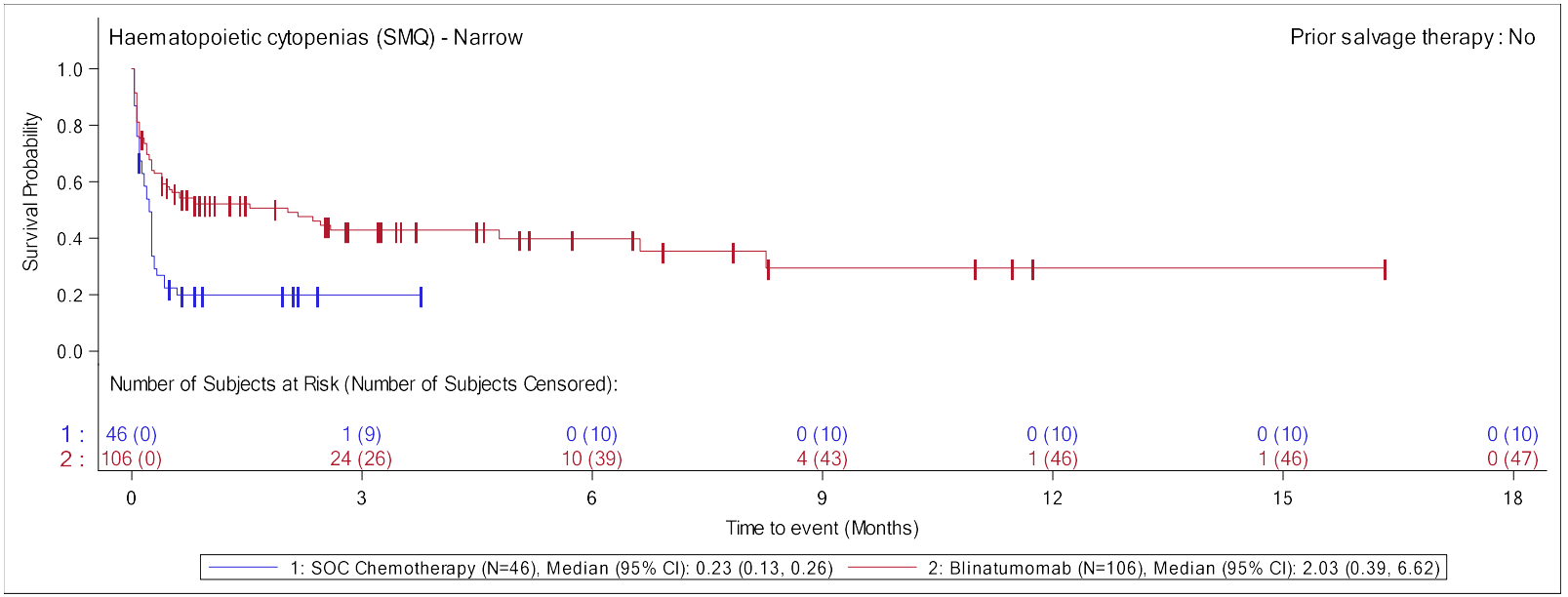
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-aesi-saf.sas
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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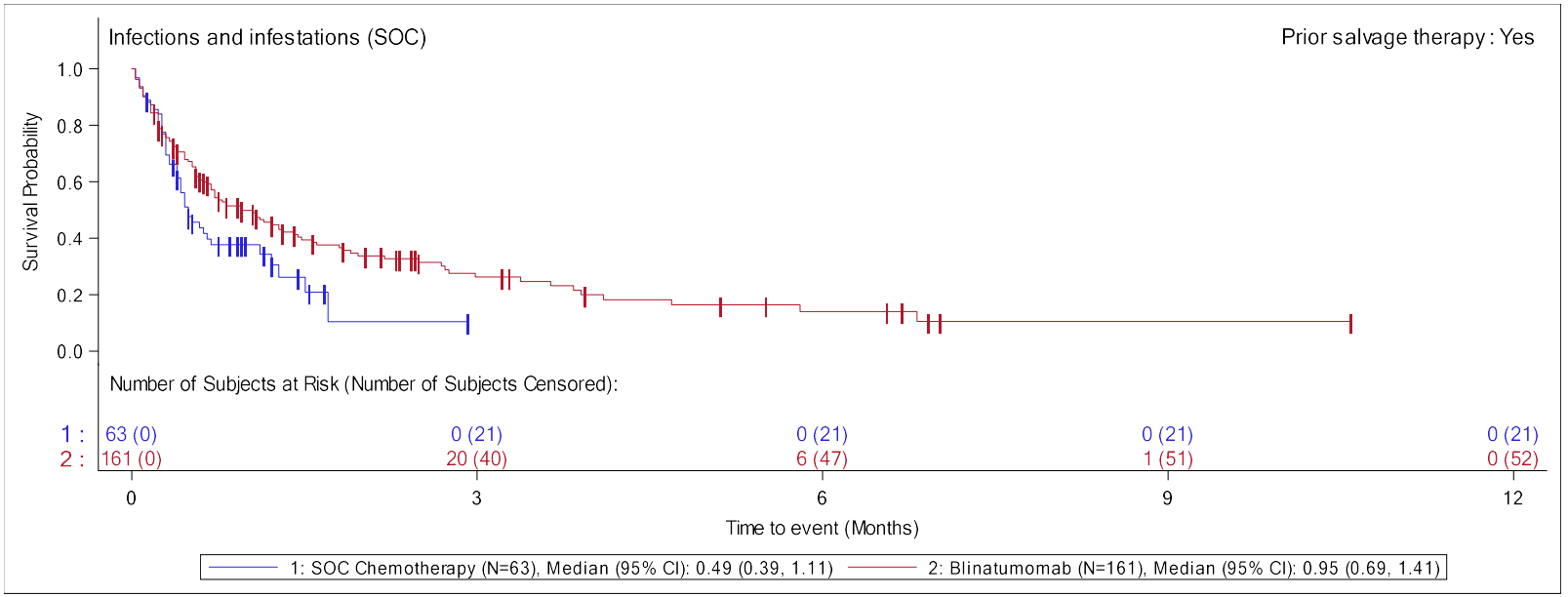
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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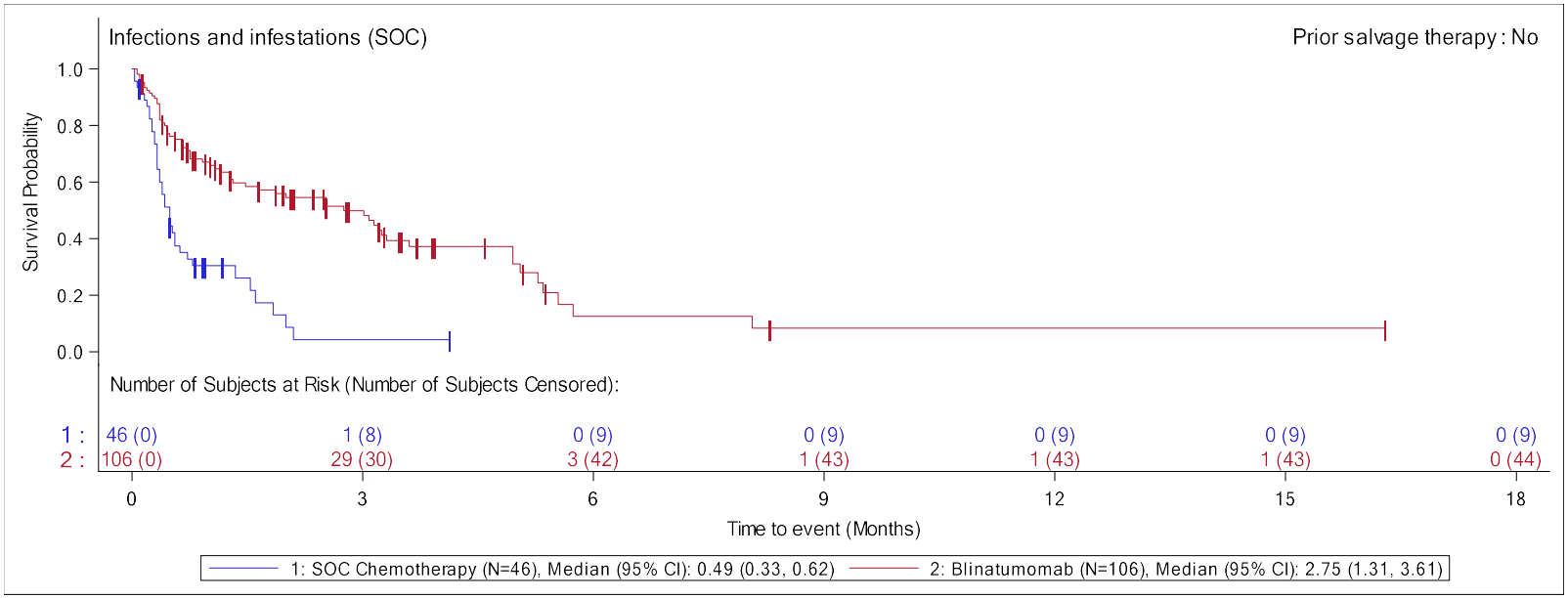
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

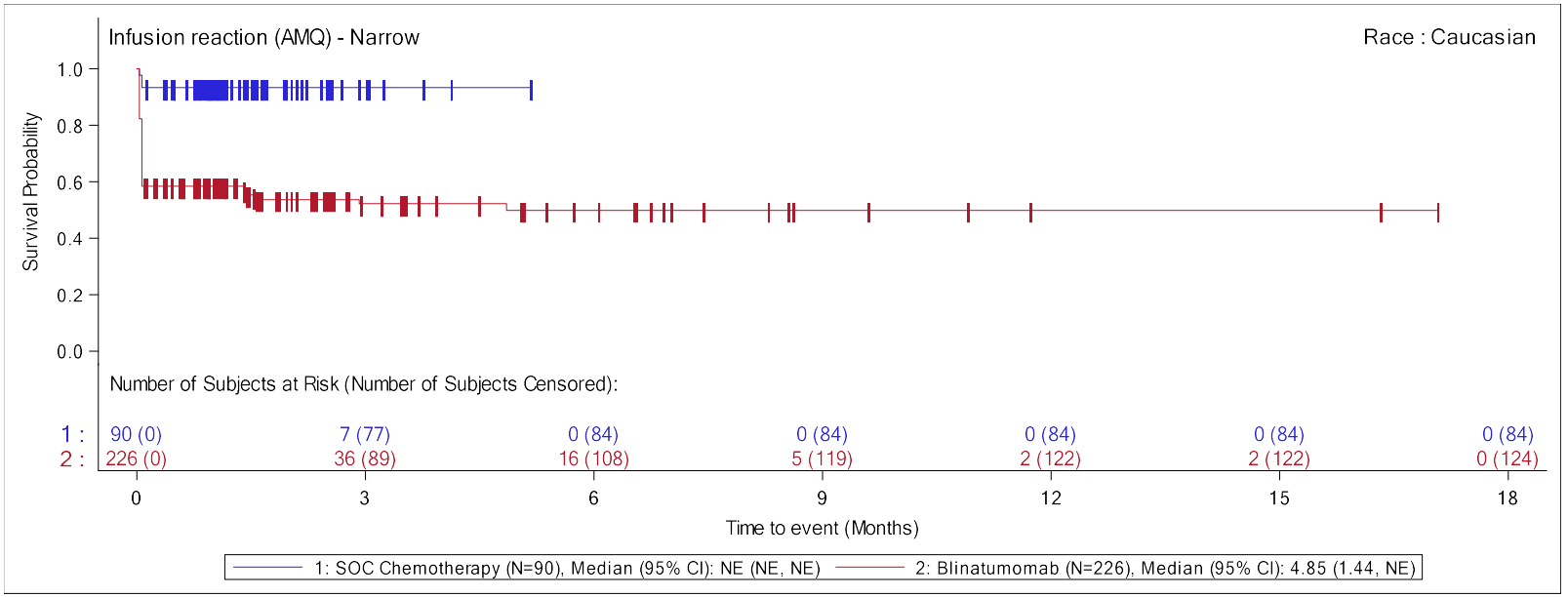
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-aesi-saf.sas
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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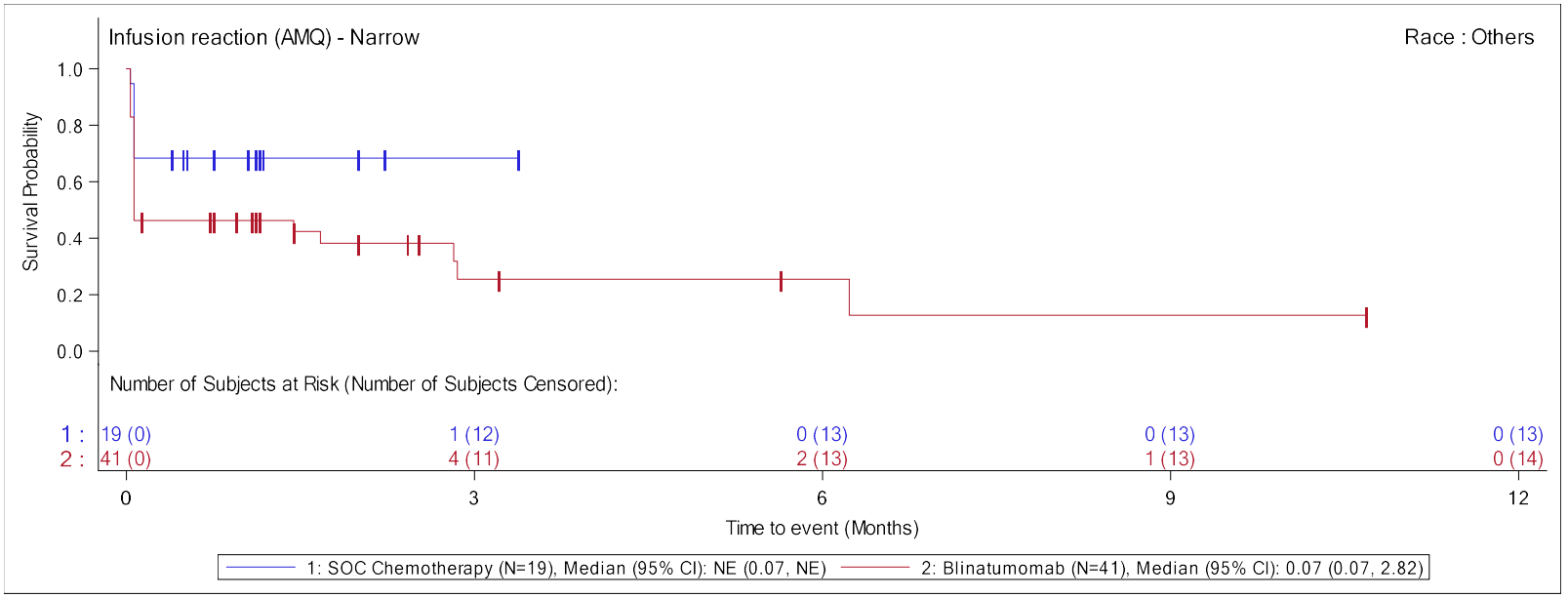
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Anhang 4-G3.7.3: Subgruppenanalysen zu SUE von besonderem Interesse

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Capillary leak syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 28MAY2025:04:56) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow	2/109 (1.8)	NE (NE, NE)	18/267 (6.7)	NE (13.15, NE)	2.67 (0.61, 11.67)	0.1738	
Age group 1							0.5425
<35 years	1/50 (2.0)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	1.26 (0.14, 11.08)	0.8346	
≥35 years	1/59 (1.7)	NE (NE, NE)	13/144 (9.0)	NE (13.15, NE)	4.25 (0.55, 32.89)	0.1305	
Age group 2							0.9091
<35 years	1/50 (2.0)	-	6/124 (4.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	8/77 (10.4)	-	-	-	
55 - 64 years	1/22 (4.5)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9623
Male	1/64 (1.6)	NE (NE, NE)	9/159 (5.7)	NE (NE, NE)	2.53 (0.32, 20.26)	0.3635	
Female	1/45 (2.2)	NE (NE, NE)	9/108 (8.3)	NE (13.15, NE)	2.99 (0.37, 24.12)	0.2794	
Region							0.8197
USA	0/13 (0.0)	NE (NE, NE)	3/30 (10.0)	NE (NE, NE)	NE (NE, NE)	0.2854	
Europe	1/68 (1.5)	NE (NE, NE)	11/177 (6.2)	NE (13.15, NE)	2.61 (0.33, 20.69)	0.3447	
Rest of the world	1/28 (3.6)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	1.79 (0.20, 15.99)	0.5986	
Prior salvage therapy							0.9901
Yes	0/63 (0.0)	NE (NE, NE)	11/161 (6.8)	13.15 (13.15, NE)	NE (NE, NE)	0.1085	
No	2/46 (4.3)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	1.34 (0.28, 6.49)	0.7129	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	2/55 (3.6)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	1.74 (0.37, 8.25)	0.4766	
1	0/34 (0.0)	NE (NE, NE)	5/91 (5.5)	13.15 (13.15, NE)	NE (NE, NE)	0.3362	
≥2	0/20 (0.0)	NE (NE, NE)	5/64 (7.8)	NE (NE, NE)	NE (NE, NE)	0.3196	
Prior alloHSCT							0.9641
Yes	1/35 (2.9)	NE (NE, NE)	10/93 (10.8)	NE (13.15, NE)	2.24 (0.28, 18.10)	0.4356	
No	1/74 (1.4)	NE (NE, NE)	8/174 (4.6)	NE (NE, NE)	2.94 (0.37, 23.61)	0.2878	
Race							0.3175
Caucasian	1/90 (1.1)	NE (NE, NE)	15/226 (6.6)	NE (13.15, NE)	4.45 (0.58, 34.14)	0.1154	
Others	1/19 (5.3)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.92 (0.09, 9.21)	0.9449	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9906
<50%	0/27 (0.0)	NE (NE, NE)	6/73 (8.2)	13.15 (13.15, NE)	NE (NE, NE)	0.2223	
≥50%	1/77 (1.3)	NE (NE, NE)	10/168 (6.0)	NE (NE, NE)	3.27 (0.41, 25.92)	0.2344	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Cytokine release syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	NE (NE, NE)	0.0542	
Age group 1							0.9998
<35 years	0/50 (0.0)	-	2/123 (1.6)	-	-	-	
≥35 years	0/59 (0.0)	-	8/144 (5.6)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	2/124 (1.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	4/77 (5.2)	-	-	-	
55 - 64 years	0/22 (0.0)	-	2/33 (6.1)	-	-	-	
≥65 years	0/12 (0.0)	-	2/33 (6.1)	-	-	-	

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[a] p-values were calculated using the unstratified log-rank test.
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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 28MAY2025:04:56) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	-	4/159 (2.5)	-	-	-	
Female	0/45 (0.0)	-	6/108 (5.6)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	6/177 (3.4)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	-	8/161 (5.0)	-	-	-	
No	0/46 (0.0)	-	2/106 (1.9)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	2/112 (1.8)	-	-	-	
1	0/34 (0.0)	-	6/91 (6.6)	-	-	-	
≥2	0/20 (0.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.9999
Yes	0/35 (0.0)	-	2/93 (2.2)	-	-	-	
No	0/74 (0.0)	-	8/174 (4.6)	-	-	-	
Race							>0.9999
Caucasian	0/90 (0.0)	-	9/226 (4.0)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9998
<50%	0/27 (0.0)	-	1/73 (1.4)	-	-	-	
≥50%	0/77 (0.0)	-	9/168 (5.4)	-	-	-	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Decreased immunoglobulins (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Haematopoietic cytopenias (SMQ) - Narrow	17/109 (15.6)	NE (2.82, NE)	34/267 (12.7)	NE (14.07, NE)	0.48 (0.26, 0.89)	0.0166	
Age group 1							0.9932
<35 years	8/50 (16.0)	NE (2.82, NE)	15/123 (12.2)	NE (NE, NE)	0.51 (0.21, 1.22)	0.1233	
≥35 years	9/59 (15.3)	NE (1.87, NE)	19/144 (13.2)	NE (14.07, NE)	0.45 (0.20, 1.06)	0.0613	
Age group 2							0.6169
<35 years	8/50 (16.0)	NE (2.82, NE)	15/124 (12.1)	NE (NE, NE)	0.50 (0.21, 1.22)	0.1226	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	7/77 (9.1)	NE (14.07, NE)	0.70 (0.14, 3.55)	0.6714	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	7/33 (21.2)	NE (2.59, NE)	0.92 (0.23, 3.70)	0.9114	
≥65 years	4/12 (33.3)	NE (0.20, NE)	5/33 (15.2)	NE (4.59, NE)	0.13 (0.02, 0.71)	0.0059	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1451
Male	9/64 (14.1)	NE (2.82, NE)	24/159 (15.1)	14.07 (14.07, NE)	0.64 (0.29, 1.41)	0.2619	
Female	8/45 (17.8)	NE (1.77, NE)	10/108 (9.3)	NE (NE, NE)	0.33 (0.12, 0.87)	0.0194	
Region							0.4684
USA	3/13 (23.1)	NE (1.28, NE)	9/30 (30.0)	NE (1.31, NE)	1.11 (0.30, 4.14)	0.8818	
Europe	8/68 (11.8)	NE (2.82, NE)	15/177 (8.5)	NE (NE, NE)	0.39 (0.16, 0.96)	0.0341	
Rest of the world	6/28 (21.4)	1.97 (1.77, NE)	10/60 (16.7)	14.07 (NE, NE)	0.42 (0.14, 1.27)	0.1159	
Prior salvage therapy							0.0029
Yes	7/63 (11.1)	NE (1.84, NE)	28/161 (17.4)	14.07 (NE, NE)	0.95 (0.41, 2.23)	0.9110	
No	10/46 (21.7)	2.82 (1.97, NE)	6/106 (5.7)	NE (NE, NE)	0.15 (0.05, 0.44)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0951
0	10/55 (18.2)	NE (2.82, NE)	8/112 (7.1)	NE (NE, NE)	0.22 (0.08, 0.60)	0.0013	
1	3/34 (8.8)	NE (1.77, NE)	15/91 (16.5)	14.07 (4.62, NE)	1.01 (0.28, 3.65)	0.9906	
≥2	4/20 (20.0)	NE (1.84, NE)	11/64 (17.2)	NE (NE, NE)	0.52 (0.16, 1.69)	0.2702	
Prior alloHSCT							0.0189
Yes	9/35 (25.7)	1.97 (1.28, NE)	10/93 (10.8)	NE (14.07, NE)	0.15 (0.06, 0.42)	<0.0001	
No	8/74 (10.8)	NE (NE, NE)	24/174 (13.8)	NE (NE, NE)	0.89 (0.39, 2.02)	0.7834	
Race							0.6133
Caucasian	16/90 (17.8)	NE (2.82, NE)	31/226 (13.7)	NE (14.07, NE)	0.46 (0.24, 0.86)	0.0124	
Others	1/19 (5.3)	NE (1.84, NE)	3/41 (7.3)	NE (NE, NE)	1.04 (0.11, 10.11)	0.9743	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7924
<50%	4/27 (14.8)	NE (NE, NE)	9/73 (12.3)	NE (NE, NE)	0.46 (0.13, 1.61)	0.2149	
≥50%	13/77 (16.9)	NE (1.97, NE)	24/168 (14.3)	NE (NE, NE)	0.53 (0.26, 1.07)	0.0736	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infections and infestations (SOC)	33/109 (30.3)	NE (2.03, NE)	75/267 (28.1)	7.44 (5.80, NE)	0.52 (0.33, 0.80)	0.0023	
Age group 1							0.5382
<35 years	13/50 (26.0)	NE (2.03, NE)	34/123 (27.6)	7.44 (4.59, NE)	0.57 (0.29, 1.12)	0.0972	
≥35 years	20/59 (33.9)	NE (1.57, NE)	41/144 (28.5)	7.25 (5.54, NE)	0.49 (0.28, 0.86)	0.0123	
Age group 2							0.5730
<35 years	13/50 (26.0)	NE (2.03, NE)	34/124 (27.4)	7.44 (4.59, NE)	0.57 (0.29, 1.12)	0.0963	
35 - 54 years	9/25 (36.0)	1.87 (0.66, NE)	19/77 (24.7)	NE (5.05, NE)	0.31 (0.13, 0.72)	0.0046	
55 - 64 years	7/22 (31.8)	NE (0.62, NE)	11/33 (33.3)	8.07 (1.84, NE)	0.61 (0.22, 1.69)	0.3403	
≥65 years	4/12 (33.3)	NE (0.75, NE)	11/33 (33.3)	6.10 (4.79, NE)	0.80 (0.24, 2.68)	0.7208	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1949
Male	19/64 (29.7)	NE (2.03, NE)	50/159 (31.4)	6.10 (5.54, 9.97)	0.62 (0.35, 1.07)	0.0830	
Female	14/45 (31.1)	NE (1.87, NE)	25/108 (23.1)	NE (5.80, NE)	0.39 (0.19, 0.80)	0.0076	
Region							0.2846
USA	2/13 (15.4)	NE (1.21, NE)	7/30 (23.3)	5.74 (2.46, NE)	1.10 (0.22, 5.52)	0.9097	
Europe	18/68 (26.5)	NE (2.03, NE)	45/177 (25.4)	8.07 (6.10, NE)	0.54 (0.30, 0.96)	0.0334	
Rest of the world	13/28 (46.4)	1.11 (0.39, NE)	23/60 (38.3)	4.79 (2.56, NE)	0.36 (0.17, 0.77)	0.0059	
Prior salvage therapy							0.2200
Yes	17/63 (27.0)	NE (1.57, NE)	46/161 (28.6)	7.44 (4.79, NE)	0.68 (0.38, 1.21)	0.1856	
No	16/46 (34.8)	NE (1.87, NE)	29/106 (27.4)	8.07 (5.74, NE)	0.34 (0.17, 0.67)	0.0013	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3410
0	16/55 (29.1)	NE (2.03, NE)	30/112 (26.8)	8.07 (6.10, NE)	0.45 (0.23, 0.89)	0.0179	
1	13/34 (38.2)	1.57 (0.98, NE)	25/91 (27.5)	5.80 (4.59, NE)	0.37 (0.18, 0.75)	0.0044	
≥2	4/20 (20.0)	NE (1.21, NE)	20/64 (31.3)	6.07 (4.03, NE)	1.06 (0.35, 3.16)	0.9257	
Prior alloHSCT							0.1940
Yes	14/35 (40.0)	NE (0.56, NE)	31/93 (33.3)	7.25 (5.05, NE)	0.36 (0.18, 0.71)	0.0022	
No	19/74 (25.7)	NE (2.03, NE)	44/174 (25.3)	7.44 (5.74, NE)	0.62 (0.36, 1.10)	0.0985	
Race							0.4219
Caucasian	28/90 (31.1)	NE (1.87, NE)	62/226 (27.4)	7.57 (6.07, NE)	0.49 (0.31, 0.79)	0.0030	
Others	5/19 (26.3)	NE (0.89, NE)	13/41 (31.7)	4.79 (2.56, NE)	0.66 (0.22, 1.96)	0.4469	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 28MAY2025:04:56) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3164
<50%	10/27 (37.0)	2.10 (1.57, NE)	19/73 (26.0)	7.25 (5.54, NE)	0.21 (0.08, 0.54)	0.0004	
≥50%	22/77 (28.6)	NE (2.03, NE)	46/168 (27.4)	7.44 (5.54, NE)	0.57 (0.33, 0.97)	0.0368	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infusion reaction (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	3/267 (1.1)	NE (NE, NE)	NE (NE, NE)	0.2674	
Age group 1							0.9987
<35 years	0/50 (0.0)	-	0/123 (0.0)	-	-	-	
≥35 years	0/59 (0.0)	-	3/144 (2.1)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	0/124 (0.0)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	2/33 (6.1)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9998
Male	0/64 (0.0)	-	1/159 (0.6)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	1/177 (0.6)	-	-	-	
Rest of the world	0/28 (0.0)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	2/161 (1.2)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	2/91 (2.2)	-	-	-	
≥2	0/20 (0.0)	-	0/64 (0.0)	-	-	-	
Prior alloHSCT							0.9987
Yes	0/35 (0.0)	-	0/93 (0.0)	-	-	-	
No	0/74 (0.0)	-	3/174 (1.7)	-	-	-	
Race							0.9999
Caucasian	0/90 (0.0)	-	2/226 (0.9)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9987
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	3/168 (1.8)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	3/267 (1.1)	NE (NE, NE)	NE (NE, NE)	0.2766	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	2/123 (1.6)	-	-	-	
≥35 years	0/59 (0.0)	-	1/144 (0.7)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	2/124 (1.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	2/159 (1.3)	-	-	-	
Female	0/45 (0.0)	-	1/108 (0.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	0/177 (0.0)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	2/161 (1.2)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	1/91 (1.1)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	1/93 (1.1)	-	-	-	
No	0/74 (0.0)	-	2/174 (1.1)	-	-	-	
Race							0.9989
Caucasian	0/90 (0.0)	-	3/226 (1.3)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9987
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	3/168 (1.8)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Lymphopenia (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Medication errors and product use issues (AMQ) - Broad	0/109 (0.0)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	NE (NE, NE)	0.0355	
Age group 1							0.9999
<35 years	0/50 (0.0)	-	7/123 (5.7)	-	-	-	
≥35 years	0/59 (0.0)	-	5/144 (3.5)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	7/124 (5.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	6/159 (3.8)	-	-	-	
Female	0/45 (0.0)	-	6/108 (5.6)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	7/177 (4.0)	-	-	-	
Rest of the world	0/28 (0.0)	-	5/60 (8.3)	-	-	-	
Prior salvage therapy							0.9999
Yes	0/63 (0.0)	-	5/161 (3.1)	-	-	-	
No	0/46 (0.0)	-	7/106 (6.6)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	9/112 (8.0)	-	-	-	
1	0/34 (0.0)	-	2/91 (2.2)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	3/93 (3.2)	-	-	-	
No	0/74 (0.0)	-	9/174 (5.2)	-	-	-	
Race							0.9998
Caucasian	0/90 (0.0)	-	7/226 (3.1)	-	-	-	
Others	0/19 (0.0)	-	5/41 (12.2)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 28MAY2025:04:56) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9974
<50%	0/27 (0.0)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0242	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Neutropenia (AMQ) - Narrow	15/109 (13.8)	NE (2.82, NE)	28/267 (10.5)	NE (14.07, NE)	0.44 (0.23, 0.86)	0.0137	
Age group 1							0.7963
<35 years	8/50 (16.0)	NE (1.97, NE)	13/123 (10.6)	NE (NE, NE)	0.41 (0.17, 1.03)	0.0517	
≥35 years	7/59 (11.9)	NE (NE, NE)	15/144 (10.4)	NE (14.07, NE)	0.49 (0.19, 1.26)	0.1326	
Age group 2							0.9527
<35 years	8/50 (16.0)	NE (1.97, NE)	13/124 (10.5)	NE (NE, NE)	0.41 (0.17, 1.03)	0.0515	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	6/77 (7.8)	NE (14.07, NE)	0.58 (0.11, 3.07)	0.5186	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	5/33 (15.2)	NE (NE, NE)	0.72 (0.17, 3.13)	0.6638	
≥65 years	2/12 (16.7)	NE (1.87, NE)	4/33 (12.1)	NE (4.59, NE)	0.23 (0.03, 1.81)	0.1307	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0093
Male	7/64 (10.9)	NE (2.82, NE)	23/159 (14.5)	14.07 (14.07, NE)	0.81 (0.34, 1.93)	0.6330	
Female	8/45 (17.8)	NE (1.77, NE)	5/108 (4.6)	NE (NE, NE)	0.15 (0.04, 0.52)	0.0006	
Region							0.5530
USA	2/13 (15.4)	NE (1.28, NE)	6/30 (20.0)	NE (2.30, NE)	1.10 (0.22, 5.51)	0.9101	
Europe	7/68 (10.3)	NE (2.82, NE)	12/177 (6.8)	NE (NE, NE)	0.34 (0.13, 0.92)	0.0277	
Rest of the world	6/28 (21.4)	1.97 (1.77, NE)	10/60 (16.7)	14.07 (NE, NE)	0.42 (0.14, 1.27)	0.1159	
Prior salvage therapy							0.0016
Yes	5/63 (7.9)	NE (NE, NE)	23/161 (14.3)	14.07 (NE, NE)	1.09 (0.40, 2.96)	0.8622	
No	10/46 (21.7)	2.82 (1.97, NE)	5/106 (4.7)	NE (NE, NE)	0.13 (0.04, 0.38)	<0.0001	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0534
0	10/55 (18.2)	NE (2.82, NE)	7/112 (6.3)	NE (NE, NE)	0.19 (0.07, 0.54)	0.0005	
1	2/34 (5.9)	NE (1.77, NE)	14/91 (15.4)	14.07 (4.62, NE)	1.35 (0.29, 6.24)	0.7013	
≥2	3/20 (15.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	0.50 (0.13, 2.01)	0.3213	
Prior alloHSCT							0.0134
Yes	9/35 (25.7)	1.97 (1.28, NE)	9/93 (9.7)	NE (14.07, NE)	0.13 (0.05, 0.37)	<0.0001	
No	6/74 (8.1)	NE (NE, NE)	19/174 (10.9)	NE (NE, NE)	0.95 (0.37, 2.44)	0.9202	
Race							0.9888
Caucasian	15/90 (16.7)	NE (2.82, NE)	26/226 (11.5)	NE (14.07, NE)	0.40 (0.20, 0.78)	0.0054	
Others	0/19 (0.0)	NE (NE, NE)	2/41 (4.9)	NE (NE, NE)	NE (NE, NE)	0.3828	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7107
<50%	4/27 (14.8)	NE (NE, NE)	8/73 (11.0)	NE (NE, NE)	0.40 (0.11, 1.42)	0.1413	
≥50%	11/77 (14.3)	NE (1.97, NE)	19/168 (11.3)	NE (NE, NE)	0.50 (0.23, 1.09)	0.0778	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Tumour lysis syndrome (SMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	3/267 (1.1)	NE (NE, NE)	NE (NE, NE)	0.3178	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	1/123 (0.8)	-	-	-	
≥35 years	0/59 (0.0)	-	2/144 (1.4)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	0/77 (0.0)	-	-	-	
55 - 64 years	0/22 (0.0)	-	2/33 (6.1)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9987
Male	0/64 (0.0)	-	3/159 (1.9)	-	-	-	
Female	0/45 (0.0)	-	0/108 (0.0)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	1/177 (0.6)	-	-	-	
Rest of the world	0/28 (0.0)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	2/161 (1.2)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	1/91 (1.1)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	1/93 (1.1)	-	-	-	
No	0/74 (0.0)	-	2/174 (1.1)	-	-	-	
Race							0.9990
Caucasian	0/90 (0.0)	-	3/226 (1.3)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

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	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9990
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	2/168 (1.2)	-	-	-	

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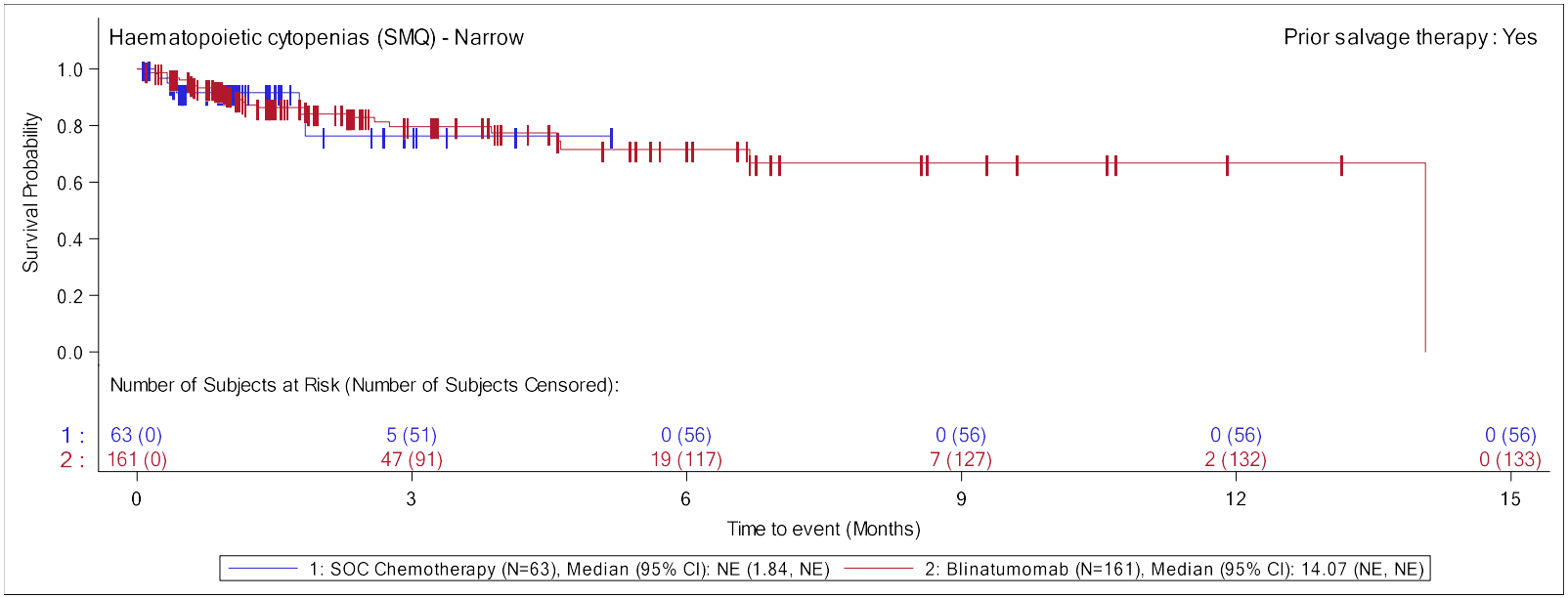
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

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Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

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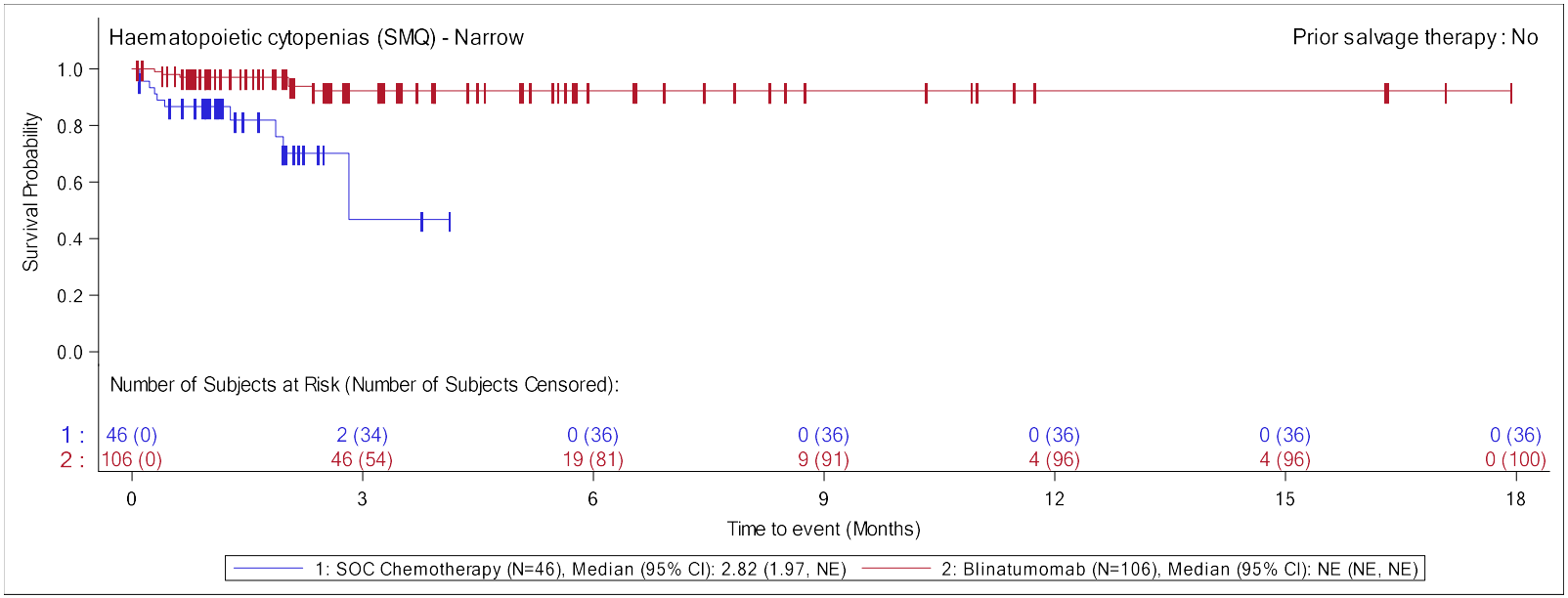

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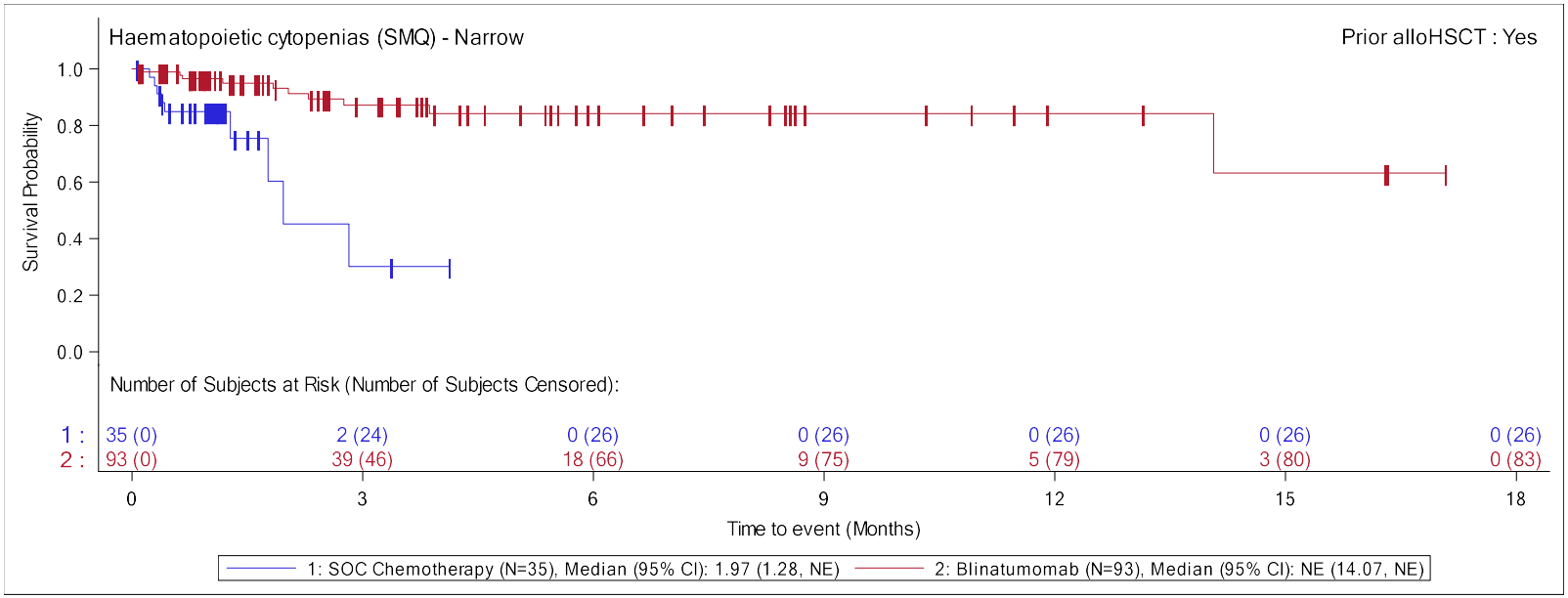

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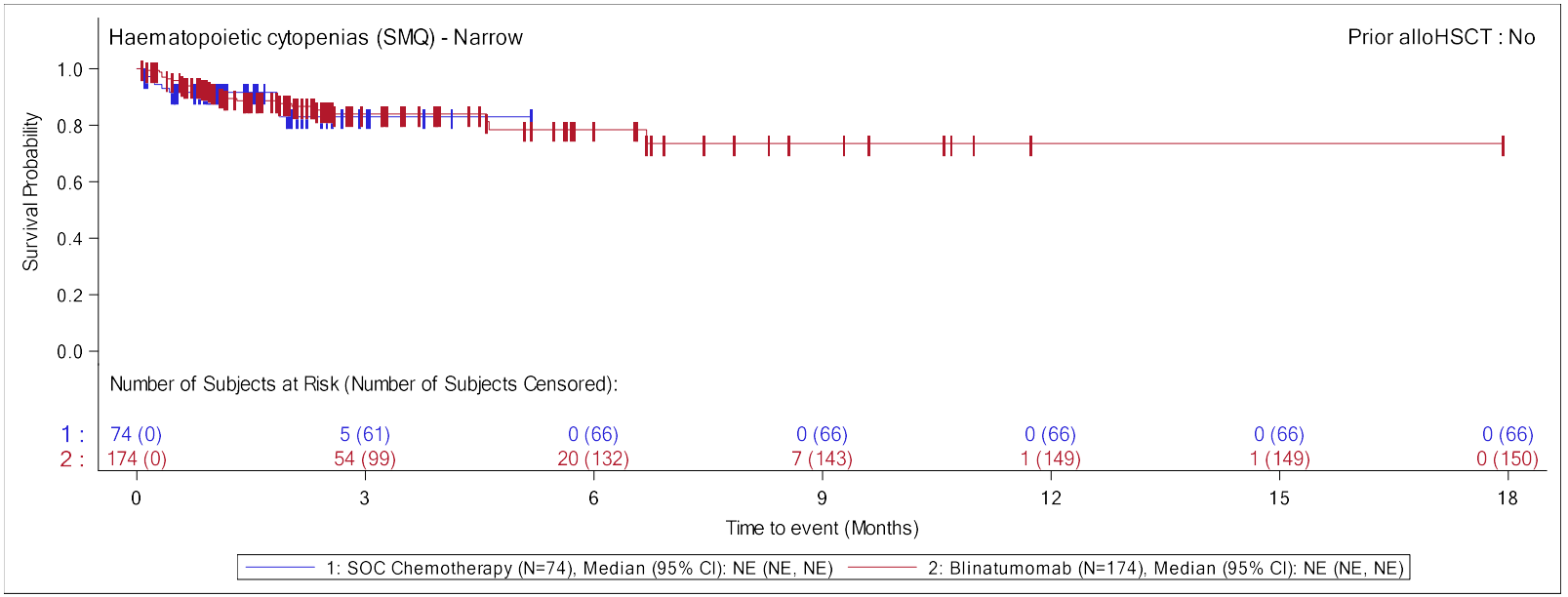

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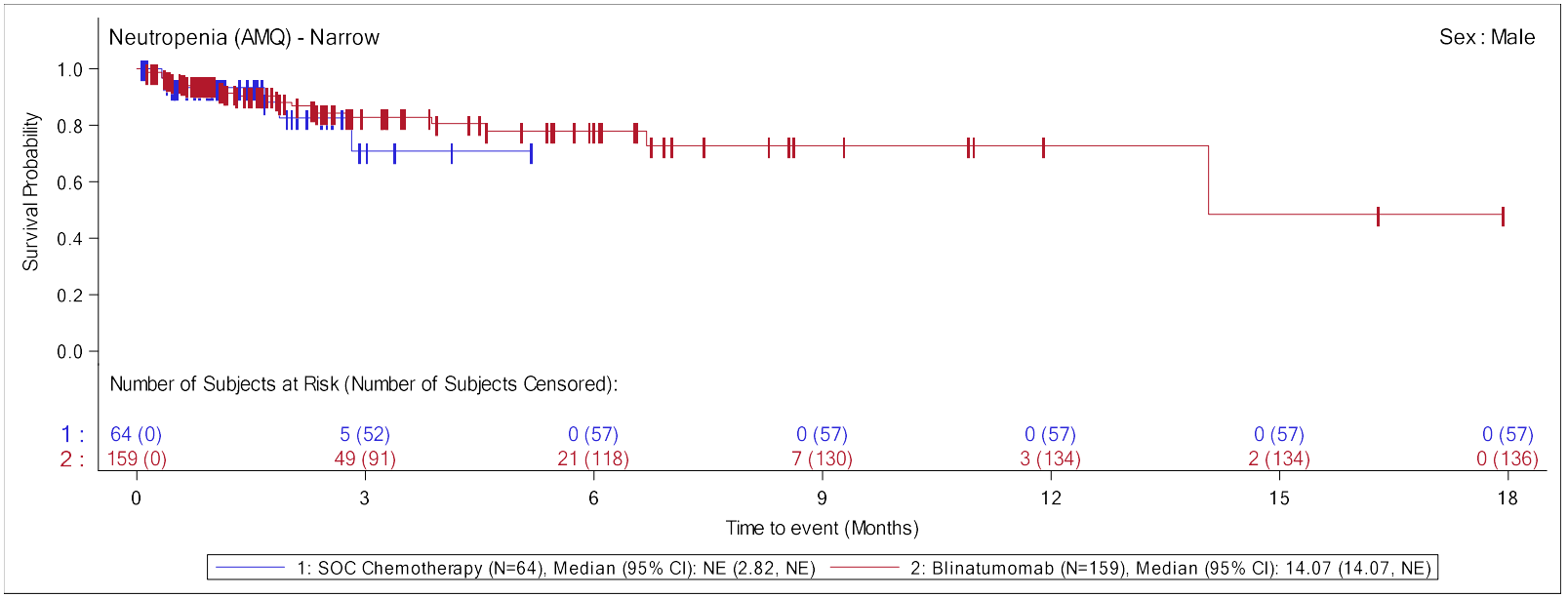
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

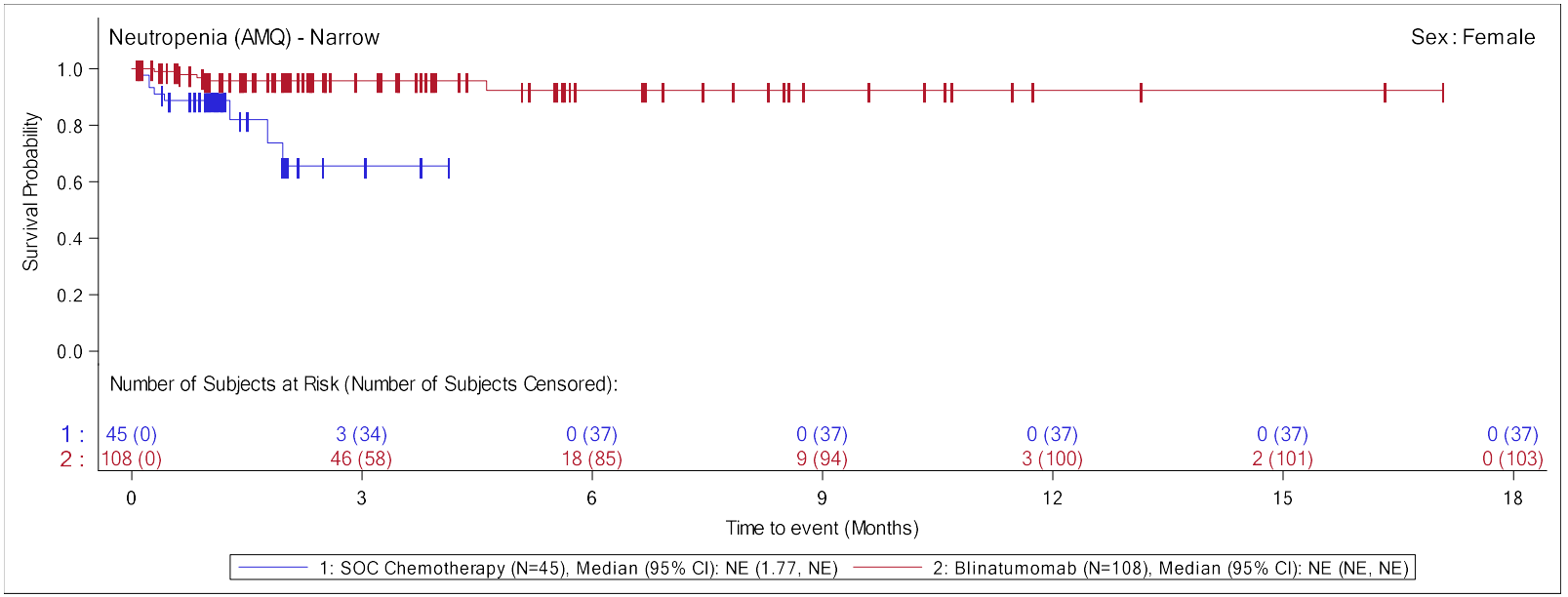
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-aesi-saf.sas
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

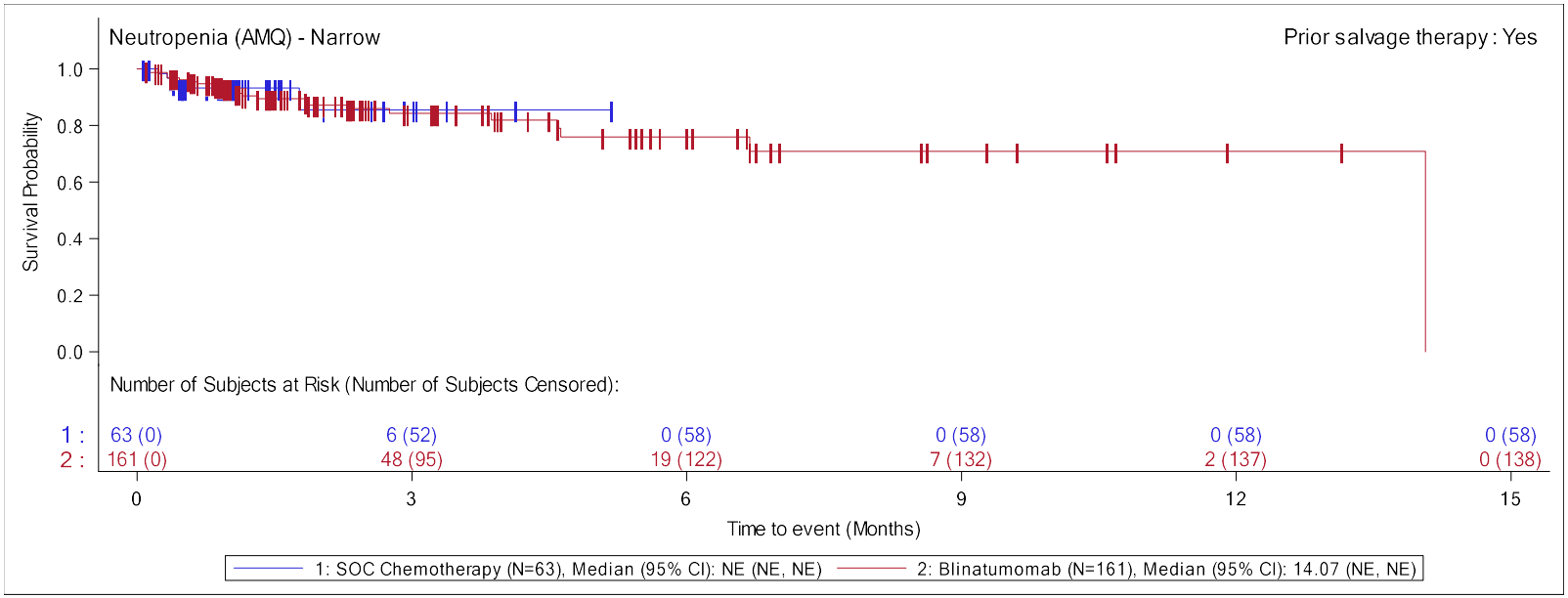
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-aesi-saf.sas
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

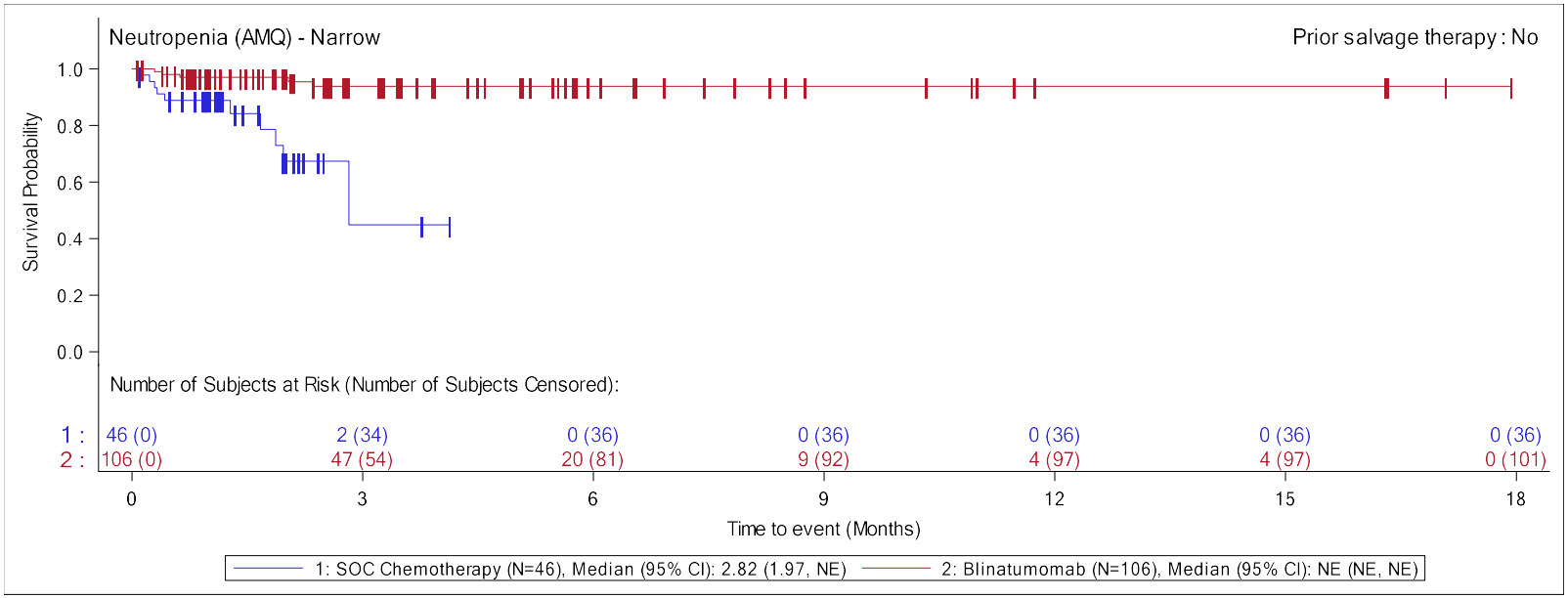
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-aesi-saf.sas
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

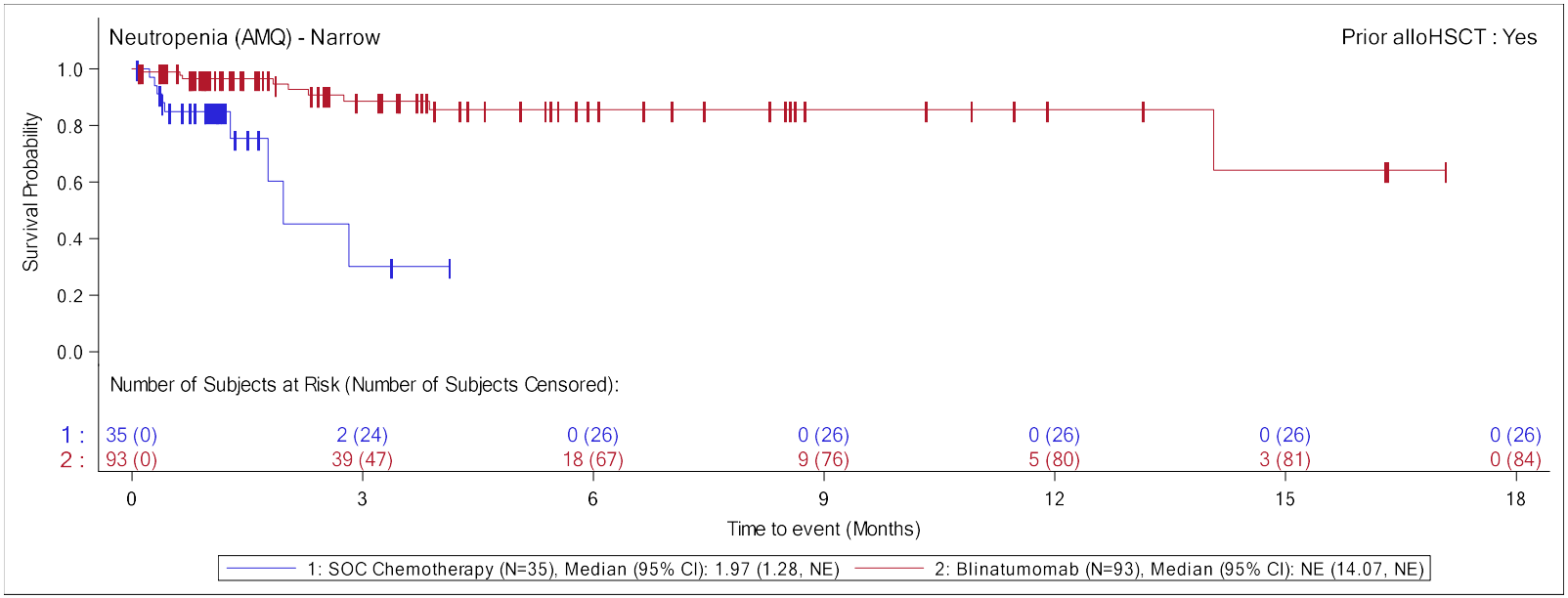
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-aesi-saf.sas
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

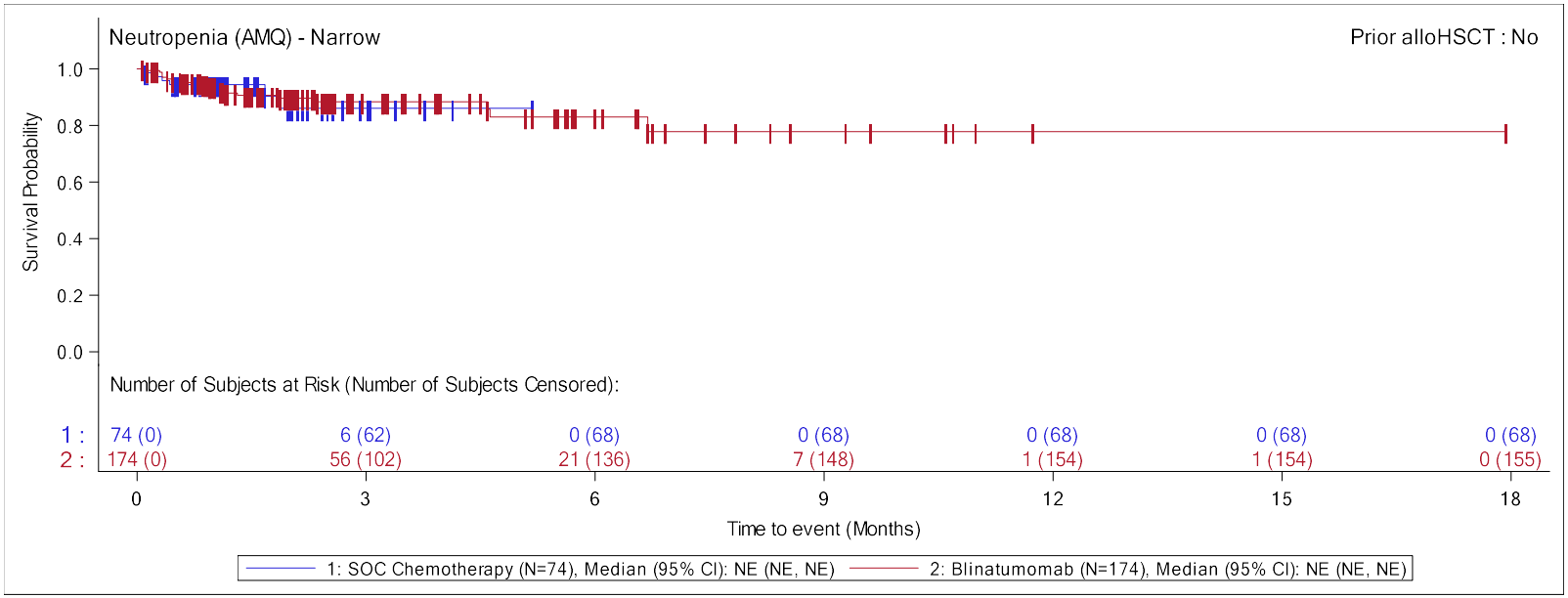
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-aesi-saf.sas
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-aesi-saf.sas
Output: f14-06-002-006-km-sub-ser-teae-aesi-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Anhang 4-G3.7.4: Subgruppenanalysen zu schweren UE von besonderem Interesse

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Capillary leak syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow	9/109 (8.3)	NE (NE, NE)	25/267 (9.4)	NE (13.15, NE)	0.92 (0.42, 1.99)	0.8294	
Age group 1							0.2983
<35 years	5/50 (10.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	0.53 (0.17, 1.60)	0.2489	
≥35 years	4/59 (6.8)	NE (NE, NE)	16/144 (11.1)	NE (13.15, NE)	1.45 (0.48, 4.37)	0.5111	
Age group 2							0.9468
<35 years	5/50 (10.0)	NE (NE, NE)	10/124 (8.1)	NE (NE, NE)	0.60 (0.20, 1.78)	0.3502	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	9/77 (11.7)	NE (NE, NE)	1.22 (0.26, 5.68)	0.8009	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	2/33 (6.1)	13.15 (NE, NE)	0.32 (0.03, 3.57)	0.3320	
≥65 years	0/12 (0.0)	NE (NE, NE)	4/33 (12.1)	NE (NE, NE)	NE (NE, NE)	0.2149	

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[a] p-values were calculated using the unstratified log-rank test.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8370
Male	5/64 (7.8)	NE (NE, NE)	13/159 (8.2)	NE (NE, NE)	0.84 (0.30, 2.39)	0.7485	
Female	4/45 (8.9)	NE (NE, NE)	12/108 (11.1)	13.15 (13.15, NE)	1.03 (0.33, 3.25)	0.9621	
Region							0.8279
USA	0/13 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	NE (NE, NE)	0.3674	
Europe	6/68 (8.8)	NE (NE, NE)	18/177 (10.2)	NE (13.15, NE)	0.93 (0.37, 2.38)	0.8826	
Rest of the world	3/28 (10.7)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)	0.56 (0.13, 2.51)	0.4462	
Prior salvage therapy							0.1716
Yes	4/63 (6.3)	NE (NE, NE)	18/161 (11.2)	13.15 (13.15, NE)	1.34 (0.45, 4.03)	0.5955	
No	5/46 (10.9)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	0.54 (0.17, 1.73)	0.2959	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6633
0	5/55 (9.1)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	0.88 (0.30, 2.60)	0.8245	
1	1/34 (2.9)	NE (NE, NE)	7/91 (7.7)	13.15 (13.15, NE)	2.01 (0.24, 16.81)	0.5119	
≥2	3/20 (15.0)	NE (1.11, NE)	8/64 (12.5)	NE (NE, NE)	0.60 (0.15, 2.30)	0.4463	
Prior alloHSCT							0.6310
Yes	5/35 (14.3)	NE (NE, NE)	13/93 (14.0)	NE (13.15, NE)	0.75 (0.26, 2.15)	0.5902	
No	4/74 (5.4)	NE (NE, NE)	12/174 (6.9)	NE (NE, NE)	1.06 (0.34, 3.33)	0.9176	
Race							0.2055
Caucasian	6/90 (6.7)	NE (NE, NE)	22/226 (9.7)	NE (13.15, NE)	1.25 (0.50, 3.12)	0.6250	
Others	3/19 (15.8)	NE (1.11, NE)	3/41 (7.3)	NE (NE, NE)	0.27 (0.05, 1.43)	0.0998	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2252
<50%	3/27 (11.1)	NE (NE, NE)	5/73 (6.8)	13.15 (13.15, NE)	0.30 (0.06, 1.49)	0.1184	
≥50%	5/77 (6.5)	NE (NE, NE)	17/168 (10.1)	NE (NE, NE)	1.38 (0.51, 3.76)	0.5256	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Cytokine release syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	NE (NE, NE)	0.0326	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	5/123 (4.1)	-	-	-	
≥35 years	0/59 (0.0)	-	8/144 (5.6)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	5/124 (4.0)	-	-	-	
35 - 54 years	0/25 (0.0)	-	3/77 (3.9)	-	-	-	
55 - 64 years	0/22 (0.0)	-	2/33 (6.1)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9998
Male	0/64 (0.0)	-	5/159 (3.1)	-	-	-	
Female	0/45 (0.0)	-	8/108 (7.4)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	9/177 (5.1)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	9/161 (5.6)	-	-	-	
No	0/46 (0.0)	-	4/106 (3.8)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	4/112 (3.6)	-	-	-	
1	0/34 (0.0)	-	7/91 (7.7)	-	-	-	
≥2	0/20 (0.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.9998
Yes	0/35 (0.0)	NE (NE, NE)	2/93 (2.2)	NE (NE, NE)	NE (NE, NE)	0.4614	
No	0/74 (0.0)	NE (NE, NE)	11/174 (6.3)	NE (8.33, NE)	NE (NE, NE)	0.0419	
Race							0.9999
Caucasian	0/90 (0.0)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	NE (NE, NE)	0.0431	
Others	0/19 (0.0)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	NE (NE, NE)	0.4960	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9974
<50%	0/27 (0.0)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0224	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Decreased immunoglobulins (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	7/267 (2.6)	NE (NE, NE)	NE (NE, NE)	0.4170	
Age group 1							0.9997
<35 years	0/50 (0.0)	-	6/123 (4.9)	-	-	-	
≥35 years	0/59 (0.0)	-	1/144 (0.7)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	6/124 (4.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	-	5/159 (3.1)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	5/177 (2.8)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							0.9997
Yes	0/63 (0.0)	-	6/161 (3.7)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	5/91 (5.5)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.9998
Yes	0/35 (0.0)	-	6/93 (6.5)	-	-	-	
No	0/74 (0.0)	-	1/174 (0.6)	-	-	-	
Race							>0.9999
Caucasian	0/90 (0.0)	-	6/226 (2.7)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9999
<50%	0/27 (0.0)	-	3/73 (4.1)	-	-	-	
≥50%	0/77 (0.0)	-	2/168 (1.2)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Haematopoietic cytopenias (SMQ) - Narrow	74/109 (67.9)	0.26 (0.26, 0.36)	141/267 (52.8)	2.07 (1.08, 3.11)	0.52 (0.39, 0.69)	<0.0001	
Age group 1							0.4675
<35 years	29/50 (58.0)	0.33 (0.26, NE)	61/123 (49.6)	2.52 (1.54, 4.43)	0.57 (0.36, 0.89)	0.0122	
≥35 years	45/59 (76.3)	0.26 (0.20, 0.30)	80/144 (55.6)	1.31 (0.52, 3.11)	0.49 (0.34, 0.71)	0.0001	
Age group 2							0.7395
<35 years	29/50 (58.0)	0.33 (0.26, NE)	61/124 (49.2)	2.52 (1.54, 6.69)	0.56 (0.36, 0.89)	0.0117	
35 - 54 years	18/25 (72.0)	0.26 (0.23, 0.56)	43/77 (55.8)	0.85 (0.52, 3.11)	0.57 (0.32, 0.99)	0.0419	
55 - 64 years	19/22 (86.4)	0.26 (0.10, 0.43)	19/33 (57.6)	1.18 (0.39, NE)	0.36 (0.18, 0.71)	0.0023	
≥65 years	8/12 (66.7)	0.23 (0.03, NE)	18/33 (54.5)	4.52 (0.23, 8.26)	0.53 (0.22, 1.27)	0.1373	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2648
Male	40/64 (62.5)	0.33 (0.26, 0.56)	84/159 (52.8)	2.07 (1.08, 3.87)	0.57 (0.39, 0.84)	0.0035	
Female	34/45 (75.6)	0.26 (0.20, 0.30)	57/108 (52.8)	2.10 (0.62, 4.62)	0.47 (0.30, 0.73)	0.0006	
Region							0.2342
USA	8/13 (61.5)	0.39 (0.20, NE)	20/30 (66.7)	0.51 (0.33, 1.31)	0.91 (0.40, 2.09)	0.8141	
Europe	44/68 (64.7)	0.26 (0.26, 0.43)	89/177 (50.3)	2.59 (0.92, 4.75)	0.55 (0.38, 0.80)	0.0013	
Rest of the world	22/28 (78.6)	0.26 (0.13, 0.36)	32/60 (53.3)	2.10 (0.79, 3.87)	0.31 (0.17, 0.55)	<0.0001	
Prior salvage therapy							0.0631
Yes	39/63 (61.9)	0.36 (0.26, 0.59)	88/161 (54.7)	1.93 (0.92, 3.02)	0.61 (0.42, 0.90)	0.0104	
No	35/46 (76.1)	0.26 (0.20, 0.30)	53/106 (50.0)	2.36 (0.62, NE)	0.42 (0.27, 0.65)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4544
0	39/55 (70.9)	0.26 (0.23, 0.30)	57/112 (50.9)	2.59 (0.75, 6.85)	0.46 (0.30, 0.70)	0.0003	
1	23/34 (67.6)	0.33 (0.20, 0.59)	49/91 (53.8)	1.93 (0.79, 3.57)	0.47 (0.27, 0.79)	0.0031	
≥2	12/20 (60.0)	0.39 (0.20, NE)	35/64 (54.7)	1.08 (0.52, 3.87)	0.69 (0.36, 1.34)	0.2560	
Prior alloHSCT							0.2618
Yes	27/35 (77.1)	0.26 (0.20, 0.39)	47/93 (50.5)	2.52 (1.18, 4.43)	0.43 (0.26, 0.71)	0.0005	
No	47/74 (63.5)	0.30 (0.23, 0.43)	94/174 (54.0)	1.54 (0.79, 4.52)	0.58 (0.41, 0.83)	0.0025	
Race							0.8440
Caucasian	61/90 (67.8)	0.26 (0.23, 0.36)	121/226 (53.5)	2.20 (0.92, 3.57)	0.54 (0.39, 0.74)	<0.0001	
Others	13/19 (68.4)	0.36 (0.26, 0.59)	20/41 (48.8)	1.64 (0.59, NE)	0.44 (0.21, 0.89)	0.0203	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0642
<50%	20/27 (74.1)	0.26 (0.16, 0.36)	35/73 (47.9)	4.43 (2.07, NE)	0.30 (0.17, 0.55)	<0.0001	
≥50%	52/77 (67.5)	0.30 (0.23, 0.43)	92/168 (54.8)	0.92 (0.52, 3.11)	0.62 (0.44, 0.88)	0.0058	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infections and infestations (SOC)	57/109 (52.3)	1.11 (0.62, 2.03)	91/267 (34.1)	6.10 (5.54, NE)	0.33 (0.23, 0.48)	<0.0001	
Age group 1							0.1698
<35 years	21/50 (42.0)	2.00 (0.62, NE)	41/123 (33.3)	6.07 (4.36, NE)	0.40 (0.23, 0.70)	0.0010	
≥35 years	36/59 (61.0)	0.66 (0.43, 1.51)	50/144 (34.7)	7.25 (5.05, NE)	0.30 (0.19, 0.47)	<0.0001	
Age group 2							0.6259
<35 years	21/50 (42.0)	2.00 (0.62, NE)	41/124 (33.1)	6.07 (4.36, NE)	0.40 (0.23, 0.70)	0.0010	
35 - 54 years	14/25 (56.0)	0.66 (0.36, NE)	25/77 (32.5)	7.25 (2.75, NE)	0.25 (0.13, 0.52)	<0.0001	
55 - 64 years	14/22 (63.6)	0.67 (0.30, NE)	13/33 (39.4)	5.80 (1.84, NE)	0.31 (0.13, 0.71)	0.0037	
≥65 years	8/12 (66.7)	0.62 (0.26, NE)	12/33 (36.4)	6.10 (1.48, NE)	0.40 (0.16, 1.02)	0.0465	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9286
Male	35/64 (54.7)	1.11 (0.52, 2.03)	57/159 (35.8)	6.07 (4.59, 8.07)	0.33 (0.21, 0.52)	<0.0001	
Female	22/45 (48.9)	1.34 (0.49, NE)	34/108 (31.5)	7.25 (4.79, NE)	0.35 (0.20, 0.62)	0.0002	
Region							0.2684
USA	5/13 (38.5)	NE (0.33, NE)	11/30 (36.7)	5.74 (1.48, NE)	0.62 (0.21, 1.86)	0.3896	
Europe	33/68 (48.5)	1.51 (0.62, NE)	55/177 (31.1)	7.44 (5.87, NE)	0.34 (0.22, 0.55)	<0.0001	
Rest of the world	19/28 (67.9)	0.49 (0.39, 0.69)	25/60 (41.7)	4.36 (2.10, NE)	0.21 (0.11, 0.42)	<0.0001	
Prior salvage therapy							0.1184
Yes	32/63 (50.8)	1.11 (0.49, NE)	62/161 (38.5)	5.80 (2.75, 7.57)	0.42 (0.27, 0.65)	<0.0001	
No	25/46 (54.3)	1.34 (0.49, 2.10)	29/106 (27.4)	8.07 (5.74, NE)	0.22 (0.12, 0.40)	<0.0001	

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Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1179
0	28/55 (50.9)	1.34 (0.52, NE)	33/112 (29.5)	8.07 (5.87, NE)	0.26 (0.15, 0.46)	<0.0001	
1	22/34 (64.7)	0.59 (0.33, 1.11)	33/91 (36.3)	4.79 (2.69, 7.57)	0.27 (0.15, 0.47)	<0.0001	
≥2	7/20 (35.0)	NE (0.49, NE)	25/64 (39.1)	5.05 (1.61, NE)	0.70 (0.30, 1.68)	0.4250	
Prior alloHSCT							0.6087
Yes	19/35 (54.3)	0.72 (0.46, NE)	34/93 (36.6)	6.07 (4.59, NE)	0.28 (0.15, 0.52)	<0.0001	
No	38/74 (51.4)	1.34 (0.62, 2.10)	57/174 (32.8)	7.44 (4.36, NE)	0.36 (0.23, 0.55)	<0.0001	
Race							0.5744
Caucasian	47/90 (52.2)	1.34 (0.59, 2.10)	73/226 (32.3)	7.25 (5.80, NE)	0.33 (0.22, 0.48)	<0.0001	
Others	10/19 (52.6)	0.89 (0.33, NE)	18/41 (43.9)	3.38 (1.31, NE)	0.35 (0.15, 0.83)	0.0128	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4672
<50%	14/27 (51.9)	1.51 (0.43, NE)	23/73 (31.5)	5.87 (5.54, NE)	0.14 (0.06, 0.33)	<0.0001	
≥50%	41/77 (53.2)	0.89 (0.52, 2.03)	59/168 (35.1)	6.10 (4.30, NE)	0.38 (0.25, 0.58)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infusion reaction (AMQ) - Narrow	1/109 (0.9)	NE (NE, NE)	17/267 (6.4)	NE (NE, NE)	6.38 (0.84, 48.20)	0.0384	
Age group 1							0.9904
<35 years	1/50 (2.0)	NE (NE, NE)	7/123 (5.7)	NE (NE, NE)	2.19 (0.26, 18.39)	0.4587	
≥35 years	0/59 (0.0)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)	NE (NE, NE)	0.0391	
Age group 2							>0.9999
<35 years	1/50 (2.0)	-	7/124 (5.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	6/77 (7.8)	-	-	-	
55 - 64 years	0/22 (0.0)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9919
Male	1/64 (1.6)	NE (NE, NE)	6/159 (3.8)	NE (NE, NE)	1.77 (0.20, 15.38)	0.5983	
Female	0/45 (0.0)	NE (NE, NE)	11/108 (10.2)	NE (NE, NE)	NE (NE, NE)	0.0274	
Region							0.9999
USA	0/13 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	NE (NE, NE)	0.3461	
Europe	0/68 (0.0)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	NE (NE, NE)	0.0463	
Rest of the world	1/28 (3.6)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	1.41 (0.15, 13.53)	0.7657	
Prior salvage therapy							0.9916
Yes	1/63 (1.6)	NE (NE, NE)	9/161 (5.6)	NE (NE, NE)	2.93 (0.36, 23.52)	0.2884	
No	0/46 (0.0)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	NE (NE, NE)	0.0573	

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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	8/112 (7.1)	-	-	-	
1	0/34 (0.0)	-	5/91 (5.5)	-	-	-	
≥2	1/20 (5.0)	-	4/64 (6.3)	-	-	-	
Prior alloHSCT							0.9888
Yes	1/35 (2.9)	NE (NE, NE)	3/93 (3.2)	NE (NE, NE)	0.76 (0.07, 8.34)	0.8201	
No	0/74 (0.0)	NE (NE, NE)	14/174 (8.0)	NE (NE, NE)	NE (NE, NE)	0.0153	
Race							0.9919
Caucasian	1/90 (1.1)	NE (NE, NE)	13/226 (5.8)	NE (NE, NE)	4.88 (0.63, 37.56)	0.0903	
Others	0/19 (0.0)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	NE (NE, NE)	0.2220	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9909
<50%	0/27 (0.0)	NE (NE, NE)	3/73 (4.1)	NE (NE, NE)	NE (NE, NE)	0.3814	
≥50%	1/77 (1.3)	NE (NE, NE)	13/168 (7.7)	NE (NE, NE)	6.16 (0.81, 47.07)	0.0442	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow	16/109 (14.7)	NE (3.02, NE)	34/267 (12.7)	NE (NE, NE)	0.80 (0.44, 1.46)	0.4688	
Age group 1							0.1175
<35 years	10/50 (20.0)	NE (3.02, NE)	14/123 (11.4)	NE (NE, NE)	0.48 (0.21, 1.10)	0.0756	
≥35 years	6/59 (10.2)	NE (NE, NE)	20/144 (13.9)	NE (NE, NE)	1.37 (0.55, 3.43)	0.4971	
Age group 2							0.1307
<35 years	10/50 (20.0)	NE (3.02, NE)	14/124 (11.3)	NE (NE, NE)	0.48 (0.21, 1.09)	0.0746	
35 - 54 years	3/25 (12.0)	NE (NE, NE)	12/77 (15.6)	NE (NE, NE)	1.20 (0.34, 4.27)	0.7806	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	7/33 (21.2)	NE (NE, NE)	4.97 (0.61, 40.43)	0.0943	
≥65 years	2/12 (16.7)	NE (0.95, NE)	1/33 (3.0)	NE (NE, NE)	0.21 (0.02, 2.37)	0.1666	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8067
Male	11/64 (17.2)	NE (NE, NE)	25/159 (15.7)	NE (NE, NE)	0.82 (0.40, 1.68)	0.5917	
Female	5/45 (11.1)	NE (3.02, NE)	9/108 (8.3)	NE (NE, NE)	0.72 (0.24, 2.19)	0.5582	
Region							0.9840
USA	4/13 (30.8)	3.02 (0.95, NE)	8/30 (26.7)	NE (2.46, NE)	0.79 (0.24, 2.65)	0.7144	
Europe	8/68 (11.8)	NE (NE, NE)	17/177 (9.6)	NE (NE, NE)	0.81 (0.35, 1.89)	0.6260	
Rest of the world	4/28 (14.3)	NE (NE, NE)	9/60 (15.0)	NE (NE, NE)	1.01 (0.31, 3.28)	0.9857	
Prior salvage therapy							0.3377
Yes	11/63 (17.5)	NE (NE, NE)	20/161 (12.4)	NE (NE, NE)	0.64 (0.30, 1.33)	0.2262	
No	5/46 (10.9)	NE (3.02, NE)	14/106 (13.2)	NE (NE, NE)	1.17 (0.42, 3.28)	0.7683	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5977
0	6/55 (10.9)	NE (3.02, NE)	14/112 (12.5)	NE (NE, NE)	1.09 (0.42, 2.87)	0.8588	
1	5/34 (14.7)	NE (NE, NE)	8/91 (8.8)	NE (NE, NE)	0.53 (0.17, 1.64)	0.2650	
≥2	5/20 (25.0)	NE (0.56, NE)	12/64 (18.8)	NE (NE, NE)	0.66 (0.23, 1.90)	0.4397	
Prior alloHSCT							0.8944
Yes	6/35 (17.1)	NE (NE, NE)	15/93 (16.1)	NE (NE, NE)	0.87 (0.34, 2.27)	0.7728	
No	10/74 (13.5)	NE (3.02, NE)	19/174 (10.9)	NE (NE, NE)	0.75 (0.35, 1.62)	0.4570	
Race							0.9801
Caucasian	14/90 (15.6)	NE (3.02, NE)	30/226 (13.3)	NE (NE, NE)	0.81 (0.43, 1.54)	0.5177	
Others	2/19 (10.5)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.69 (0.12, 3.97)	0.6795	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1413
<50%	1/27 (3.7)	NE (NE, NE)	10/73 (13.7)	NE (NE, NE)	3.62 (0.46, 28.41)	0.1905	
≥50%	14/77 (18.2)	NE (NE, NE)	23/168 (13.7)	NE (NE, NE)	0.71 (0.36, 1.38)	0.3051	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Lymphopenia (AMQ) - Narrow	4/109 (3.7)	NE (NE, NE)	4/267 (1.5)	NE (NE, NE)	0.30 (0.07, 1.36)	0.0980	
Age group 1							0.9704
<35 years	1/50 (2.0)	-	1/123 (0.8)	-	-	-	
≥35 years	3/59 (5.1)	-	3/144 (2.1)	-	-	-	
Age group 2							0.9603
<35 years	1/50 (2.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	2/25 (8.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	1/22 (4.5)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4945
Male	3/64 (4.7)	-	2/159 (1.3)	-	-	-	
Female	1/45 (2.2)	-	2/108 (1.9)	-	-	-	
Region							0.7321
USA	1/13 (7.7)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	2/177 (1.1)	-	-	-	
Rest of the world	3/28 (10.7)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							0.9445
Yes	2/63 (3.2)	-	2/161 (1.2)	-	-	-	
No	2/46 (4.3)	-	2/106 (1.9)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6821
0	1/55 (1.8)	-	2/112 (1.8)	-	-	-	
1	2/34 (5.9)	-	1/91 (1.1)	-	-	-	
≥2	1/20 (5.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.7924
Yes	2/35 (5.7)	-	2/93 (2.2)	-	-	-	
No	2/74 (2.7)	-	2/174 (1.1)	-	-	-	
Race							0.9944
Caucasian	4/90 (4.4)	-	3/226 (1.3)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5703
<50%	1/27 (3.7)	-	2/73 (2.7)	-	-	-	
≥50%	3/77 (3.9)	-	2/168 (1.2)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Medication errors and product use issues (AMQ) - Broad	0/109 (0.0)	NE (NE, NE)	4/267 (1.5)	NE (NE, NE)	NE (NE, NE)	0.2829	
Age group 1							0.9998
<35 years	0/50 (0.0)	-	1/123 (0.8)	-	-	-	
≥35 years	0/59 (0.0)	-	3/144 (2.1)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	0/77 (0.0)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	2/159 (1.3)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	4/177 (2.3)	-	-	-	
Rest of the world	0/28 (0.0)	-	0/60 (0.0)	-	-	-	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	-	1/161 (0.6)	-	-	-	
No	0/46 (0.0)	-	3/106 (2.8)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	4/112 (3.6)	-	-	-	
1	0/34 (0.0)	-	0/91 (0.0)	-	-	-	
≥2	0/20 (0.0)	-	0/64 (0.0)	-	-	-	
Prior alloHSCT							0.9986
Yes	0/35 (0.0)	-	0/93 (0.0)	-	-	-	
No	0/74 (0.0)	-	4/174 (2.3)	-	-	-	
Race							0.9988
Caucasian	0/90 (0.0)	-	4/226 (1.8)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9986
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	4/168 (2.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Neutropenia (AMQ) - Narrow	63/109 (57.8)	0.43 (0.30, 0.95)	101/267 (37.8)	4.95 (3.87, NE)	0.40 (0.29, 0.55)	<0.0001	
Age group 1							0.4355
<35 years	24/50 (48.0)	1.05 (0.30, NE)	43/123 (35.0)	6.69 (2.59, NE)	0.46 (0.28, 0.77)	0.0026	
≥35 years	39/59 (66.1)	0.36 (0.26, 0.56)	58/144 (40.3)	4.75 (2.89, NE)	0.35 (0.23, 0.54)	<0.0001	
Age group 2							0.8171
<35 years	24/50 (48.0)	1.05 (0.30, NE)	43/124 (34.7)	6.69 (2.59, NE)	0.46 (0.28, 0.77)	0.0025	
35 - 54 years	18/25 (72.0)	0.30 (0.23, 0.56)	32/77 (41.6)	6.69 (1.54, NE)	0.33 (0.18, 0.61)	0.0002	
55 - 64 years	15/22 (68.2)	0.39 (0.20, 0.59)	15/33 (45.5)	2.20 (0.49, NE)	0.42 (0.20, 0.87)	0.0175	
≥65 years	6/12 (50.0)	NE (0.10, NE)	11/33 (33.3)	4.95 (4.59, NE)	0.27 (0.08, 0.88)	0.0202	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1993
Male	35/64 (54.7)	0.46 (0.33, NE)	64/159 (40.3)	4.59 (2.52, 8.26)	0.44 (0.29, 0.68)	0.0001	
Female	28/45 (62.2)	0.30 (0.26, 1.05)	37/108 (34.3)	NE (3.11, NE)	0.35 (0.21, 0.59)	<0.0001	
Region							0.6754
USA	9/13 (69.2)	0.33 (0.23, NE)	14/30 (46.7)	1.31 (0.46, NE)	0.42 (0.18, 0.99)	0.0428	
Europe	32/68 (47.1)	NE (0.36, NE)	57/177 (32.2)	8.26 (4.75, NE)	0.47 (0.30, 0.73)	0.0006	
Rest of the world	22/28 (78.6)	0.30 (0.20, 0.36)	30/60 (50.0)	2.36 (1.41, 4.43)	0.25 (0.13, 0.45)	<0.0001	
Prior salvage therapy							0.1326
Yes	34/63 (54.0)	0.56 (0.33, NE)	64/161 (39.8)	4.43 (2.52, 6.69)	0.46 (0.30, 0.71)	0.0003	
No	29/46 (63.0)	0.30 (0.26, 0.59)	37/106 (34.9)	8.26 (4.95, NE)	0.33 (0.20, 0.55)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6855
0	32/55 (58.2)	0.36 (0.26, NE)	40/112 (35.7)	6.69 (4.75, NE)	0.36 (0.22, 0.59)	<0.0001	
1	20/34 (58.8)	0.43 (0.26, NE)	38/91 (41.8)	3.11 (1.93, NE)	0.39 (0.22, 0.70)	0.0009	
≥2	11/20 (55.0)	0.43 (0.26, NE)	23/64 (35.9)	3.87 (2.07, NE)	0.45 (0.22, 0.94)	0.0266	
Prior alloHSCT							0.0611
Yes	24/35 (68.6)	0.30 (0.23, 0.56)	32/93 (34.4)	6.69 (2.59, NE)	0.27 (0.15, 0.47)	<0.0001	
No	39/74 (52.7)	0.46 (0.33, NE)	69/174 (39.7)	4.75 (3.02, NE)	0.49 (0.33, 0.73)	0.0004	
Race							0.6489
Caucasian	50/90 (55.6)	0.43 (0.30, NE)	84/226 (37.2)	4.95 (3.87, NE)	0.41 (0.29, 0.60)	<0.0001	
Others	13/19 (68.4)	0.36 (0.26, 0.59)	17/41 (41.5)	1.93 (0.79, NE)	0.33 (0.16, 0.70)	0.0025	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3430
<50%	15/27 (55.6)	0.46 (0.26, NE)	25/73 (34.2)	6.69 (4.43, NE)	0.26 (0.12, 0.53)	<0.0001	
≥50%	46/77 (59.7)	0.39 (0.26, 0.95)	68/168 (40.5)	4.62 (2.10, NE)	0.48 (0.33, 0.70)	0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Tumour lysis syndrome (SMQ) - Narrow	1/109 (0.9)	NE (NE, NE)	8/267 (3.0)	NE (NE, NE)	3.01 (0.38, 24.08)	0.2756	
Age group 1							0.9934
<35 years	0/50 (0.0)	-	4/123 (3.3)	-	-	-	
≥35 years	1/59 (1.7)	-	4/144 (2.8)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	4/124 (3.2)	-	-	-	
35 - 54 years	1/25 (4.0)	-	0/77 (0.0)	-	-	-	
55 - 64 years	0/22 (0.0)	-	3/33 (9.1)	-	-	-	
≥65 years	0/12 (0.0)	-	1/33 (3.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 28MAY2025:06:05) Source data: adam_pa.adsl, adam_pa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9948
Male	1/64 (1.6)	-	7/159 (4.4)	-	-	-	
Female	0/45 (0.0)	-	1/108 (0.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	4/177 (2.3)	-	-	-	
Rest of the world	1/28 (3.6)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							0.9935
Yes	1/63 (1.6)	-	5/161 (3.1)	-	-	-	
No	0/46 (0.0)	-	3/106 (2.8)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	4/112 (3.6)	-	-	-	
1	1/34 (2.9)	-	3/91 (3.3)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.9945
Yes	0/35 (0.0)	-	3/93 (3.2)	-	-	-	
No	1/74 (1.4)	-	5/174 (2.9)	-	-	-	
Race							0.9998
Caucasian	1/90 (1.1)	-	8/226 (3.5)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade >= 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9999
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	1/77 (1.3)	-	5/168 (3.0)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Anhang 4-G3.7.5: Subgruppenanalysen UE nach SOC und PT

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Blood and lymphatic system disorders							
Overall	83/109 (76.1)	0.26 (0.20, 0.30)	183/267 (68.5)	0.52 (0.39, 0.79)	0.63 (0.48, 0.82)	0.0006	
Age group 1							0.5972
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	83/123 (67.5)	0.82 (0.39, 1.74)	0.66 (0.44, 1.00)	0.0455	
≥35 years	49/59 (83.1)	0.23 (0.16, 0.26)	100/144 (69.4)	0.46 (0.30, 0.69)	0.61 (0.43, 0.87)	0.0050	
Age group 2							0.8948
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	84/124 (67.7)	0.82 (0.39, 1.74)	0.67 (0.45, 1.01)	0.0526	
35 - 54 years	22/25 (88.0)	0.26 (0.13, 0.30)	54/77 (70.1)	0.46 (0.20, 0.75)	0.56 (0.34, 0.94)	0.0249	
55 - 64 years	20/22 (90.9)	0.20 (0.10, 0.30)	26/33 (78.8)	0.33 (0.07, 0.52)	0.63 (0.34, 1.15)	0.1186	
≥65 years	7/12 (58.3)	0.30 (0.03, NE)	19/33 (57.6)	2.36 (0.33, 4.95)	0.67 (0.27, 1.66)	0.3802	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4170
Male	45/64 (70.3)	0.30 (0.16, 0.36)	109/159 (68.6)	0.59 (0.39, 1.15)	0.69 (0.48, 0.98)	0.0384	
Female	38/45 (84.4)	0.23 (0.20, 0.26)	74/108 (68.5)	0.49 (0.26, 0.79)	0.57 (0.38, 0.86)	0.0057	
Region							0.2341
USA	8/13 (61.5)	0.33 (0.13, NE)	25/30 (83.3)	0.49 (0.20, 0.98)	1.05 (0.47, 2.37)	0.8965	
Europe	52/68 (76.5)	0.26 (0.16, 0.30)	114/177 (64.4)	0.52 (0.33, 1.44)	0.62 (0.44, 0.87)	0.0041	
Rest of the world	23/28 (82.1)	0.23 (0.16, 0.36)	44/60 (73.3)	0.39 (0.26, 1.90)	0.50 (0.29, 0.85)	0.0091	
Prior salvage therapy							0.1155
Yes	45/63 (71.4)	0.30 (0.20, 0.43)	112/161 (69.6)	0.56 (0.33, 0.92)	0.72 (0.50, 1.03)	0.0594	
No	38/46 (82.6)	0.23 (0.10, 0.26)	71/106 (67.0)	0.49 (0.26, 1.54)	0.53 (0.35, 0.80)	0.0022	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3536
0	44/55 (80.0)	0.23 (0.13, 0.26)	77/112 (68.8)	0.56 (0.26, 1.38)	0.58 (0.40, 0.85)	0.0048	
1	25/34 (73.5)	0.26 (0.16, 0.56)	60/91 (65.9)	0.79 (0.46, 1.74)	0.58 (0.36, 0.95)	0.0233	
≥2	14/20 (70.0)	0.39 (0.20, 0.52)	46/64 (71.9)	0.46 (0.26, 0.75)	0.89 (0.49, 1.63)	0.6626	
Prior alloHSCT							0.8579
Yes	29/35 (82.9)	0.26 (0.20, 0.36)	68/93 (73.1)	0.33 (0.26, 0.72)	0.64 (0.41, 1.01)	0.0427	
No	54/74 (73.0)	0.26 (0.16, 0.33)	115/174 (66.1)	0.69 (0.46, 1.15)	0.63 (0.45, 0.87)	0.0052	
Race							0.9968
Caucasian	69/90 (76.7)	0.23 (0.20, 0.30)	155/226 (68.6)	0.52 (0.33, 0.82)	0.64 (0.48, 0.86)	0.0023	
Others	14/19 (73.7)	0.33 (0.10, 0.56)	28/41 (68.3)	0.75 (0.30, 1.90)	0.54 (0.28, 1.06)	0.0723	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3835
<50%	20/27 (74.1)	0.26 (0.10, 0.56)	47/73 (64.4)	1.31 (0.33, 2.59)	0.56 (0.33, 0.97)	0.0347	
≥50%	58/77 (75.3)	0.26 (0.20, 0.33)	116/168 (69.0)	0.46 (0.30, 0.69)	0.70 (0.50, 0.96)	0.0235	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Anaemia							
Overall	46/109 (42.2)	1.93 (0.79, NE)	69/267 (25.8)	NE (11.90, NE)	0.53 (0.37, 0.78)	0.0008	
Age group 1							0.2620
<35 years	21/50 (42.0)	1.93 (0.43, NE)	26/123 (21.1)	11.90 (11.90, NE)	0.39 (0.21, 0.70)	0.0010	
≥35 years	25/59 (42.4)	NE (0.46, NE)	43/144 (29.9)	NE (NE, NE)	0.67 (0.41, 1.10)	0.1088	
Age group 2							0.6348
<35 years	21/50 (42.0)	1.93 (0.43, NE)	26/124 (21.0)	11.90 (11.90, NE)	0.38 (0.21, 0.69)	0.0009	
35 - 54 years	10/25 (40.0)	NE (0.36, NE)	25/77 (32.5)	NE (NE, NE)	0.79 (0.38, 1.65)	0.5205	
55 - 64 years	11/22 (50.0)	0.79 (0.13, NE)	10/33 (30.3)	NE (NE, NE)	0.60 (0.26, 1.42)	0.2235	
≥65 years	4/12 (33.3)	NE (0.10, NE)	8/33 (24.2)	NE (NE, NE)	0.67 (0.20, 2.21)	0.5118	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3657
Male	25/64 (39.1)	NE (0.79, NE)	34/159 (21.4)	NE (11.90, NE)	0.44 (0.26, 0.74)	0.0016	
Female	21/45 (46.7)	1.93 (0.36, NE)	35/108 (32.4)	NE (NE, NE)	0.67 (0.39, 1.15)	0.1407	
Region							0.3346
USA	6/13 (46.2)	NE (0.13, NE)	7/30 (23.3)	NE (NE, NE)	0.45 (0.15, 1.36)	0.1465	
Europe	27/68 (39.7)	NE (0.79, NE)	51/177 (28.8)	NE (11.90, NE)	0.64 (0.40, 1.03)	0.0640	
Rest of the world	13/28 (46.4)	1.08 (0.33, NE)	11/60 (18.3)	NE (NE, NE)	0.33 (0.14, 0.73)	0.0039	
Prior salvage therapy							0.5531
Yes	23/63 (36.5)	1.93 (1.08, NE)	38/161 (23.6)	11.90 (11.90, NE)	0.56 (0.33, 0.95)	0.0283	
No	23/46 (50.0)	0.66 (0.26, NE)	31/106 (29.2)	NE (NE, NE)	0.50 (0.29, 0.86)	0.0107	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9656
0	25/55 (45.5)	NE (0.33, NE)	34/112 (30.4)	NE (6.79, NE)	0.58 (0.35, 0.98)	0.0391	
1	14/34 (41.2)	1.15 (0.79, NE)	21/91 (23.1)	NE (NE, NE)	0.51 (0.26, 1.01)	0.0480	
≥2	7/20 (35.0)	1.93 (0.43, NE)	14/64 (21.9)	11.90 (NE, NE)	0.53 (0.21, 1.32)	0.1606	
Prior alloHSCT							0.7452
Yes	17/35 (48.6)	1.08 (0.36, NE)	26/93 (28.0)	NE (11.90, NE)	0.49 (0.27, 0.91)	0.0204	
No	29/74 (39.2)	NE (0.79, NE)	43/174 (24.7)	NE (6.79, NE)	0.56 (0.35, 0.90)	0.0147	
Race							0.9376
Caucasian	41/90 (45.6)	1.93 (0.46, NE)	63/226 (27.9)	NE (11.90, NE)	0.53 (0.36, 0.79)	0.0013	
Others	5/19 (26.3)	NE (1.15, NE)	6/41 (14.6)	NE (NE, NE)	0.50 (0.15, 1.64)	0.2400	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3213
<50%	16/27 (59.3)	0.79 (0.23, NE)	20/73 (27.4)	NE (NE, NE)	0.38 (0.20, 0.74)	0.0032	
≥50%	28/77 (36.4)	NE (1.08, NE)	39/168 (23.2)	NE (NE, NE)	0.58 (0.35, 0.94)	0.0241	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Febrile neutropenia							
Overall	43/109 (39.4)	2.82 (1.77, NE)	64/267 (24.0)	NE (NE, NE)	0.48 (0.32, 0.71)	0.0002	
Age group 1							0.9530
<35 years	20/50 (40.0)	2.49 (0.95, NE)	30/123 (24.4)	NE (6.69, NE)	0.43 (0.24, 0.77)	0.0037	
≥35 years	23/59 (39.0)	NE (0.59, NE)	34/144 (23.6)	NE (NE, NE)	0.53 (0.31, 0.91)	0.0184	
Age group 2							0.8383
<35 years	20/50 (40.0)	2.49 (0.95, NE)	31/124 (25.0)	NE (6.69, NE)	0.45 (0.25, 0.80)	0.0055	
35 - 54 years	11/25 (44.0)	NE (0.33, NE)	17/77 (22.1)	NE (NE, NE)	0.45 (0.21, 0.97)	0.0354	
55 - 64 years	9/22 (40.9)	NE (0.43, NE)	10/33 (30.3)	NE (1.31, NE)	0.67 (0.27, 1.66)	0.3910	
≥65 years	3/12 (25.0)	NE (0.33, NE)	6/33 (18.2)	NE (4.59, NE)	0.49 (0.11, 2.18)	0.3395	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8043
Male	28/64 (43.8)	2.49 (0.56, NE)	44/159 (27.7)	NE (6.69, NE)	0.46 (0.29, 0.75)	0.0014	
Female	15/45 (33.3)	NE (1.77, NE)	20/108 (18.5)	NE (NE, NE)	0.51 (0.26, 0.99)	0.0459	
Region							0.5275
USA	6/13 (46.2)	NE (0.33, NE)	14/30 (46.7)	2.30 (0.52, NE)	0.75 (0.28, 1.97)	0.5646	
Europe	22/68 (32.4)	NE (2.49, NE)	31/177 (17.5)	NE (NE, NE)	0.44 (0.25, 0.77)	0.0028	
Rest of the world	15/28 (53.6)	0.56 (0.36, NE)	19/60 (31.7)	NE (3.87, NE)	0.43 (0.21, 0.87)	0.0166	
Prior salvage therapy							0.0668
Yes	23/63 (36.5)	2.49 (1.77, NE)	45/161 (28.0)	NE (6.69, NE)	0.61 (0.37, 1.02)	0.0549	
No	20/46 (43.5)	2.82 (0.43, NE)	19/106 (17.9)	NE (NE, NE)	0.32 (0.17, 0.61)	0.0003	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4885
0	21/55 (38.2)	NE (0.59, NE)	21/112 (18.8)	NE (NE, NE)	0.39 (0.21, 0.72)	0.0019	
1	13/34 (38.2)	1.77 (0.56, NE)	27/91 (29.7)	NE (4.59, NE)	0.61 (0.31, 1.20)	0.1478	
≥2	9/20 (45.0)	2.49 (0.39, NE)	16/64 (25.0)	NE (3.87, NE)	0.40 (0.17, 0.94)	0.0282	
Prior alloHSCT							0.1167
Yes	17/35 (48.6)	1.77 (0.43, 2.82)	19/93 (20.4)	NE (NE, NE)	0.27 (0.14, 0.54)	<0.0001	
No	26/74 (35.1)	NE (NE, NE)	45/174 (25.9)	NE (NE, NE)	0.62 (0.38, 1.01)	0.0519	
Race							0.3315
Caucasian	32/90 (35.6)	2.82 (1.77, NE)	52/226 (23.0)	NE (NE, NE)	0.52 (0.33, 0.81)	0.0035	
Others	11/19 (57.9)	0.56 (0.30, NE)	12/41 (29.3)	NE (1.64, NE)	0.34 (0.15, 0.79)	0.0092	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0970
<50%	10/27 (37.0)	NE (0.43, NE)	11/73 (15.1)	NE (NE, NE)	0.27 (0.11, 0.67)	0.0026	
≥50%	32/77 (41.6)	2.49 (0.59, NE)	50/168 (29.8)	NE (6.69, NE)	0.60 (0.39, 0.95)	0.0258	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutropenia							
Overall	33/109 (30.3)	NE (2.30, NE)	53/267 (19.9)	NE (8.26, NE)	0.41 (0.26, 0.65)	<0.0001	
Age group 1							0.7477
<35 years	15/50 (30.0)	NE (2.30, NE)	26/123 (21.1)	NE (5.02, NE)	0.45 (0.23, 0.87)	0.0151	
≥35 years	18/59 (30.5)	NE (NE, NE)	27/144 (18.8)	NE (6.69, NE)	0.38 (0.20, 0.72)	0.0021	
Age group 2							0.7637
<35 years	15/50 (30.0)	NE (2.30, NE)	26/124 (21.0)	NE (5.02, NE)	0.45 (0.23, 0.87)	0.0148	
35 - 54 years	8/25 (32.0)	NE (0.52, NE)	17/77 (22.1)	NE (4.79, NE)	0.40 (0.16, 0.96)	0.0355	
55 - 64 years	8/22 (36.4)	NE (0.26, NE)	5/33 (15.2)	NE (NE, NE)	0.32 (0.10, 1.00)	0.0404	
≥65 years	2/12 (16.7)	NE (0.36, NE)	5/33 (15.2)	8.26 (4.95, NE)	0.39 (0.05, 2.74)	0.3235	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0497
Male	14/64 (21.9)	NE (2.30, NE)	31/159 (19.5)	NE (8.26, NE)	0.61 (0.32, 1.17)	0.1371	
Female	19/45 (42.2)	NE (0.30, NE)	22/108 (20.4)	NE (6.69, NE)	0.26 (0.13, 0.51)	<0.0001	
Region							0.4315
USA	1/13 (7.7)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)	1.80 (0.20, 16.11)	0.5889	
Europe	20/68 (29.4)	NE (2.30, NE)	33/177 (18.6)	NE (8.26, NE)	0.42 (0.24, 0.75)	0.0027	
Rest of the world	12/28 (42.9)	NE (0.23, NE)	16/60 (26.7)	NE (3.11, NE)	0.24 (0.10, 0.57)	0.0006	
Prior salvage therapy							0.5761
Yes	14/63 (22.2)	NE (NE, NE)	25/161 (15.5)	NE (NE, NE)	0.43 (0.22, 0.84)	0.0118	
No	19/46 (41.3)	NE (0.26, NE)	28/106 (26.4)	NE (6.69, NE)	0.40 (0.22, 0.75)	0.0034	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6438
0	20/55 (36.4)	NE (2.30, NE)	29/112 (25.9)	NE (6.69, NE)	0.47 (0.26, 0.86)	0.0128	
1	9/34 (26.5)	NE (NE, NE)	13/91 (14.3)	NE (5.02, NE)	0.26 (0.10, 0.69)	0.0037	
≥2	4/20 (20.0)	NE (NE, NE)	11/64 (17.2)	NE (3.61, NE)	0.58 (0.18, 1.85)	0.3479	
Prior alloHSCT							0.2747
Yes	15/35 (42.9)	NE (0.26, NE)	22/93 (23.7)	NE (4.79, NE)	0.28 (0.14, 0.57)	0.0002	
No	18/74 (24.3)	NE (NE, NE)	31/174 (17.8)	NE (8.26, NE)	0.51 (0.28, 0.93)	0.0263	
Race							0.3038
Caucasian	29/90 (32.2)	NE (2.30, NE)	43/226 (19.0)	NE (8.26, NE)	0.36 (0.22, 0.60)	<0.0001	
Others	4/19 (21.1)	NE (NE, NE)	10/41 (24.4)	NE (4.79, NE)	0.79 (0.24, 2.63)	0.6954	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5242
<50%	6/27 (22.2)	NE (NE, NE)	16/73 (21.9)	NE (6.69, NE)	0.57 (0.21, 1.52)	0.2563	
≥50%	25/77 (32.5)	NE (2.30, NE)	34/168 (20.2)	NE (5.02, NE)	0.42 (0.25, 0.73)	0.0014	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Thrombocytopenia							
Overall	32/109 (29.4)	NE (NE, NE)	47/267 (17.6)	NE (NE, NE)	0.51 (0.33, 0.81)	0.0036	
Age group 1							0.5624
<35 years	16/50 (32.0)	NE (2.03, NE)	22/123 (17.9)	NE (NE, NE)	0.41 (0.21, 0.79)	0.0064	
≥35 years	16/59 (27.1)	NE (NE, NE)	25/144 (17.4)	NE (NE, NE)	0.64 (0.34, 1.19)	0.1540	
Age group 2							0.9129
<35 years	16/50 (32.0)	NE (2.03, NE)	22/124 (17.7)	NE (NE, NE)	0.41 (0.21, 0.79)	0.0062	
35 - 54 years	6/25 (24.0)	NE (NE, NE)	14/77 (18.2)	NE (NE, NE)	0.73 (0.28, 1.90)	0.5182	
55 - 64 years	7/22 (31.8)	NE (0.36, NE)	6/33 (18.2)	NE (NE, NE)	0.57 (0.19, 1.69)	0.3041	
≥65 years	3/12 (25.0)	NE (0.16, NE)	5/33 (15.2)	NE (NE, NE)	0.62 (0.15, 2.61)	0.5047	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9355
Male	18/64 (28.1)	NE (NE, NE)	28/159 (17.6)	NE (NE, NE)	0.53 (0.29, 0.96)	0.0332	
Female	14/45 (31.1)	NE (2.03, NE)	19/108 (17.6)	NE (NE, NE)	0.50 (0.25, 1.01)	0.0492	
Region							0.1458
USA	1/13 (7.7)	NE (2.03, NE)	5/30 (16.7)	NE (NE, NE)	2.09 (0.24, 18.00)	0.4961	
Europe	25/68 (36.8)	NE (NE, NE)	39/177 (22.0)	NE (NE, NE)	0.51 (0.31, 0.85)	0.0086	
Rest of the world	6/28 (21.4)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.21 (0.05, 0.85)	0.0154	
Prior salvage therapy							0.7438
Yes	15/63 (23.8)	NE (NE, NE)	24/161 (14.9)	NE (NE, NE)	0.56 (0.29, 1.08)	0.0798	
No	17/46 (37.0)	NE (0.39, NE)	23/106 (21.7)	NE (NE, NE)	0.48 (0.25, 0.90)	0.0204	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3924
0	21/55 (38.2)	NE (0.39, NE)	23/112 (20.5)	NE (NE, NE)	0.42 (0.23, 0.78)	0.0045	
1	8/34 (23.5)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)	0.51 (0.20, 1.27)	0.1375	
≥2	3/20 (15.0)	NE (NE, NE)	12/64 (18.8)	NE (NE, NE)	1.15 (0.32, 4.07)	0.8326	
Prior alloHSCT							0.4643
Yes	10/35 (28.6)	NE (NE, NE)	20/93 (21.5)	NE (NE, NE)	0.63 (0.29, 1.38)	0.2399	
No	22/74 (29.7)	NE (2.03, NE)	27/174 (15.5)	NE (NE, NE)	0.46 (0.26, 0.81)	0.0062	
Race							0.8557
Caucasian	30/90 (33.3)	NE (2.03, NE)	44/226 (19.5)	NE (NE, NE)	0.50 (0.31, 0.80)	0.0033	
Others	2/19 (10.5)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.63 (0.11, 3.78)	0.6115	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1491
<50%	14/27 (51.9)	0.39 (0.26, NE)	15/73 (20.5)	NE (6.62, NE)	0.26 (0.12, 0.56)	0.0003	
≥50%	17/77 (22.1)	NE (NE, NE)	26/168 (15.5)	NE (NE, NE)	0.67 (0.36, 1.24)	0.1973	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Leukopenia							
Overall	5/109 (4.6)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.77 (0.26, 2.27)	0.6380	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Cardiac disorders							
Overall	26/109 (23.9)	NE (2.26, NE)	49/267 (18.4)	NE (NE, NE)	0.64 (0.39, 1.03)	0.0638	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Tachycardia							
Overall	10/109 (9.2)	NE (2.82, NE)	18/267 (6.7)	NE (NE, NE)	0.61 (0.28, 1.34)	0.2118	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sinus tachycardia							
Overall	6/109 (5.5)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.94 (0.36, 2.44)	0.9009	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Ear and labyrinth disorders							
Overall	4/109 (3.7)	NE (NE, NE)	15/267 (5.6)	NE (13.54, NE)	1.13 (0.36, 3.51)	0.8348	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Eye disorders							
Overall	15/109 (13.8)	NE (NE, NE)	27/267 (10.1)	NE (NE, NE)	0.52 (0.27, 1.00)	0.0471	
Age group 1							0.2356
<35 years	7/50 (14.0)	NE (NE, NE)	8/123 (6.5)	NE (8.72, NE)	0.33 (0.12, 0.97)	0.0342	
≥35 years	8/59 (13.6)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)	0.68 (0.29, 1.62)	0.3809	
Age group 2							0.3912
<35 years	7/50 (14.0)	NE (NE, NE)	9/124 (7.3)	NE (8.72, NE)	0.39 (0.14, 1.08)	0.0610	
35 - 54 years	5/25 (20.0)	NE (1.05, NE)	9/77 (11.7)	NE (NE, NE)	0.28 (0.09, 0.93)	0.0278	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	6/33 (18.2)	8.10 (8.10, NE)	1.73 (0.33, 8.90)	0.5064	
≥65 years	1/12 (8.3)	NE (NE, NE)	3/33 (9.1)	NE (4.75, NE)	0.90 (0.08, 9.92)	0.9288	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3546
Male	11/64 (17.2)	NE (NE, NE)	16/159 (10.1)	NE (NE, NE)	0.49 (0.23, 1.07)	0.0693	
Female	4/45 (8.9)	NE (NE, NE)	11/108 (10.2)	NE (8.72, NE)	0.50 (0.14, 1.84)	0.2919	
Region							0.8501
USA	1/13 (7.7)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	0.84 (0.08, 9.32)	0.8890	
Europe	7/68 (10.3)	NE (NE, NE)	15/177 (8.5)	NE (NE, NE)	0.60 (0.23, 1.52)	0.2742	
Rest of the world	7/28 (25.0)	NE (NE, NE)	10/60 (16.7)	NE (5.77, NE)	0.37 (0.13, 1.09)	0.0603	
Prior salvage therapy							0.9901
Yes	9/63 (14.3)	NE (NE, NE)	16/161 (9.9)	NE (NE, NE)	0.49 (0.21, 1.13)	0.0890	
No	6/46 (13.0)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	0.57 (0.20, 1.63)	0.2867	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1444
0	8/55 (14.5)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	0.56 (0.22, 1.42)	0.2163	
1	6/34 (17.6)	NE (NE, NE)	5/91 (5.5)	NE (8.10, NE)	0.14 (0.03, 0.57)	0.0015	
≥2	1/20 (5.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)	2.57 (0.32, 20.41)	0.3534	
Prior alloHSCT							0.3423
Yes	3/35 (8.6)	NE (NE, NE)	11/93 (11.8)	NE (8.72, NE)	0.75 (0.19, 2.97)	0.6825	
No	12/74 (16.2)	NE (NE, NE)	16/174 (9.2)	NE (NE, NE)	0.46 (0.22, 0.99)	0.0423	
Race							0.9654
Caucasian	11/90 (12.2)	NE (NE, NE)	20/226 (8.8)	NE (NE, NE)	0.53 (0.25, 1.15)	0.1052	
Others	4/19 (21.1)	NE (NE, NE)	7/41 (17.1)	NE (5.77, NE)	0.46 (0.12, 1.72)	0.2365	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9211
<50%	3/27 (11.1)	NE (NE, NE)	6/73 (8.2)	NE (8.10, NE)	0.28 (0.05, 1.49)	0.1145	
≥50%	11/77 (14.3)	NE (NE, NE)	15/168 (8.9)	NE (NE, NE)	0.50 (0.23, 1.12)	0.0880	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Gastrointestinal disorders							
Overall	87/109 (79.8)	0.23 (0.10, 0.26)	150/267 (56.2)	1.21 (0.95, 2.13)	0.38 (0.29, 0.50)	<0.0001	
Age group 1							0.2695
<35 years	39/50 (78.0)	0.16 (0.10, 0.26)	64/123 (52.0)	1.74 (0.98, 5.90)	0.32 (0.21, 0.49)	<0.0001	
≥35 years	48/59 (81.4)	0.23 (0.13, 0.30)	86/144 (59.7)	0.95 (0.59, 2.39)	0.44 (0.31, 0.64)	<0.0001	
Age group 2							0.1067
<35 years	39/50 (78.0)	0.16 (0.10, 0.26)	65/124 (52.4)	1.48 (0.98, 5.90)	0.33 (0.22, 0.50)	<0.0001	
35 - 54 years	21/25 (84.0)	0.23 (0.10, 0.30)	48/77 (62.3)	0.95 (0.46, 2.62)	0.36 (0.21, 0.61)	0.0001	
55 - 64 years	17/22 (77.3)	0.30 (0.10, 0.92)	24/33 (72.7)	0.56 (0.13, 1.08)	0.78 (0.41, 1.47)	0.4331	
≥65 years	10/12 (83.3)	0.20 (0.03, 1.57)	13/33 (39.4)	7.48 (0.59, NE)	0.26 (0.11, 0.61)	0.0010	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0368
Male	47/64 (73.4)	0.26 (0.16, 0.46)	88/159 (55.3)	1.18 (0.72, 2.39)	0.48 (0.33, 0.69)	<0.0001	
Female	40/45 (88.9)	0.10 (0.10, 0.23)	62/108 (57.4)	1.61 (0.62, 2.98)	0.27 (0.18, 0.41)	<0.0001	
Region							0.4754
USA	11/13 (84.6)	0.23 (0.07, 0.33)	19/30 (63.3)	0.98 (0.49, 1.31)	0.36 (0.16, 0.77)	0.0068	
Europe	53/68 (77.9)	0.23 (0.10, 0.26)	89/177 (50.3)	2.59 (1.15, 6.69)	0.34 (0.24, 0.48)	<0.0001	
Rest of the world	23/28 (82.1)	0.15 (0.07, 0.23)	42/60 (70.0)	0.46 (0.20, 0.95)	0.54 (0.32, 0.91)	0.0210	
Prior salvage therapy							0.0152
Yes	45/63 (71.4)	0.26 (0.20, 0.46)	89/161 (55.3)	1.15 (0.72, 2.13)	0.50 (0.35, 0.72)	0.0002	
No	42/46 (91.3)	0.10 (0.07, 0.23)	61/106 (57.5)	1.74 (0.59, 2.89)	0.26 (0.17, 0.39)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0056
0	51/55 (92.7)	0.10 (0.07, 0.20)	65/112 (58.0)	1.93 (0.62, 2.98)	0.25 (0.17, 0.37)	<0.0001	
1	23/34 (67.6)	0.30 (0.23, 2.16)	47/91 (51.6)	1.61 (0.62, NE)	0.53 (0.32, 0.88)	0.0126	
≥2	13/20 (65.0)	0.46 (0.10, 1.51)	38/64 (59.4)	1.08 (0.39, 1.38)	0.65 (0.34, 1.23)	0.1831	
Prior alloHSCT							0.0421
Yes	33/35 (94.3)	0.10 (0.07, 0.20)	58/93 (62.4)	1.11 (0.62, 2.13)	0.23 (0.14, 0.36)	<0.0001	
No	54/74 (73.0)	0.26 (0.16, 0.30)	92/174 (52.9)	1.28 (0.72, 2.95)	0.46 (0.33, 0.65)	<0.0001	
Race							0.8240
Caucasian	72/90 (80.0)	0.23 (0.13, 0.26)	123/226 (54.4)	1.48 (0.95, 2.62)	0.38 (0.28, 0.51)	<0.0001	
Others	15/19 (78.9)	0.10 (0.07, 0.23)	27/41 (65.9)	0.69 (0.39, 1.61)	0.43 (0.23, 0.83)	0.0121	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0058
<50%	24/27 (88.9)	0.10 (0.07, 0.30)	34/73 (46.6)	5.90 (2.59, NE)	0.19 (0.10, 0.33)	<0.0001	
≥50%	58/77 (75.3)	0.23 (0.13, 0.26)	105/168 (62.5)	0.72 (0.43, 1.15)	0.55 (0.39, 0.76)	0.0003	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Diarrhoea							
Overall	38/109 (34.9)	NE (1.67, NE)	58/267 (21.7)	NE (11.28, NE)	0.40 (0.26, 0.61)	<0.0001	
Age group 1							0.0210
<35 years	19/50 (38.0)	NE (0.49, NE)	18/123 (14.6)	NE (NE, NE)	0.24 (0.12, 0.46)	<0.0001	
≥35 years	19/59 (32.2)	NE (1.51, NE)	40/144 (27.8)	11.28 (5.48, NE)	0.58 (0.33, 1.02)	0.0548	
Age group 2							0.0898
<35 years	19/50 (38.0)	NE (0.49, NE)	18/124 (14.5)	NE (NE, NE)	0.24 (0.12, 0.46)	<0.0001	
35 - 54 years	7/25 (28.0)	NE (0.66, NE)	24/77 (31.2)	NE (2.98, NE)	0.66 (0.28, 1.56)	0.3472	
55 - 64 years	9/22 (40.9)	2.16 (0.33, NE)	12/33 (36.4)	11.28 (1.54, NE)	0.60 (0.24, 1.48)	0.2597	
≥65 years	3/12 (25.0)	NE (0.23, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.11, 2.16)	0.3387	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6715
Male	22/64 (34.4)	NE (1.67, NE)	34/159 (21.4)	NE (NE, NE)	0.45 (0.26, 0.78)	0.0038	
Female	16/45 (35.6)	NE (1.21, NE)	24/108 (22.2)	11.28 (5.48, NE)	0.31 (0.16, 0.61)	0.0004	
Region							0.1551
USA	6/13 (46.2)	1.51 (0.23, NE)	8/30 (26.7)	NE (1.21, NE)	0.43 (0.15, 1.25)	0.1102	
Europe	19/68 (27.9)	NE (2.16, NE)	38/177 (21.5)	NE (11.28, NE)	0.52 (0.29, 0.92)	0.0219	
Rest of the world	13/28 (46.4)	1.21 (0.30, NE)	12/60 (20.0)	NE (3.38, NE)	0.16 (0.06, 0.40)	<0.0001	
Prior salvage therapy							0.2079
Yes	18/63 (28.6)	NE (2.16, NE)	35/161 (21.7)	11.28 (11.28, NE)	0.50 (0.28, 0.89)	0.0165	
No	20/46 (43.5)	1.67 (0.43, NE)	23/106 (21.7)	NE (5.90, NE)	0.30 (0.16, 0.57)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1192
0	22/55 (40.0)	NE (1.21, NE)	20/112 (17.9)	NE (NE, NE)	0.25 (0.13, 0.48)	<0.0001	
1	12/34 (35.3)	2.16 (0.66, NE)	23/91 (25.3)	11.28 (3.38, NE)	0.42 (0.21, 0.88)	0.0175	
≥2	4/20 (20.0)	NE (NE, NE)	15/64 (23.4)	NE (3.02, NE)	0.93 (0.31, 2.81)	0.8944	
Prior alloHSCT							0.0620
Yes	20/35 (57.1)	0.66 (0.30, NE)	25/93 (26.9)	11.28 (4.75, NE)	0.23 (0.12, 0.43)	<0.0001	
No	18/74 (24.3)	NE (NE, NE)	33/174 (19.0)	NE (NE, NE)	0.57 (0.32, 1.02)	0.0555	
Race							0.9687
Caucasian	32/90 (35.6)	NE (1.67, NE)	49/226 (21.7)	NE (11.28, NE)	0.40 (0.25, 0.63)	<0.0001	
Others	6/19 (31.6)	NE (0.56, NE)	9/41 (22.0)	NE (3.02, NE)	0.39 (0.13, 1.13)	0.0728	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1198
<50%	12/27 (44.4)	2.16 (0.39, NE)	16/73 (21.9)	11.28 (5.90, NE)	0.11 (0.04, 0.30)	<0.0001	
≥50%	23/77 (29.9)	NE (1.51, NE)	38/168 (22.6)	NE (NE, NE)	0.59 (0.35, 1.00)	0.0470	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Nausea							
Overall	46/109 (42.2)	1.61 (1.02, NE)	51/267 (19.1)	NE (NE, NE)	0.28 (0.19, 0.43)	<0.0001	
Age group 1							0.0034
<35 years	28/50 (56.0)	1.02 (0.30, 1.61)	19/123 (15.4)	NE (NE, NE)	0.14 (0.08, 0.26)	<0.0001	
≥35 years	18/59 (30.5)	NE (1.51, NE)	32/144 (22.2)	NE (NE, NE)	0.53 (0.29, 0.96)	0.0327	
Age group 2							0.0089
<35 years	28/50 (56.0)	1.02 (0.30, 1.61)	20/124 (16.1)	NE (NE, NE)	0.15 (0.08, 0.28)	<0.0001	
35 - 54 years	10/25 (40.0)	NE (0.23, NE)	17/77 (22.1)	NE (NE, NE)	0.26 (0.11, 0.61)	0.0009	
55 - 64 years	5/22 (22.7)	NE (1.51, NE)	11/33 (33.3)	6.13 (5.41, NE)	1.24 (0.41, 3.70)	0.7106	
≥65 years	3/12 (25.0)	NE (0.30, NE)	3/33 (9.1)	NE (NE, NE)	0.39 (0.08, 1.93)	0.2324	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5013
Male	24/64 (37.5)	NE (1.02, NE)	28/159 (17.6)	NE (NE, NE)	0.31 (0.18, 0.54)	<0.0001	
Female	22/45 (48.9)	1.51 (0.23, NE)	23/108 (21.3)	NE (NE, NE)	0.25 (0.13, 0.46)	<0.0001	
Region							0.0148
USA	4/13 (30.8)	NE (0.66, NE)	7/30 (23.3)	5.41 (2.98, NE)	0.50 (0.14, 1.78)	0.2701	
Europe	29/68 (42.6)	1.77 (0.85, NE)	20/177 (11.3)	NE (NE, NE)	0.17 (0.09, 0.30)	<0.0001	
Rest of the world	13/28 (46.4)	1.31 (0.16, NE)	24/60 (40.0)	NE (1.44, NE)	0.50 (0.24, 1.02)	0.0511	
Prior salvage therapy							0.5478
Yes	26/63 (41.3)	1.77 (0.79, NE)	31/161 (19.3)	NE (NE, NE)	0.31 (0.18, 0.52)	<0.0001	
No	20/46 (43.5)	1.51 (0.66, NE)	20/106 (18.9)	NE (NE, NE)	0.25 (0.13, 0.49)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4150
0	27/55 (49.1)	1.31 (0.56, NE)	22/112 (19.6)	NE (NE, NE)	0.22 (0.12, 0.40)	<0.0001	
1	11/34 (32.4)	NE (0.89, NE)	17/91 (18.7)	NE (NE, NE)	0.44 (0.20, 0.95)	0.0328	
≥2	8/20 (40.0)	1.51 (0.46, NE)	12/64 (18.8)	NE (2.98, NE)	0.27 (0.11, 0.68)	0.0031	
Prior alloHSCT							0.0473
Yes	19/35 (54.3)	1.02 (0.16, NE)	16/93 (17.2)	NE (NE, NE)	0.16 (0.08, 0.33)	<0.0001	
No	27/74 (36.5)	NE (1.31, NE)	35/174 (20.1)	NE (NE, NE)	0.37 (0.22, 0.62)	<0.0001	
Race							0.7480
Caucasian	35/90 (38.9)	1.77 (1.51, NE)	37/226 (16.4)	NE (NE, NE)	0.28 (0.17, 0.45)	<0.0001	
Others	11/19 (57.9)	0.59 (0.10, NE)	14/41 (34.1)	5.41 (1.67, NE)	0.27 (0.12, 0.62)	0.0012	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6627
<50%	11/27 (40.7)	NE (0.56, NE)	12/73 (16.4)	NE (NE, NE)	0.20 (0.08, 0.48)	0.0001	
≥50%	33/77 (42.9)	1.61 (0.89, NE)	32/168 (19.0)	NE (NE, NE)	0.30 (0.18, 0.49)	<0.0001	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Constipation							
Overall	27/109 (24.8)	NE (1.90, NE)	34/267 (12.7)	NE (NE, NE)	0.41 (0.25, 0.69)	0.0005	
Age group 1							0.5353
<35 years	10/50 (20.0)	NE (1.90, NE)	10/123 (8.1)	NE (NE, NE)	0.32 (0.13, 0.77)	0.0076	
≥35 years	17/59 (28.8)	NE (1.57, NE)	24/144 (16.7)	NE (NE, NE)	0.47 (0.25, 0.89)	0.0180	
Age group 2							0.0468
<35 years	10/50 (20.0)	NE (1.90, NE)	10/124 (8.1)	NE (NE, NE)	0.32 (0.13, 0.77)	0.0074	
35 - 54 years	9/25 (36.0)	NE (0.59, NE)	10/77 (13.0)	NE (NE, NE)	0.29 (0.11, 0.72)	0.0047	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	10/33 (30.3)	NE (1.31, NE)	1.94 (0.52, 7.21)	0.3100	
≥65 years	5/12 (41.7)	1.57 (0.16, NE)	4/33 (12.1)	NE (NE, NE)	0.25 (0.06, 0.93)	0.0250	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1701
Male	12/64 (18.8)	NE (NE, NE)	21/159 (13.2)	NE (NE, NE)	0.56 (0.27, 1.15)	0.1116	
Female	15/45 (33.3)	NE (1.28, NE)	13/108 (12.0)	NE (NE, NE)	0.30 (0.14, 0.64)	0.0010	
Region							0.7194
USA	3/13 (23.1)	NE (0.59, NE)	5/30 (16.7)	NE (NE, NE)	0.68 (0.16, 2.83)	0.5887	
Europe	16/68 (23.5)	NE (NE, NE)	21/177 (11.9)	NE (NE, NE)	0.44 (0.23, 0.84)	0.0112	
Rest of the world	8/28 (28.6)	1.90 (1.90, NE)	8/60 (13.3)	NE (NE, NE)	0.28 (0.10, 0.79)	0.0106	
Prior salvage therapy							0.1181
Yes	10/63 (15.9)	NE (1.90, NE)	20/161 (12.4)	NE (NE, NE)	0.62 (0.29, 1.34)	0.2235	
No	17/46 (37.0)	NE (1.28, NE)	14/106 (13.2)	NE (NE, NE)	0.30 (0.15, 0.61)	0.0004	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4378
0	19/55 (34.5)	NE (1.28, NE)	17/112 (15.2)	NE (NE, NE)	0.33 (0.17, 0.65)	0.0007	
1	4/34 (11.8)	NE (1.90, NE)	10/91 (11.0)	NE (NE, NE)	0.87 (0.27, 2.79)	0.8115	
≥2	4/20 (20.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	0.44 (0.12, 1.53)	0.1853	
Prior alloHSCT							0.4143
Yes	10/35 (28.6)	NE (1.28, NE)	11/93 (11.8)	NE (NE, NE)	0.30 (0.12, 0.71)	0.0040	
No	17/74 (23.0)	NE (NE, NE)	23/174 (13.2)	NE (NE, NE)	0.49 (0.26, 0.92)	0.0224	
Race							0.2254
Caucasian	20/90 (22.2)	NE (1.90, NE)	29/226 (12.8)	NE (NE, NE)	0.48 (0.27, 0.86)	0.0119	
Others	7/19 (36.8)	NE (0.43, NE)	5/41 (12.2)	NE (NE, NE)	0.21 (0.06, 0.67)	0.0040	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0137
<50%	9/27 (33.3)	NE (0.98, NE)	4/73 (5.5)	NE (NE, NE)	0.13 (0.04, 0.44)	<0.0001	
≥50%	18/77 (23.4)	NE (1.90, NE)	28/168 (16.7)	NE (NE, NE)	0.58 (0.32, 1.06)	0.0729	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Vomiting							
Overall	26/109 (23.9)	NE (NE, NE)	33/267 (12.4)	NE (NE, NE)	0.23 (0.13, 0.41)	<0.0001	
Age group 1							0.8775
<35 years	13/50 (26.0)	NE (1.70, NE)	17/123 (13.8)	NE (NE, NE)	0.28 (0.13, 0.60)	0.0005	
≥35 years	13/59 (22.0)	NE (NE, NE)	16/144 (11.1)	NE (8.30, NE)	0.19 (0.08, 0.45)	<0.0001	
Age group 2							0.9119
<35 years	13/50 (26.0)	NE (1.70, NE)	18/124 (14.5)	NE (NE, NE)	0.30 (0.14, 0.64)	0.0010	
35 - 54 years	7/25 (28.0)	NE (NE, NE)	10/77 (13.0)	NE (8.30, NE)	0.13 (0.04, 0.45)	0.0002	
55 - 64 years	4/22 (18.2)	NE (1.44, NE)	3/33 (9.1)	NE (5.64, NE)	0.10 (0.01, 0.93)	0.0156	
≥65 years	2/12 (16.7)	NE (0.30, NE)	2/33 (6.1)	NE (NE, NE)	0.27 (0.04, 1.93)	0.1611	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2920
Male	13/64 (20.3)	NE (NE, NE)	19/159 (11.9)	NE (NE, NE)	0.34 (0.16, 0.72)	0.0032	
Female	13/45 (28.9)	NE (1.44, NE)	14/108 (13.0)	NE (6.13, NE)	0.12 (0.05, 0.32)	<0.0001	
Region							0.8343
USA	5/13 (38.5)	NE (0.13, NE)	4/30 (13.3)	5.64 (2.98, NE)	0.17 (0.04, 0.75)	0.0088	
Europe	13/68 (19.1)	NE (NE, NE)	20/177 (11.3)	NE (NE, NE)	0.28 (0.13, 0.60)	0.0006	
Rest of the world	8/28 (28.6)	1.77 (1.70, NE)	9/60 (15.0)	NE (NE, NE)	0.21 (0.07, 0.62)	0.0021	
Prior salvage therapy							0.2477
Yes	10/63 (15.9)	NE (NE, NE)	16/161 (9.9)	NE (NE, NE)	0.35 (0.15, 0.80)	0.0097	
No	16/46 (34.8)	NE (1.44, NE)	17/106 (16.0)	NE (8.30, NE)	0.16 (0.07, 0.36)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4692
0	18/55 (32.7)	NE (1.70, NE)	18/112 (16.1)	NE (8.30, NE)	0.17 (0.08, 0.38)	<0.0001	
1	6/34 (17.6)	NE (NE, NE)	10/91 (11.0)	NE (NE, NE)	0.32 (0.11, 0.92)	0.0278	
≥2	2/20 (10.0)	NE (1.11, NE)	5/64 (7.8)	NE (NE, NE)	0.53 (0.10, 2.79)	0.4448	
Prior alloHSCT							0.2809
Yes	12/35 (34.3)	1.70 (1.44, NE)	15/93 (16.1)	NE (NE, NE)	0.19 (0.08, 0.45)	<0.0001	
No	14/74 (18.9)	NE (NE, NE)	18/174 (10.3)	NE (6.62, NE)	0.25 (0.11, 0.54)	0.0002	
Race							0.4758
Caucasian	19/90 (21.1)	NE (NE, NE)	27/226 (11.9)	NE (NE, NE)	0.26 (0.13, 0.49)	<0.0001	
Others	7/19 (36.8)	1.77 (0.23, NE)	6/41 (14.6)	NE (5.64, NE)	0.19 (0.06, 0.61)	0.0023	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5110
<50%	8/27 (29.6)	NE (1.77, NE)	10/73 (13.7)	NE (6.13, NE)	0.13 (0.04, 0.41)	<0.0001	
≥50%	17/77 (22.1)	NE (1.70, NE)	21/168 (12.5)	NE (8.30, NE)	0.30 (0.15, 0.60)	0.0004	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Stomatitis							
Overall	14/109 (12.8)	NE (2.79, NE)	18/267 (6.7)	NE (11.80, NE)	0.31 (0.15, 0.66)	0.0015	
Age group 1							0.2754
<35 years	8/50 (16.0)	NE (2.07, NE)	7/123 (5.7)	11.80 (11.80, NE)	0.14 (0.04, 0.46)	0.0002	
≥35 years	6/59 (10.2)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)	0.59 (0.21, 1.64)	0.3038	
Age group 2							0.7200
<35 years	8/50 (16.0)	NE (2.07, NE)	7/124 (5.6)	11.80 (11.80, NE)	0.14 (0.04, 0.46)	0.0002	
35 - 54 years	4/25 (16.0)	NE (NE, NE)	8/77 (10.4)	NE (NE, NE)	0.50 (0.14, 1.73)	0.2635	
55 - 64 years	1/22 (4.5)	NE (1.28, NE)	2/33 (6.1)	NE (NE, NE)	1.21 (0.11, 13.51)	0.8789	
≥65 years	1/12 (8.3)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.32 (0.02, 5.27)	0.4049	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1918
Male	5/64 (7.8)	NE (2.79, NE)	10/159 (6.3)	NE (11.80, NE)	0.47 (0.15, 1.48)	0.1890	
Female	9/45 (20.0)	NE (NE, NE)	8/108 (7.4)	NE (NE, NE)	0.22 (0.08, 0.61)	0.0016	
Region							0.3290
USA	2/13 (15.4)	NE (1.28, NE)	3/30 (10.0)	NE (NE, NE)	0.61 (0.10, 3.63)	0.5796	
Europe	7/68 (10.3)	NE (2.79, NE)	5/177 (2.8)	NE (11.80, NE)	0.14 (0.04, 0.50)	0.0006	
Rest of the world	5/28 (17.9)	2.07 (2.07, NE)	10/60 (16.7)	NE (NE, NE)	0.50 (0.15, 1.62)	0.2421	
Prior salvage therapy							0.4064
Yes	6/63 (9.5)	NE (2.07, NE)	10/161 (6.2)	NE (11.80, NE)	0.43 (0.15, 1.25)	0.1124	
No	8/46 (17.4)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	0.23 (0.08, 0.69)	0.0046	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6412
0	12/55 (21.8)	NE (2.79, NE)	9/112 (8.0)	NE (NE, NE)	0.19 (0.07, 0.49)	0.0002	
1	2/34 (5.9)	NE (NE, NE)	4/91 (4.4)	NE (NE, NE)	0.60 (0.11, 3.35)	0.5541	
≥2	0/20 (0.0)	NE (NE, NE)	5/64 (7.8)	11.80 (NE, NE)	NE (NE, NE)	0.3246	
Prior alloHSCT							0.1370
Yes	6/35 (17.1)	NE (NE, NE)	5/93 (5.4)	NE (11.80, NE)	0.13 (0.03, 0.56)	0.0014	
No	8/74 (10.8)	NE (2.79, NE)	13/174 (7.5)	NE (NE, NE)	0.46 (0.18, 1.15)	0.0896	
Race							0.0207
Caucasian	11/90 (12.2)	NE (2.79, NE)	8/226 (3.5)	NE (11.80, NE)	0.15 (0.05, 0.41)	<0.0001	
Others	3/19 (15.8)	NE (2.07, NE)	10/41 (24.4)	NE (2.95, NE)	1.03 (0.28, 3.89)	0.9594	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6401
<50%	4/27 (14.8)	NE (2.07, NE)	7/73 (9.6)	NE (NE, NE)	0.31 (0.08, 1.24)	0.0817	
≥50%	10/77 (13.0)	NE (2.79, NE)	8/168 (4.8)	NE (NE, NE)	0.25 (0.09, 0.68)	0.0033	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Abdominal pain							
Overall	19/109 (17.4)	NE (NE, NE)	17/267 (6.4)	NE (NE, NE)	0.23 (0.12, 0.46)	<0.0001	
Age group 1							0.4738
<35 years	8/50 (16.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	0.31 (0.12, 0.81)	0.0115	
≥35 years	11/59 (18.6)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)	0.18 (0.07, 0.49)	0.0002	
Age group 2							0.9521
<35 years	8/50 (16.0)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)	0.31 (0.12, 0.81)	0.0115	
35 - 54 years	5/25 (20.0)	NE (1.34, NE)	7/77 (9.1)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0197	
55 - 64 years	3/22 (13.6)	NE (NE, NE)	1/33 (3.0)	NE (5.64, NE)	0.00 (0.00, NE)	0.0339	
≥65 years	3/12 (25.0)	NE (0.36, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0050	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1024
Male	8/64 (12.5)	NE (NE, NE)	11/159 (6.9)	NE (NE, NE)	0.40 (0.16, 1.01)	0.0441	
Female	11/45 (24.4)	NE (1.70, NE)	6/108 (5.6)	NE (NE, NE)	0.12 (0.04, 0.36)	<0.0001	
Region							0.0267
USA	2/13 (15.4)	NE (0.66, NE)	5/30 (16.7)	5.64 (2.98, NE)	0.71 (0.13, 3.89)	0.6929	
Europe	12/68 (17.6)	NE (NE, NE)	4/177 (2.3)	NE (NE, NE)	0.09 (0.03, 0.29)	<0.0001	
Rest of the world	5/28 (17.9)	NE (1.70, NE)	8/60 (13.3)	NE (NE, NE)	0.43 (0.13, 1.44)	0.1624	
Prior salvage therapy							0.1615
Yes	9/63 (14.3)	NE (NE, NE)	12/161 (7.5)	NE (NE, NE)	0.35 (0.15, 0.86)	0.0168	
No	10/46 (21.7)	NE (NE, NE)	5/106 (4.7)	NE (NE, NE)	0.13 (0.04, 0.43)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1306
0	11/55 (20.0)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)	0.10 (0.03, 0.38)	<0.0001	
1	6/34 (17.6)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)	0.25 (0.08, 0.82)	0.0137	
≥2	2/20 (10.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	0.67 (0.13, 3.29)	0.6153	
Prior alloHSCT							0.7360
Yes	5/35 (14.3)	NE (1.70, NE)	6/93 (6.5)	NE (NE, NE)	0.30 (0.09, 1.03)	0.0428	
No	14/74 (18.9)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	0.20 (0.09, 0.47)	<0.0001	
Race							0.2997
Caucasian	13/90 (14.4)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.20 (0.09, 0.48)	<0.0001	
Others	6/19 (31.6)	NE (0.46, NE)	8/41 (19.5)	NE (2.98, NE)	0.29 (0.09, 0.90)	0.0233	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3315
<50%	5/27 (18.5)	NE (NE, NE)	3/73 (4.1)	NE (NE, NE)	0.07 (0.01, 0.46)	0.0005	
≥50%	14/77 (18.2)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	0.27 (0.12, 0.59)	0.0006	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Dyspepsia							
Overall	7/109 (6.4)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.43 (0.16, 1.15)	0.0849	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: General disorders and administration site conditions							
Overall	84/109 (77.1)	0.33 (0.23, 0.39)	210/267 (78.7)	0.20 (0.13, 0.33)	1.07 (0.83, 1.38)	0.7310	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pyrexia							
Overall	49/109 (45.0)	1.70 (1.08, 2.62)	159/267 (59.6)	0.69 (0.36, 1.34)	1.54 (1.12, 2.12)	0.0123	
Age group 1							0.7844
<35 years	24/50 (48.0)	1.70 (1.05, 2.62)	76/123 (61.8)	0.59 (0.20, 1.54)	1.45 (0.91, 2.29)	0.1395	
≥35 years	25/59 (42.4)	1.51 (0.75, NE)	83/144 (57.6)	0.75 (0.33, 1.84)	1.63 (1.04, 2.56)	0.0390	
Age group 2							0.2167
<35 years	24/50 (48.0)	1.70 (1.05, 2.62)	76/124 (61.3)	0.59 (0.20, 1.54)	1.44 (0.91, 2.28)	0.1465	
35 - 54 years	9/25 (36.0)	NE (0.56, NE)	53/77 (68.8)	0.36 (0.13, 1.25)	2.31 (1.13, 4.70)	0.0191	
55 - 64 years	11/22 (50.0)	1.51 (0.33, NE)	13/33 (39.4)	NE (0.46, NE)	0.79 (0.35, 1.78)	0.5566	
≥65 years	5/12 (41.7)	NE (0.26, NE)	17/33 (51.5)	0.85 (0.07, NE)	1.68 (0.62, 4.58)	0.3664	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4518
Male	32/64 (50.0)	1.41 (0.52, 2.62)	97/159 (61.0)	0.56 (0.30, 1.54)	1.38 (0.92, 2.06)	0.1473	
Female	17/45 (37.8)	2.10 (1.51, NE)	62/108 (57.4)	0.75 (0.20, 5.41)	1.83 (1.06, 3.14)	0.0321	
Region							0.6215
USA	3/13 (23.1)	NE (2.10, NE)	10/30 (33.3)	NE (1.25, NE)	1.62 (0.44, 5.89)	0.4909	
Europe	31/68 (45.6)	1.51 (0.98, NE)	111/177 (62.7)	0.39 (0.20, 1.25)	1.71 (1.14, 2.55)	0.0114	
Rest of the world	15/28 (53.6)	1.05 (0.39, NE)	38/60 (63.3)	0.66 (0.13, 1.54)	1.18 (0.65, 2.16)	0.6193	
Prior salvage therapy							0.4425
Yes	27/63 (42.9)	2.30 (0.75, NE)	88/161 (54.7)	0.85 (0.36, 6.23)	1.43 (0.93, 2.21)	0.1163	
No	22/46 (47.8)	1.70 (1.08, NE)	71/106 (67.0)	0.46 (0.07, 1.44)	1.71 (1.05, 2.77)	0.0420	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4583
0	28/55 (50.9)	1.51 (0.75, 2.62)	78/112 (69.6)	0.33 (0.07, 0.89)	1.66 (1.07, 2.57)	0.0325	
1	16/34 (47.1)	1.51 (0.33, NE)	47/91 (51.6)	0.85 (0.26, NE)	1.29 (0.73, 2.27)	0.4265	
≥2	5/20 (25.0)	NE (0.52, NE)	34/64 (53.1)	1.25 (0.36, NE)	2.39 (0.93, 6.13)	0.0613	
Prior alloHSCT							0.8047
Yes	16/35 (45.7)	1.70 (0.52, NE)	61/93 (65.6)	0.66 (0.20, 1.44)	1.51 (0.87, 2.64)	0.1597	
No	33/74 (44.6)	1.51 (1.08, NE)	98/174 (56.3)	0.69 (0.30, 1.67)	1.53 (1.03, 2.27)	0.0499	
Race							0.6067
Caucasian	40/90 (44.4)	1.70 (1.08, NE)	129/226 (57.1)	0.85 (0.43, 1.57)	1.49 (1.04, 2.13)	0.0375	
Others	9/19 (47.4)	1.41 (0.07, NE)	30/41 (73.2)	0.13 (0.07, 0.56)	1.82 (0.86, 3.86)	0.1133	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3122
<50%	11/27 (40.7)	NE (0.39, NE)	50/73 (68.5)	0.36 (0.07, 1.25)	2.10 (1.09, 4.05)	0.0284	
≥50%	36/77 (46.8)	1.70 (0.75, NE)	100/168 (59.5)	0.56 (0.30, 1.34)	1.49 (1.02, 2.19)	0.0505	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Oedema peripheral							
Overall	16/109 (14.7)	NE (NE, NE)	39/267 (14.6)	NE (NE, NE)	0.84 (0.47, 1.51)	0.5559	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Fatigue							
Overall	14/109 (12.8)	NE (NE, NE)	34/267 (12.7)	NE (NE, NE)	0.74 (0.39, 1.41)	0.3653	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Asthenia							
Overall	11/109 (10.1)	NE (NE, NE)	21/267 (7.9)	NE (NE, NE)	0.60 (0.28, 1.25)	0.1682	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Chills							
Overall	12/109 (11.0)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	0.45 (0.21, 0.96)	0.0347	
Age group 1							0.4242
<35 years	4/50 (8.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	0.56 (0.16, 1.96)	0.3577	
≥35 years	8/59 (13.6)	NE (NE, NE)	10/144 (6.9)	NE (10.03, NE)	0.40 (0.15, 1.07)	0.0573	
Age group 2							0.1758
<35 years	4/50 (8.0)	NE (NE, NE)	10/124 (8.1)	NE (NE, NE)	0.66 (0.19, 2.22)	0.4908	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	7/77 (9.1)	NE (10.03, NE)	0.76 (0.15, 3.87)	0.7405	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2278	
≥65 years	5/12 (41.7)	NE (0.20, NE)	2/33 (6.1)	NE (NE, NE)	0.14 (0.03, 0.72)	0.0058	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1984
Male	9/64 (14.1)	NE (NE, NE)	10/159 (6.3)	NE (10.03, NE)	0.31 (0.12, 0.82)	0.0121	
Female	3/45 (6.7)	NE (NE, NE)	9/108 (8.3)	NE (NE, NE)	0.87 (0.22, 3.44)	0.8367	
Region							0.5355
USA	3/13 (23.1)	NE (0.39, NE)	7/30 (23.3)	NE (NE, NE)	0.97 (0.25, 3.78)	0.9737	
Europe	5/68 (7.4)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.34 (0.10, 1.19)	0.0781	
Rest of the world	4/28 (14.3)	NE (2.00, NE)	4/60 (6.7)	10.03 (10.03, NE)	0.26 (0.06, 1.21)	0.0666	
Prior salvage therapy							0.8114
Yes	4/63 (6.3)	NE (NE, NE)	7/161 (4.3)	NE (10.03, NE)	0.40 (0.11, 1.52)	0.1647	
No	8/46 (17.4)	NE (NE, NE)	12/106 (11.3)	NE (NE, NE)	0.47 (0.18, 1.22)	0.1141	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5725
0	9/55 (16.4)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	0.38 (0.14, 0.99)	0.0389	
1	2/34 (5.9)	NE (NE, NE)	6/91 (6.6)	NE (10.03, NE)	0.91 (0.18, 4.71)	0.9122	
≥2	1/20 (5.0)	NE (NE, NE)	3/64 (4.7)	NE (5.90, NE)	0.49 (0.04, 5.69)	0.5646	
Prior alloHSCT							0.2777
Yes	2/35 (5.7)	NE (NE, NE)	8/93 (8.6)	NE (10.03, NE)	0.67 (0.12, 3.64)	0.6386	
No	10/74 (13.5)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	0.41 (0.17, 0.98)	0.0373	
Race							0.7692
Caucasian	9/90 (10.0)	NE (NE, NE)	14/226 (6.2)	NE (NE, NE)	0.39 (0.16, 0.97)	0.0365	
Others	3/19 (15.8)	NE (2.00, NE)	5/41 (12.2)	NE (NE, NE)	0.67 (0.16, 2.81)	0.5754	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0282
<50%	8/27 (29.6)	NE (0.95, NE)	6/73 (8.2)	NE (NE, NE)	0.20 (0.06, 0.62)	0.0019	
≥50%	3/77 (3.9)	NE (NE, NE)	10/168 (6.0)	NE (NE, NE)	1.04 (0.27, 3.99)	0.9483	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pain							
Overall	6/109 (5.5)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.77 (0.29, 2.02)	0.5919	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Mucosal inflammation							
Overall	14/109 (12.8)	NE (NE, NE)	9/267 (3.4)	NE (NE, NE)	0.20 (0.08, 0.47)	<0.0001	
Age group 1							0.5806
<35 years	6/50 (12.0)	NE (NE, NE)	3/123 (2.4)	NE (NE, NE)	0.11 (0.03, 0.50)	0.0008	
≥35 years	8/59 (13.6)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.28 (0.10, 0.82)	0.0137	
Age group 2							0.8904
<35 years	6/50 (12.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	4/25 (16.0)	-	5/77 (6.5)	-	-	-	
55 - 64 years	3/22 (13.6)	-	0/33 (0.0)	-	-	-	
≥65 years	1/12 (8.3)	-	1/33 (3.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9283
Male	5/64 (7.8)	NE (NE, NE)	3/159 (1.9)	NE (NE, NE)	0.16 (0.04, 0.71)	0.0066	
Female	9/45 (20.0)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	0.23 (0.08, 0.68)	0.0038	
Region							0.8781
USA	1/13 (7.7)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	0.41 (0.03, 6.61)	0.5180	
Europe	13/68 (19.1)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.17 (0.07, 0.44)	<0.0001	
Rest of the world	0/28 (0.0)	NE (NE, NE)	0/60 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
Prior salvage therapy							0.6914
Yes	10/63 (15.9)	NE (NE, NE)	6/161 (3.7)	NE (NE, NE)	0.16 (0.06, 0.48)	0.0002	
No	4/46 (8.7)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.29 (0.07, 1.32)	0.0888	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9715
0	8/55 (14.5)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)	0.22 (0.07, 0.73)	0.0067	
1	4/34 (11.8)	NE (NE, NE)	3/91 (3.3)	NE (NE, NE)	0.12 (0.02, 0.75)	0.0080	
≥2	2/20 (10.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.28 (0.04, 2.00)	0.1756	
Prior alloHSCT							0.3595
Yes	5/35 (14.3)	NE (NE, NE)	2/93 (2.2)	NE (NE, NE)	0.14 (0.03, 0.72)	0.0059	
No	9/74 (12.2)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.23 (0.08, 0.66)	0.0030	
Race							0.9922
Caucasian	13/90 (14.4)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.21 (0.09, 0.51)	0.0001	
Others	1/19 (5.3)	NE (NE, NE)	0/41 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1360	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0130
<50%	8/27 (29.6)	NE (1.70, NE)	1/73 (1.4)	NE (NE, NE)	0.04 (0.00, 0.30)	<0.0001	
≥50%	5/77 (6.5)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.57 (0.18, 1.81)	0.3368	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Hepatobiliary disorders							
Overall	15/109 (13.8)	NE (NE, NE)	30/267 (11.2)	NE (NE, NE)	0.67 (0.36, 1.26)	0.2158	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Immune system disorders							
Overall	4/109 (3.7)	NE (NE, NE)	63/267 (23.6)	NE (7.74, NE)	5.49 (1.99, 15.17)	0.0002	
Age group 1							0.9834
<35 years	0/50 (0.0)	NE (NE, NE)	31/123 (25.2)	NE (7.02, NE)	NE (NE, NE)	0.0006	
≥35 years	4/59 (6.8)	NE (NE, NE)	32/144 (22.2)	NE (7.74, NE)	2.57 (0.89, 7.38)	0.0713	
Age group 2							0.7527
<35 years	0/50 (0.0)	NE (NE, NE)	31/124 (25.0)	NE (7.02, NE)	NE (NE, NE)	0.0007	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	18/77 (23.4)	8.30 (5.08, NE)	4.01 (0.52, 30.65)	0.1486	
55 - 64 years	3/22 (13.6)	NE (NE, NE)	6/33 (18.2)	NE (5.80, NE)	1.15 (0.27, 4.80)	0.8646	
≥65 years	0/12 (0.0)	NE (NE, NE)	8/33 (24.2)	7.74 (7.74, NE)	NE (NE, NE)	0.1161	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7685
Male	2/64 (3.1)	NE (NE, NE)	36/159 (22.6)	NE (7.02, NE)	6.36 (1.52, 26.55)	0.0036	
Female	2/45 (4.4)	NE (NE, NE)	27/108 (25.0)	NE (5.80, NE)	4.50 (1.06, 19.18)	0.0260	
Region							0.9998
USA	0/13 (0.0)	NE (NE, NE)	8/30 (26.7)	NE (3.02, NE)	NE (NE, NE)	0.0533	
Europe	4/68 (5.9)	NE (NE, NE)	36/177 (20.3)	NE (7.74, NE)	2.55 (0.89, 7.27)	0.0700	
Rest of the world	0/28 (0.0)	NE (NE, NE)	19/60 (31.7)	NE (2.52, NE)	NE (NE, NE)	0.0023	
Prior salvage therapy							0.1835
Yes	1/63 (1.6)	NE (NE, NE)	39/161 (24.2)	NE (7.02, NE)	14.01 (1.92, 102.36)	0.0006	
No	3/46 (6.5)	NE (NE, NE)	24/106 (22.6)	NE (7.74, NE)	2.67 (0.79, 9.00)	0.1018	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9464
0	3/55 (5.5)	NE (NE, NE)	27/112 (24.1)	NE (7.02, NE)	3.27 (0.97, 10.95)	0.0431	
1	0/34 (0.0)	NE (NE, NE)	27/91 (29.7)	NE (5.80, NE)	NE (NE, NE)	0.0017	
≥2	1/20 (5.0)	NE (1.15, NE)	9/64 (14.1)	NE (NE, NE)	2.40 (0.30, 19.12)	0.3945	
Prior alloHSCT							0.6273
Yes	2/35 (5.7)	NE (NE, NE)	27/93 (29.0)	8.30 (5.08, NE)	3.56 (0.83, 15.22)	0.0681	
No	2/74 (2.7)	NE (NE, NE)	36/174 (20.7)	NE (7.74, NE)	7.29 (1.75, 30.40)	0.0014	
Race							0.9856
Caucasian	4/90 (4.4)	NE (NE, NE)	55/226 (24.3)	NE (7.74, NE)	4.81 (1.73, 13.36)	0.0009	
Others	0/19 (0.0)	NE (NE, NE)	8/41 (19.5)	NE (3.02, NE)	NE (NE, NE)	0.1156	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3761
<50%	2/27 (7.4)	NE (NE, NE)	20/73 (27.4)	NE (5.80, NE)	2.71 (0.62, 11.86)	0.1697	
≥50%	2/77 (2.6)	NE (NE, NE)	37/168 (22.0)	NE (8.30, NE)	7.89 (1.89, 32.88)	0.0008	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Cytokine release syndrome							
Overall	0/109 (0.0)	NE (NE, NE)	38/267 (14.2)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Age group 1							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/123 (14.6)	NE (NE, NE)	NE (NE, NE)	0.0057	
≥35 years	0/59 (0.0)	NE (NE, NE)	20/144 (13.9)	NE (NE, NE)	NE (NE, NE)	0.0033	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/124 (14.5)	NE (NE, NE)	NE (NE, NE)	0.0059	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	10/77 (13.0)	NE (NE, NE)	NE (NE, NE)	0.0726	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	5/33 (15.2)	NE (NE, NE)	NE (NE, NE)	0.0595	
≥65 years	0/12 (0.0)	NE (NE, NE)	5/33 (15.2)	NE (NE, NE)	NE (NE, NE)	0.1600	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	NE (NE, NE)	20/159 (12.6)	NE (NE, NE)	NE (NE, NE)	0.0034	
Female	0/45 (0.0)	NE (NE, NE)	18/108 (16.7)	NE (NE, NE)	NE (NE, NE)	0.0055	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (NE, NE)	NE (NE, NE)	0.0629	
Europe	0/68 (0.0)	NE (NE, NE)	15/177 (8.5)	NE (NE, NE)	NE (NE, NE)	0.0155	
Rest of the world	0/28 (0.0)	NE (NE, NE)	16/60 (26.7)	NE (NE, NE)	NE (NE, NE)	0.0039	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	NE (NE, NE)	27/161 (16.8)	NE (NE, NE)	NE (NE, NE)	0.0008	
No	0/46 (0.0)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	NE (NE, NE)	0.0271	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)	NE (NE, NE)	0.0140	
1	0/34 (0.0)	NE (NE, NE)	19/91 (20.9)	NE (NE, NE)	NE (NE, NE)	0.0046	
≥2	0/20 (0.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	NE (NE, NE)	0.1500	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	NE (NE, NE)	12/93 (12.9)	NE (NE, NE)	NE (NE, NE)	0.0319	
No	0/74 (0.0)	NE (NE, NE)	26/174 (14.9)	NE (NE, NE)	NE (NE, NE)	0.0006	
Race							0.9998
Caucasian	0/90 (0.0)	NE (NE, NE)	35/226 (15.5)	NE (NE, NE)	NE (NE, NE)	0.0001	
Others	0/19 (0.0)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	NE (NE, NE)	0.2831	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	NE (NE, NE)	11/73 (15.1)	NE (NE, NE)	NE (NE, NE)	0.0353	
≥50%	0/77 (0.0)	NE (NE, NE)	25/168 (14.9)	NE (NE, NE)	NE (NE, NE)	0.0005	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypogammaglobulinaemia							
Overall	1/109 (0.9)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	2.38 (0.30, 18.84)	0.3970	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Infections and infestations							
Overall	79/109 (72.5)	0.49 (0.39, 0.62)	171/267 (64.0)	1.31 (1.05, 1.90)	0.50 (0.38, 0.66)	<0.0001	
Age group 1							0.1421
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/123 (61.0)	1.28 (1.02, 2.72)	0.62 (0.40, 0.95)	0.0265	
≥35 years	48/59 (81.4)	0.43 (0.33, 0.56)	96/144 (66.7)	1.31 (0.75, 1.90)	0.42 (0.29, 0.61)	<0.0001	
Age group 2							0.2777
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/124 (60.5)	1.28 (1.02, 2.72)	0.62 (0.40, 0.95)	0.0261	
35 - 54 years	20/25 (80.0)	0.43 (0.30, 0.62)	53/77 (68.8)	1.08 (0.69, 2.49)	0.37 (0.21, 0.65)	0.0003	
55 - 64 years	17/22 (77.3)	0.41 (0.30, 0.79)	25/33 (75.8)	1.15 (0.46, 1.84)	0.55 (0.29, 1.08)	0.0778	
≥65 years	11/12 (91.7)	0.41 (0.10, 1.54)	18/33 (54.5)	3.08 (0.56, 5.54)	0.33 (0.15, 0.74)	0.0047	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8457
Male	46/64 (71.9)	0.49 (0.39, 0.72)	100/159 (62.9)	1.28 (0.79, 2.72)	0.51 (0.35, 0.74)	0.0002	
Female	33/45 (73.3)	0.49 (0.33, 0.69)	71/108 (65.7)	1.48 (0.95, 2.52)	0.48 (0.31, 0.74)	0.0008	
Region							0.8360
USA	8/13 (61.5)	1.21 (0.16, NE)	17/30 (56.7)	1.31 (0.72, NE)	0.64 (0.27, 1.52)	0.3130	
Europe	49/68 (72.1)	0.49 (0.36, 0.72)	111/177 (62.7)	1.80 (1.11, 2.69)	0.46 (0.33, 0.66)	<0.0001	
Rest of the world	22/28 (78.6)	0.46 (0.36, 0.49)	43/60 (71.7)	0.79 (0.56, 1.48)	0.48 (0.27, 0.84)	0.0090	
Prior salvage therapy							0.0379
Yes	42/63 (66.7)	0.49 (0.39, 1.11)	109/161 (67.7)	0.95 (0.69, 1.41)	0.66 (0.46, 0.96)	0.0265	
No	37/46 (80.4)	0.49 (0.33, 0.62)	62/106 (58.5)	2.75 (1.31, 3.61)	0.32 (0.21, 0.50)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0601
0	40/55 (72.7)	0.49 (0.36, 0.72)	69/112 (61.6)	2.75 (1.28, 3.64)	0.38 (0.25, 0.58)	<0.0001	
1	27/34 (79.4)	0.46 (0.30, 0.66)	57/91 (62.6)	1.21 (0.69, 1.97)	0.42 (0.26, 0.69)	0.0003	
≥2	12/20 (60.0)	0.49 (0.33, NE)	45/64 (70.3)	0.72 (0.46, 1.28)	0.95 (0.50, 1.82)	0.8630	
Prior alloHSCT							0.5569
Yes	24/35 (68.6)	0.49 (0.36, 1.11)	65/93 (69.9)	1.31 (0.92, 2.00)	0.48 (0.29, 0.81)	0.0049	
No	55/74 (74.3)	0.49 (0.39, 0.62)	106/174 (60.9)	1.28 (0.75, 2.69)	0.49 (0.35, 0.68)	<0.0001	
Race							0.2409
Caucasian	66/90 (73.3)	0.49 (0.39, 0.62)	140/226 (61.9)	1.61 (1.15, 2.52)	0.46 (0.34, 0.63)	<0.0001	
Others	13/19 (68.4)	0.43 (0.20, 1.11)	31/41 (75.6)	0.72 (0.36, 1.02)	0.70 (0.36, 1.38)	0.2942	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0848
<50%	22/27 (81.5)	0.49 (0.33, 1.51)	45/73 (61.6)	3.21 (2.52, 4.10)	0.23 (0.13, 0.42)	<0.0001	
≥50%	54/77 (70.1)	0.49 (0.39, 0.59)	108/168 (64.3)	1.02 (0.69, 1.31)	0.60 (0.43, 0.84)	0.0026	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Upper respiratory tract infection							
Overall	1/109 (0.9)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	3.29 (0.42, 25.52)	0.2284	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Device related infection							
Overall	6/109 (5.5)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.60 (0.22, 1.64)	0.3117	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pneumonia							
Overall	16/109 (14.7)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.22 (0.10, 0.48)	<0.0001	
Age group 1							0.0549
<35 years	9/50 (18.0)	NE (NE, NE)	4/123 (3.3)	NE (NE, NE)	0.11 (0.03, 0.42)	<0.0001	
≥35 years	7/59 (11.9)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)	0.37 (0.13, 1.03)	0.0494	
Age group 2							0.4464
<35 years	9/50 (18.0)	NE (NE, NE)	4/124 (3.2)	NE (NE, NE)	0.11 (0.03, 0.42)	<0.0001	
35 - 54 years	4/25 (16.0)	NE (1.48, NE)	7/77 (9.1)	NE (8.30, NE)	0.28 (0.07, 1.09)	0.0519	
55 - 64 years	3/22 (13.6)	NE (1.57, NE)	3/33 (9.1)	NE (NE, NE)	0.47 (0.09, 2.50)	0.3654	
≥65 years	0/12 (0.0)	NE (NE, NE)	2/33 (6.1)	NE (5.54, NE)	NE (NE, NE)	0.7893	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8987
Male	9/64 (14.1)	NE (NE, NE)	9/159 (5.7)	NE (NE, NE)	0.21 (0.07, 0.61)	0.0016	
Female	7/45 (15.6)	NE (NE, NE)	7/108 (6.5)	NE (NE, NE)	0.24 (0.07, 0.75)	0.0081	
Region							0.9975
USA	0/13 (0.0)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	NE (NE, NE)	0.5032	
Europe	12/68 (17.6)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	0.16 (0.06, 0.42)	<0.0001	
Rest of the world	4/28 (14.3)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	0.32 (0.07, 1.43)	0.1163	
Prior salvage therapy							0.4089
Yes	12/63 (19.0)	NE (NE, NE)	10/161 (6.2)	NE (NE, NE)	0.24 (0.10, 0.58)	0.0006	
No	4/46 (8.7)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	0.15 (0.03, 0.76)	0.0107	

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Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4598
0	7/55 (12.7)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	0.27 (0.08, 0.84)	0.0166	
1	7/34 (20.6)	NE (1.57, NE)	4/91 (4.4)	NE (NE, NE)	0.11 (0.03, 0.45)	0.0002	
≥2	2/20 (10.0)	NE (NE, NE)	4/64 (6.3)	NE (NE, NE)	0.44 (0.07, 2.64)	0.3585	
Prior alloHSCT							0.3556
Yes	5/35 (14.3)	NE (NE, NE)	9/93 (9.7)	NE (NE, NE)	0.33 (0.10, 1.11)	0.0607	
No	11/74 (14.9)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.17 (0.06, 0.47)	0.0001	
Race							0.3765
Caucasian	14/90 (15.6)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	0.17 (0.07, 0.42)	<0.0001	
Others	2/19 (10.5)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.68 (0.12, 3.90)	0.6572	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2656
<50%	5/27 (18.5)	NE (1.48, NE)	3/73 (4.1)	NE (8.30, NE)	0.11 (0.02, 0.57)	0.0017	
≥50%	11/77 (14.3)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.27 (0.11, 0.68)	0.0030	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Oral herpes							
Overall	9/109 (8.3)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.47 (0.20, 1.11)	0.0772	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sepsis							
Overall	8/109 (7.3)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.44 (0.18, 1.08)	0.0660	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Nasopharyngitis							
Overall	0/109 (0.0)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	NE (NE, NE)	0.2049	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Urinary tract infection							
Overall	2/109 (1.8)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	1.56 (0.34, 7.26)	0.5668	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Injury, poisoning and procedural complications							
Overall	10/109 (9.2)	NE (NE, NE)	38/267 (14.2)	NE (NE, NE)	1.10 (0.54, 2.24)	0.7940	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Investigations							
Overall	40/109 (36.7)	NE (1.41, NE)	111/267 (41.6)	5.31 (2.85, NE)	1.02 (0.71, 1.46)	0.9382	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Alanine aminotransferase increased							
Overall	11/109 (10.1)	NE (NE, NE)	24/267 (9.0)	NE (NE, NE)	0.82 (0.40, 1.69)	0.5947	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Platelet count decreased							
Overall	13/109 (11.9)	NE (NE, NE)	17/267 (6.4)	NE (NE, NE)	0.42 (0.20, 0.89)	0.0192	
Age group 1							0.5263
<35 years	6/50 (12.0)	NE (NE, NE)	6/123 (4.9)	NE (NE, NE)	0.29 (0.09, 0.94)	0.0291	
≥35 years	7/59 (11.9)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)	0.54 (0.20, 1.43)	0.2057	
Age group 2							0.6444
<35 years	6/50 (12.0)	NE (NE, NE)	6/124 (4.8)	NE (NE, NE)	0.29 (0.09, 0.94)	0.0286	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	6/77 (7.8)	NE (NE, NE)	0.69 (0.13, 3.66)	0.6585	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	2/33 (6.1)	NE (NE, NE)	0.32 (0.06, 1.72)	0.1598	
≥65 years	1/12 (8.3)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	1.13 (0.12, 10.89)	0.9142	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1858
Male	7/64 (10.9)	NE (NE, NE)	5/159 (3.1)	NE (NE, NE)	0.16 (0.04, 0.59)	0.0019	
Female	6/45 (13.3)	NE (NE, NE)	12/108 (11.1)	NE (NE, NE)	0.77 (0.28, 2.07)	0.5991	
Region							0.8230
USA	4/13 (30.8)	NE (0.30, NE)	3/30 (10.0)	NE (NE, NE)	0.31 (0.07, 1.38)	0.0998	
Europe	4/68 (5.9)	NE (NE, NE)	7/177 (4.0)	NE (NE, NE)	0.54 (0.15, 1.93)	0.3384	
Rest of the world	5/28 (17.9)	NE (NE, NE)	7/60 (11.7)	NE (NE, NE)	0.43 (0.13, 1.44)	0.1588	
Prior salvage therapy							0.1493
Yes	5/63 (7.9)	NE (NE, NE)	11/161 (6.8)	NE (NE, NE)	0.63 (0.21, 1.90)	0.4114	
No	8/46 (17.4)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	0.30 (0.10, 0.86)	0.0167	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9573
0	7/55 (12.7)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	0.40 (0.13, 1.17)	0.0820	
1	4/34 (11.8)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)	0.39 (0.10, 1.48)	0.1518	
≥2	2/20 (10.0)	NE (1.25, NE)	4/64 (6.3)	NE (NE, NE)	0.56 (0.10, 3.08)	0.4990	
Prior alloHSCT							0.2096
Yes	5/35 (14.3)	NE (1.25, NE)	4/93 (4.3)	NE (NE, NE)	0.21 (0.05, 0.83)	0.0153	
No	8/74 (10.8)	NE (NE, NE)	13/174 (7.5)	NE (NE, NE)	0.57 (0.23, 1.41)	0.2149	
Race							0.2862
Caucasian	11/90 (12.2)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	0.37 (0.16, 0.85)	0.0150	
Others	2/19 (10.5)	NE (NE, NE)	5/41 (12.2)	NE (4.59, NE)	0.73 (0.13, 4.09)	0.7196	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4153
<50%	3/27 (11.1)	NE (NE, NE)	2/73 (2.7)	NE (NE, NE)	0.16 (0.02, 1.12)	0.0385	
≥50%	10/77 (13.0)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.38 (0.15, 0.93)	0.0280	

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[a] p-values were calculated using the unstratified log-rank test.
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Data cut-off date: 04JAN2016

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Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Aspartate aminotransferase increased							
Overall	10/109 (9.2)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.57 (0.25, 1.27)	0.1630	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: White blood cell count decreased							
Overall	6/109 (5.5)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.79 (0.30, 2.09)	0.6303	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Gamma-glutamyltransferase increased							
Overall	4/109 (3.7)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	1.17 (0.38, 3.64)	0.7809	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Blood bilirubin increased							
Overall	9/109 (8.3)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.42 (0.17, 1.03)	0.0519	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutrophil count decreased							
Overall	11/109 (10.1)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.27 (0.11, 0.67)	0.0025	
Age group 1							0.8194
<35 years	6/50 (12.0)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	0.27 (0.08, 0.88)	0.0206	
≥35 years	5/59 (8.5)	NE (NE, NE)	5/144 (3.5)	NE (NE, NE)	0.28 (0.07, 1.07)	0.0469	
Age group 2							0.9989
<35 years	6/50 (12.0)	NE (NE, NE)	5/124 (4.0)	NE (NE, NE)	0.26 (0.08, 0.88)	0.0202	
35 - 54 years	3/25 (12.0)	NE (NE, NE)	4/77 (5.2)	NE (NE, NE)	0.24 (0.05, 1.28)	0.0721	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0797	
≥65 years	0/12 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.5403	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3076
Male	7/64 (10.9)	NE (NE, NE)	4/159 (2.5)	NE (NE, NE)	0.13 (0.03, 0.52)	0.0007	
Female	4/45 (8.9)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	0.58 (0.16, 2.09)	0.3996	
Region							0.8211
USA	4/13 (30.8)	NE (0.26, NE)	2/30 (6.7)	NE (NE, NE)	0.21 (0.04, 1.16)	0.0484	
Europe	2/68 (2.9)	NE (NE, NE)	2/177 (1.1)	NE (NE, NE)	0.29 (0.04, 2.09)	0.1912	
Rest of the world	5/28 (17.9)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.30 (0.08, 1.14)	0.0620	
Prior salvage therapy							0.0501
Yes	5/63 (7.9)	NE (NE, NE)	9/161 (5.6)	NE (NE, NE)	0.57 (0.19, 1.75)	0.3204	
No	6/46 (13.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	0.05 (0.01, 0.44)	0.0002	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4179
0	7/55 (12.7)	NE (NE, NE)	3/112 (2.7)	NE (NE, NE)	0.11 (0.02, 0.52)	0.0009	
1	3/34 (8.8)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)	0.54 (0.13, 2.31)	0.4013	
≥2	1/20 (5.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.63 (0.06, 6.94)	0.6980	
Prior alloHSCT							0.5353
Yes	4/35 (11.4)	NE (NE, NE)	3/93 (3.2)	NE (NE, NE)	0.21 (0.05, 1.02)	0.0340	
No	7/74 (9.5)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.32 (0.11, 0.95)	0.0303	
Race							0.2824
Caucasian	8/90 (8.9)	NE (NE, NE)	5/226 (2.2)	NE (NE, NE)	0.20 (0.06, 0.62)	0.0022	
Others	3/19 (15.8)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	0.50 (0.11, 2.29)	0.3609	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9918
<50%	3/27 (11.1)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0040	
≥50%	8/77 (10.4)	NE (NE, NE)	9/168 (5.4)	NE (NE, NE)	0.40 (0.15, 1.08)	0.0612	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Transaminases increased							
Overall	0/109 (0.0)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	NE (NE, NE)	0.0539	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	5/123 (4.1)	-	-	-	
≥35 years	0/59 (0.0)	-	5/144 (3.5)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	5/124 (4.0)	-	-	-	
35 - 54 years	0/25 (0.0)	-	5/77 (6.5)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9998
Male	0/64 (0.0)	-	8/159 (5.0)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	5/177 (2.8)	-	-	-	
Rest of the world	0/28 (0.0)	-	4/60 (6.7)	-	-	-	
Prior salvage therapy							0.9999
Yes	0/63 (0.0)	-	4/161 (2.5)	-	-	-	
No	0/46 (0.0)	-	6/106 (5.7)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	7/112 (6.3)	-	-	-	
1	0/34 (0.0)	-	0/91 (0.0)	-	-	-	
≥2	0/20 (0.0)	-	3/64 (4.7)	-	-	-	
Prior alloHSCT							0.9999
Yes	0/35 (0.0)	-	5/93 (5.4)	-	-	-	
No	0/74 (0.0)	-	5/174 (2.9)	-	-	-	
Race							>0.9999
Caucasian	0/90 (0.0)	-	9/226 (4.0)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	-	3/73 (4.1)	-	-	-	
≥50%	0/77 (0.0)	-	6/168 (3.6)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Metabolism and nutrition disorders							
Overall	57/109 (52.3)	0.82 (0.49, 2.82)	113/267 (42.3)	NE (1.90, NE)	0.67 (0.49, 0.93)	0.0142	
Age group 1							0.8468
<35 years	25/50 (50.0)	1.25 (0.43, NE)	51/123 (41.5)	6.49 (1.84, NE)	0.61 (0.38, 1.00)	0.0503	
≥35 years	32/59 (54.2)	0.79 (0.36, NE)	62/144 (43.1)	NE (1.41, NE)	0.72 (0.47, 1.11)	0.1290	
Age group 2							0.8502
<35 years	25/50 (50.0)	1.25 (0.43, NE)	51/124 (41.1)	6.49 (1.84, NE)	0.61 (0.38, 1.00)	0.0482	
35 - 54 years	14/25 (56.0)	0.82 (0.39, NE)	33/77 (42.9)	NE (1.41, NE)	0.66 (0.35, 1.25)	0.1860	
55 - 64 years	11/22 (50.0)	0.56 (0.13, NE)	17/33 (51.5)	1.41 (0.20, NE)	0.98 (0.46, 2.10)	0.9885	
≥65 years	7/12 (58.3)	0.48 (0.07, NE)	12/33 (36.4)	NE (0.43, NE)	0.60 (0.24, 1.53)	0.2676	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5396
Male	33/64 (51.6)	0.66 (0.46, NE)	71/159 (44.7)	3.87 (1.41, NE)	0.70 (0.46, 1.06)	0.0940	
Female	24/45 (53.3)	0.82 (0.36, NE)	42/108 (38.9)	NE (1.84, NE)	0.62 (0.38, 1.04)	0.0651	
Region							0.6983
USA	8/13 (61.5)	0.33 (0.07, NE)	19/30 (63.3)	0.43 (0.10, NE)	0.98 (0.43, 2.25)	0.9773	
Europe	32/68 (47.1)	1.74 (0.49, NE)	63/177 (35.6)	NE (6.49, NE)	0.63 (0.41, 0.98)	0.0368	
Rest of the world	17/28 (60.7)	0.56 (0.26, NE)	31/60 (51.7)	1.84 (0.66, NE)	0.64 (0.35, 1.18)	0.1479	
Prior salvage therapy							0.2809
Yes	31/63 (49.2)	1.25 (0.46, NE)	72/161 (44.7)	3.87 (1.41, NE)	0.75 (0.49, 1.15)	0.1855	
No	26/46 (56.5)	0.66 (0.30, NE)	41/106 (38.7)	NE (1.84, NE)	0.57 (0.35, 0.94)	0.0241	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3209
0	32/55 (58.2)	0.59 (0.36, 2.33)	43/112 (38.4)	NE (2.56, NE)	0.53 (0.33, 0.84)	0.0059	
1	16/34 (47.1)	2.82 (0.26, NE)	40/91 (44.0)	NE (0.95, NE)	0.82 (0.46, 1.47)	0.5001	
≥2	9/20 (45.0)	1.25 (0.26, NE)	30/64 (46.9)	2.92 (0.82, NE)	0.84 (0.39, 1.80)	0.6421	
Prior alloHSCT							0.7764
Yes	17/35 (48.6)	1.25 (0.49, NE)	39/93 (41.9)	3.87 (1.41, NE)	0.63 (0.35, 1.13)	0.1168	
No	40/74 (54.1)	0.62 (0.36, NE)	74/174 (42.5)	NE (1.64, NE)	0.68 (0.46, 1.01)	0.0509	
Race							0.5648
Caucasian	48/90 (53.3)	0.66 (0.46, NE)	95/226 (42.0)	NE (1.97, NE)	0.65 (0.46, 0.92)	0.0146	
Others	9/19 (47.4)	2.33 (0.33, NE)	18/41 (43.9)	1.87 (0.66, NE)	0.81 (0.36, 1.82)	0.6023	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0907
<50%	15/27 (55.6)	1.74 (0.26, NE)	22/73 (30.1)	NE (NE, NE)	0.43 (0.22, 0.84)	0.0095	
≥50%	39/77 (50.6)	0.82 (0.46, NE)	79/168 (47.0)	2.56 (1.21, NE)	0.81 (0.55, 1.19)	0.2840	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypokalaemia							
Overall	30/109 (27.5)	NE (NE, NE)	45/267 (16.9)	NE (NE, NE)	0.48 (0.30, 0.77)	0.0019	
Age group 1							0.7565
<35 years	15/50 (30.0)	NE (1.48, NE)	22/123 (17.9)	NE (NE, NE)	0.49 (0.25, 0.95)	0.0317	
≥35 years	15/59 (25.4)	NE (1.74, NE)	23/144 (16.0)	NE (7.28, NE)	0.46 (0.23, 0.91)	0.0221	
Age group 2							0.9506
<35 years	15/50 (30.0)	NE (1.48, NE)	22/124 (17.7)	NE (NE, NE)	0.49 (0.25, 0.95)	0.0311	
35 - 54 years	7/25 (28.0)	1.74 (0.79, NE)	13/77 (16.9)	NE (7.28, NE)	0.35 (0.13, 0.94)	0.0297	
55 - 64 years	5/22 (22.7)	NE (1.11, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.13, 1.79)	0.2640	
≥65 years	3/12 (25.0)	NE (0.46, NE)	6/33 (18.2)	NE (4.79, NE)	0.64 (0.15, 2.69)	0.5392	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1719
Male	13/64 (20.3)	NE (NE, NE)	26/159 (16.4)	NE (NE, NE)	0.67 (0.34, 1.32)	0.2448	
Female	17/45 (37.8)	NE (0.79, NE)	19/108 (17.6)	NE (NE, NE)	0.34 (0.17, 0.68)	0.0014	
Region							0.3866
USA	6/13 (46.2)	1.48 (0.26, NE)	8/30 (26.7)	NE (1.48, NE)	0.48 (0.17, 1.42)	0.1726	
Europe	13/68 (19.1)	NE (NE, NE)	26/177 (14.7)	NE (NE, NE)	0.65 (0.33, 1.28)	0.2085	
Rest of the world	11/28 (39.3)	NE (0.52, NE)	11/60 (18.3)	NE (5.51, NE)	0.28 (0.11, 0.67)	0.0023	
Prior salvage therapy							0.7266
Yes	16/63 (25.4)	NE (NE, NE)	27/161 (16.8)	NE (NE, NE)	0.54 (0.29, 1.01)	0.0490	
No	14/46 (30.4)	NE (1.74, NE)	18/106 (17.0)	NE (NE, NE)	0.41 (0.20, 0.85)	0.0135	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6749
0	15/55 (27.3)	NE (1.74, NE)	16/112 (14.3)	NE (NE, NE)	0.41 (0.20, 0.84)	0.0124	
1	9/34 (26.5)	NE (NE, NE)	19/91 (20.9)	NE (5.51, NE)	0.62 (0.27, 1.40)	0.2401	
≥2	6/20 (30.0)	1.48 (0.52, NE)	10/64 (15.6)	NE (NE, NE)	0.39 (0.14, 1.08)	0.0618	
Prior alloHSCT							0.2833
Yes	12/35 (34.3)	NE (1.11, NE)	16/93 (17.2)	NE (7.28, NE)	0.26 (0.12, 0.58)	0.0005	
No	18/74 (24.3)	NE (NE, NE)	29/174 (16.7)	NE (NE, NE)	0.63 (0.35, 1.15)	0.1280	
Race							0.9089
Caucasian	26/90 (28.9)	NE (1.74, NE)	39/226 (17.3)	NE (NE, NE)	0.48 (0.29, 0.79)	0.0034	
Others	4/19 (21.1)	NE (0.46, NE)	6/41 (14.6)	NE (NE, NE)	0.48 (0.13, 1.81)	0.2680	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0101
<50%	10/27 (37.0)	NE (0.52, NE)	6/73 (8.2)	NE (7.28, NE)	0.13 (0.04, 0.41)	<0.0001	
≥50%	19/77 (24.7)	NE (NE, NE)	35/168 (20.8)	NE (NE, NE)	0.72 (0.41, 1.27)	0.2495	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypomagnesaemia							
Overall	18/109 (16.5)	NE (NE, NE)	29/267 (10.9)	NE (NE, NE)	0.55 (0.30, 0.99)	0.0445	
Age group 1							0.9823
<35 years	9/50 (18.0)	NE (1.97, NE)	15/123 (12.2)	NE (NE, NE)	0.54 (0.23, 1.25)	0.1429	
≥35 years	9/59 (15.3)	NE (NE, NE)	14/144 (9.7)	NE (NE, NE)	0.55 (0.24, 1.30)	0.1682	
Age group 2							0.7919
<35 years	9/50 (18.0)	NE (1.97, NE)	15/124 (12.1)	NE (NE, NE)	0.54 (0.23, 1.25)	0.1409	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	8/77 (10.4)	NE (NE, NE)	1.00 (0.21, 4.88)	0.9940	
55 - 64 years	5/22 (22.7)	NE (1.15, NE)	4/33 (12.1)	NE (NE, NE)	0.47 (0.13, 1.78)	0.2582	
≥65 years	2/12 (16.7)	NE (0.59, NE)	2/33 (6.1)	NE (NE, NE)	0.39 (0.06, 2.79)	0.3264	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1358
Male	8/64 (12.5)	NE (NE, NE)	19/159 (11.9)	NE (NE, NE)	0.83 (0.36, 1.91)	0.6496	
Female	10/45 (22.2)	NE (1.97, NE)	10/108 (9.3)	NE (NE, NE)	0.33 (0.13, 0.80)	0.0098	
Region							0.0666
USA	7/13 (53.8)	1.25 (0.59, NE)	4/30 (13.3)	NE (3.84, NE)	0.12 (0.03, 0.48)	0.0005	
Europe	7/68 (10.3)	NE (NE, NE)	10/177 (5.6)	NE (NE, NE)	0.54 (0.21, 1.42)	0.2068	
Rest of the world	4/28 (14.3)	NE (NE, NE)	15/60 (25.0)	NE (5.51, NE)	1.40 (0.46, 4.29)	0.5645	
Prior salvage therapy							0.3574
Yes	11/63 (17.5)	NE (NE, NE)	22/161 (13.7)	NE (NE, NE)	0.64 (0.31, 1.35)	0.2382	
No	7/46 (15.2)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	0.37 (0.13, 1.05)	0.0514	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.8987
0	7/55 (12.7)	NE (NE, NE)	7/112 (6.3)	NE (NE, NE)	0.43 (0.15, 1.25)	0.1112	
1	5/34 (14.7)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)	0.56 (0.18, 1.68)	0.2924	
≥2	6/20 (30.0)	NE (0.52, NE)	13/64 (20.3)	NE (5.51, NE)	0.51 (0.19, 1.37)	0.1701	
Prior alloHSCT							0.3181
Yes	9/35 (25.7)	NE (1.25, NE)	12/93 (12.9)	NE (NE, NE)	0.36 (0.14, 0.89)	0.0211	
No	9/74 (12.2)	NE (NE, NE)	17/174 (9.8)	NE (NE, NE)	0.73 (0.32, 1.64)	0.4389	
Race							0.7876
Caucasian	14/90 (15.6)	NE (NE, NE)	24/226 (10.6)	NE (NE, NE)	0.59 (0.30, 1.14)	0.1136	
Others	4/19 (21.1)	NE (1.97, NE)	5/41 (12.2)	NE (NE, NE)	0.40 (0.10, 1.65)	0.1926	

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[a] p-values were calculated using the unstratified log-rank test.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2058
<50%	3/27 (11.1)	NE (NE, NE)	2/73 (2.7)	NE (NE, NE)	0.22 (0.04, 1.32)	0.0682	
≥50%	14/77 (18.2)	NE (NE, NE)	24/168 (14.3)	NE (NE, NE)	0.65 (0.33, 1.27)	0.2036	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hyperglycaemia							
Overall	9/109 (8.3)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	0.86 (0.39, 1.88)	0.6968	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Decreased appetite							
Overall	15/109 (13.8)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.26 (0.13, 0.55)	0.0001	
Age group 1							0.4740
<35 years	5/50 (10.0)	NE (NE, NE)	8/123 (6.5)	NE (NE, NE)	0.30 (0.09, 0.97)	0.0333	
≥35 years	10/59 (16.9)	NE (2.82, NE)	10/144 (6.9)	NE (NE, NE)	0.26 (0.10, 0.67)	0.0027	
Age group 2							0.7287
<35 years	5/50 (10.0)	NE (NE, NE)	8/124 (6.5)	NE (NE, NE)	0.30 (0.09, 0.97)	0.0331	
35 - 54 years	5/25 (20.0)	2.82 (2.82, NE)	9/77 (11.7)	NE (7.15, NE)	0.35 (0.11, 1.12)	0.0666	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.12 (0.01, 1.09)	0.0266	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1336	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1567
Male	9/64 (14.1)	NE (2.82, NE)	14/159 (8.8)	NE (NE, NE)	0.36 (0.15, 0.85)	0.0160	
Female	6/45 (13.3)	NE (NE, NE)	4/108 (3.7)	NE (NE, NE)	0.14 (0.03, 0.61)	0.0027	
Region							0.6891
USA	3/13 (23.1)	NE (0.59, NE)	3/30 (10.0)	NE (NE, NE)	0.27 (0.05, 1.38)	0.0940	
Europe	9/68 (13.2)	NE (2.82, NE)	9/177 (5.1)	NE (NE, NE)	0.19 (0.07, 0.54)	0.0005	
Rest of the world	3/28 (10.7)	2.33 (2.33, NE)	6/60 (10.0)	NE (NE, NE)	0.48 (0.11, 2.16)	0.3300	
Prior salvage therapy							0.0804
Yes	6/63 (9.5)	NE (2.82, NE)	12/161 (7.5)	NE (NE, NE)	0.41 (0.15, 1.16)	0.0841	
No	9/46 (19.6)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	0.16 (0.05, 0.49)	0.0003	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.2540
0	9/55 (16.4)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	0.24 (0.08, 0.70)	0.0046	
1	5/34 (14.7)	NE (2.82, NE)	4/91 (4.4)	NE (NE, NE)	0.19 (0.05, 0.73)	0.0080	
≥2	1/20 (5.0)	NE (NE, NE)	6/64 (9.4)	NE (NE, NE)	0.79 (0.09, 6.81)	0.8277	
Prior alloHSCT							0.2909
Yes	3/35 (8.6)	NE (2.82, NE)	8/93 (8.6)	NE (NE, NE)	0.34 (0.08, 1.45)	0.1308	
No	12/74 (16.2)	NE (NE, NE)	10/174 (5.7)	NE (NE, NE)	0.23 (0.10, 0.56)	0.0004	
Race							0.2936
Caucasian	12/90 (13.3)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	0.20 (0.08, 0.48)	<0.0001	
Others	3/19 (15.8)	2.33 (2.33, NE)	6/41 (14.6)	NE (NE, NE)	0.54 (0.13, 2.30)	0.3982	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1052
<50%	6/27 (22.2)	NE (2.33, NE)	5/73 (6.8)	NE (7.15, NE)	0.13 (0.03, 0.51)	0.0008	
≥50%	8/77 (10.4)	NE (2.82, NE)	13/168 (7.7)	NE (NE, NE)	0.44 (0.18, 1.11)	0.0757	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypoalbuminaemia							
Overall	11/109 (10.1)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.43 (0.19, 0.96)	0.0354	
Age group 1							0.5299
<35 years	6/50 (12.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	0.55 (0.19, 1.54)	0.2447	
≥35 years	5/59 (8.5)	NE (NE, NE)	4/144 (2.8)	NE (NE, NE)	0.28 (0.07, 1.05)	0.0446	
Age group 2							0.9656
<35 years	6/50 (12.0)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)	0.54 (0.19, 1.53)	0.2424	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	1/77 (1.3)	NE (NE, NE)	0.32 (0.02, 5.19)	0.4017	
55 - 64 years	3/22 (13.6)	NE (1.84, NE)	3/33 (9.1)	NE (NE, NE)	0.55 (0.11, 2.78)	0.4638	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1489	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8490
Male	7/64 (10.9)	NE (NE, NE)	8/159 (5.0)	NE (NE, NE)	0.38 (0.14, 1.07)	0.0571	
Female	4/45 (8.9)	NE (NE, NE)	5/108 (4.6)	NE (NE, NE)	0.54 (0.14, 2.00)	0.3487	
Region							0.7735
USA	2/13 (15.4)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	0.46 (0.06, 3.24)	0.4199	
Europe	7/68 (10.3)	NE (NE, NE)	10/177 (5.6)	NE (NE, NE)	0.48 (0.18, 1.28)	0.1361	
Rest of the world	2/28 (7.1)	NE (NE, NE)	1/60 (1.7)	NE (NE, NE)	0.19 (0.02, 2.07)	0.1281	
Prior salvage therapy							0.5847
Yes	7/63 (11.1)	NE (NE, NE)	10/161 (6.2)	NE (NE, NE)	0.46 (0.17, 1.23)	0.1159	
No	4/46 (8.7)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.32 (0.07, 1.45)	0.1220	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4700
0	5/55 (9.1)	NE (NE, NE)	2/112 (1.8)	NE (NE, NE)	0.19 (0.04, 0.99)	0.0276	
1	4/34 (11.8)	NE (1.84, NE)	6/91 (6.6)	NE (NE, NE)	0.47 (0.13, 1.69)	0.2334	
≥2	2/20 (10.0)	NE (NE, NE)	5/64 (7.8)	NE (NE, NE)	0.67 (0.13, 3.51)	0.6379	
Prior alloHSCT							0.6908
Yes	3/35 (8.6)	NE (NE, NE)	5/93 (5.4)	NE (NE, NE)	0.56 (0.13, 2.36)	0.4251	
No	8/74 (10.8)	NE (NE, NE)	8/174 (4.6)	NE (NE, NE)	0.38 (0.14, 1.02)	0.0475	
Race							0.1841
Caucasian	10/90 (11.1)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.31 (0.13, 0.78)	0.0083	
Others	1/19 (5.3)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	1.78 (0.20, 15.91)	0.6030	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0651
<50%	5/27 (18.5)	NE (1.84, NE)	2/73 (2.7)	NE (NE, NE)	0.12 (0.02, 0.65)	0.0035	
≥50%	6/77 (7.8)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.78 (0.29, 2.11)	0.6221	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypophosphataemia							
Overall	6/109 (5.5)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.74 (0.28, 1.99)	0.5478	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypocalcaemia							
Overall	9/109 (8.3)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.38 (0.15, 0.97)	0.0349	
Age group 1							0.0911
<35 years	6/50 (12.0)	NE (NE, NE)	3/123 (2.4)	NE (NE, NE)	0.11 (0.02, 0.56)	0.0012	
≥35 years	3/59 (5.1)	NE (NE, NE)	7/144 (4.9)	NE (NE, NE)	0.99 (0.26, 3.82)	0.9851	
Age group 2							0.2239
<35 years	6/50 (12.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	1/25 (4.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	1/22 (4.5)	-	4/33 (12.1)	-	-	-	
≥65 years	1/12 (8.3)	-	1/33 (3.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5511
Male	6/64 (9.4)	NE (NE, NE)	8/159 (5.0)	NE (NE, NE)	0.42 (0.14, 1.26)	0.1116	
Female	3/45 (6.7)	NE (NE, NE)	2/108 (1.9)	NE (NE, NE)	0.29 (0.05, 1.72)	0.1448	
Region							0.2997
USA	1/13 (7.7)	NE (1.25, NE)	3/30 (10.0)	NE (NE, NE)	1.32 (0.14, 12.68)	0.8101	
Europe	7/68 (10.3)	NE (NE, NE)	5/177 (2.8)	NE (NE, NE)	0.21 (0.06, 0.72)	0.0063	
Rest of the world	1/28 (3.6)	NE (NE, NE)	2/60 (3.3)	NE (NE, NE)	0.89 (0.08, 9.83)	0.9250	
Prior salvage therapy							0.6933
Yes	6/63 (9.5)	NE (NE, NE)	6/161 (3.7)	NE (NE, NE)	0.29 (0.09, 0.97)	0.0324	
No	3/46 (6.5)	NE (NE, NE)	4/106 (3.8)	NE (NE, NE)	0.57 (0.13, 2.55)	0.4569	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.8282
0	5/55 (9.1)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)	0.38 (0.10, 1.40)	0.1285	
1	1/34 (2.9)	NE (NE, NE)	2/91 (2.2)	NE (NE, NE)	0.75 (0.07, 8.26)	0.8126	
≥2	3/20 (15.0)	NE (1.25, NE)	3/64 (4.7)	NE (NE, NE)	0.26 (0.05, 1.33)	0.0831	
Prior alloHSCT							0.1734
Yes	3/35 (8.6)	NE (NE, NE)	1/93 (1.1)	NE (NE, NE)	0.10 (0.01, 1.00)	0.0172	
No	6/74 (8.1)	NE (NE, NE)	9/174 (5.2)	NE (NE, NE)	0.55 (0.19, 1.58)	0.2607	
Race							0.9914
Caucasian	9/90 (10.0)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.33 (0.13, 0.86)	0.0176	
Others	0/19 (0.0)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	NE (NE, NE)	0.5023	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0831
<50%	5/27 (18.5)	NE (NE, NE)	2/73 (2.7)	NE (NE, NE)	0.13 (0.03, 0.68)	0.0043	
≥50%	4/77 (5.2)	NE (NE, NE)	7/168 (4.2)	NE (NE, NE)	0.65 (0.18, 2.31)	0.5003	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Tumour lysis syndrome							
Overall	1/109 (0.9)	NE (NE, NE)	10/267 (3.7)	NE (13.87, NE)	3.42 (0.43, 27.05)	0.2142	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Musculoskeletal and connective tissue disorders							
Overall	37/109 (33.9)	NE (1.54, NE)	110/267 (41.2)	3.84 (2.92, 8.23)	0.92 (0.63, 1.34)	0.6590	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Back pain							
Overall	10/109 (9.2)	NE (NE, NE)	35/267 (13.1)	NE (NE, NE)	0.91 (0.44, 1.87)	0.7920	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Bone pain							
Overall	8/109 (7.3)	NE (NE, NE)	30/267 (11.2)	NE (NE, NE)	1.09 (0.49, 2.44)	0.8264	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pain in extremity							
Overall	8/109 (7.3)	NE (NE, NE)	25/267 (9.4)	NE (NE, NE)	0.82 (0.36, 1.88)	0.6366	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Myalgia							
Overall	6/109 (5.5)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	0.95 (0.37, 2.45)	0.9227	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Arthralgia							
Overall	5/109 (4.6)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.73 (0.25, 2.14)	0.5677	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Muscle spasms							
Overall	3/109 (2.8)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.93 (0.24, 3.55)	0.9132	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Musculoskeletal pain							
Overall	3/109 (2.8)	NE (NE, NE)	11/267 (4.1)	NE (13.18, NE)	0.92 (0.24, 3.50)	0.9028	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Nervous system disorders							
Overall	44/109 (40.4)	NE (1.11, NE)	140/267 (52.4)	1.54 (1.08, 2.85)	1.22 (0.87, 1.72)	0.2515	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Headache							
Overall	31/109 (28.4)	NE (NE, NE)	77/267 (28.8)	NE (6.66, NE)	0.84 (0.55, 1.28)	0.4070	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Tremor							
Overall	0/109 (0.0)	NE (NE, NE)	26/267 (9.7)	NE (NE, NE)	NE (NE, NE)	0.0013	
Age group 1							0.9998
<35 years	0/50 (0.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	NE (NE, NE)	0.0730	
≥35 years	0/59 (0.0)	NE (NE, NE)	17/144 (11.8)	NE (NE, NE)	NE (NE, NE)	0.0068	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)	NE (NE, NE)	0.0731	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	11/77 (14.3)	NE (NE, NE)	NE (NE, NE)	0.0615	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	NE (NE, NE)	0.1486	
≥65 years	0/12 (0.0)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	NE (NE, NE)	0.2654	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	NE (NE, NE)	15/159 (9.4)	NE (NE, NE)	NE (NE, NE)	0.0188	
Female	0/45 (0.0)	NE (NE, NE)	11/108 (10.2)	NE (NE, NE)	NE (NE, NE)	0.0256	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	5/30 (16.7)	NE (NE, NE)	NE (NE, NE)	0.1247	
Europe	0/68 (0.0)	NE (NE, NE)	16/177 (9.0)	NE (NE, NE)	NE (NE, NE)	0.0152	
Rest of the world	0/28 (0.0)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)	NE (NE, NE)	0.1302	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	NE (NE, NE)	17/161 (10.6)	NE (NE, NE)	NE (NE, NE)	0.0125	
No	0/46 (0.0)	NE (NE, NE)	9/106 (8.5)	NE (NE, NE)	NE (NE, NE)	0.0430	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	NE (NE, NE)	0.0268	
1	0/34 (0.0)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)	NE (NE, NE)	0.0632	
≥2	0/20 (0.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	NE (NE, NE)	0.1567	
Prior alloHSCT							0.9999
Yes	0/35 (0.0)	NE (NE, NE)	11/93 (11.8)	NE (NE, NE)	NE (NE, NE)	0.0478	
No	0/74 (0.0)	NE (NE, NE)	15/174 (8.6)	NE (NE, NE)	NE (NE, NE)	0.0112	
Race							0.9996
Caucasian	0/90 (0.0)	NE (NE, NE)	25/226 (11.1)	NE (NE, NE)	NE (NE, NE)	0.0016	
Others	0/19 (0.0)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	NE (NE, NE)	0.5023	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9998
<50%	0/27 (0.0)	NE (NE, NE)	11/73 (15.1)	NE (NE, NE)	NE (NE, NE)	0.0360	
≥50%	0/77 (0.0)	NE (NE, NE)	14/168 (8.3)	NE (NE, NE)	NE (NE, NE)	0.0143	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Dizziness							
Overall	8/109 (7.3)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.72 (0.31, 1.70)	0.4557	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Somnolence							
Overall	1/109 (0.9)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	5.16 (0.68, 39.41)	0.0774	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Paraesthesia							
Overall	1/109 (0.9)	NE (NE, NE)	13/267 (4.9)	NE (12.39, NE)	4.30 (0.56, 33.21)	0.1276	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Psychiatric disorders							
Overall	21/109 (19.3)	NE (NE, NE)	69/267 (25.8)	NE (NE, NE)	1.12 (0.68, 1.83)	0.6648	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Insomnia							
Overall	10/109 (9.2)	NE (NE, NE)	28/267 (10.5)	NE (NE, NE)	0.87 (0.42, 1.83)	0.7149	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Anxiety							
Overall	6/109 (5.5)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.65 (0.24, 1.76)	0.3939	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Renal and urinary disorders							
Overall	24/109 (22.0)	NE (2.59, NE)	35/267 (13.1)	NE (NE, NE)	0.38 (0.22, 0.65)	0.0003	
Age group 1							0.7587
<35 years	11/50 (22.0)	NE (NE, NE)	17/123 (13.8)	NE (NE, NE)	0.44 (0.20, 0.95)	0.0332	
≥35 years	13/59 (22.0)	2.85 (2.59, NE)	18/144 (12.5)	NE (NE, NE)	0.32 (0.15, 0.68)	0.0020	
Age group 2							0.9617
<35 years	11/50 (22.0)	NE (NE, NE)	17/124 (13.7)	NE (NE, NE)	0.44 (0.20, 0.95)	0.0331	
35 - 54 years	6/25 (24.0)	2.85 (1.28, NE)	10/77 (13.0)	NE (NE, NE)	0.20 (0.07, 0.59)	0.0016	
55 - 64 years	5/22 (22.7)	2.59 (1.28, NE)	5/33 (15.2)	NE (NE, NE)	0.44 (0.12, 1.61)	0.1987	
≥65 years	2/12 (16.7)	NE (0.52, NE)	3/33 (9.1)	NE (NE, NE)	0.59 (0.10, 3.54)	0.5620	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5246
Male	15/64 (23.4)	NE (2.59, NE)	24/159 (15.1)	NE (NE, NE)	0.44 (0.23, 0.84)	0.0114	
Female	9/45 (20.0)	NE (1.28, NE)	11/108 (10.2)	NE (NE, NE)	0.29 (0.11, 0.73)	0.0057	
Region							0.6225
USA	2/13 (15.4)	NE (1.21, NE)	4/30 (13.3)	NE (2.82, NE)	0.61 (0.11, 3.42)	0.5728	
Europe	16/68 (23.5)	NE (2.59, NE)	20/177 (11.3)	NE (NE, NE)	0.33 (0.17, 0.65)	0.0008	
Rest of the world	6/28 (21.4)	NE (NE, NE)	11/60 (18.3)	NE (NE, NE)	0.44 (0.15, 1.25)	0.1139	
Prior salvage therapy							0.8635
Yes	15/63 (23.8)	2.85 (2.59, NE)	24/161 (14.9)	NE (NE, NE)	0.38 (0.19, 0.74)	0.0031	
No	9/46 (19.6)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	0.37 (0.15, 0.93)	0.0271	

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[a] p-values were calculated using the unstratified log-rank test.
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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7164
0	11/55 (20.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	0.37 (0.16, 0.87)	0.0175	
1	7/34 (20.6)	2.59 (2.59, NE)	14/91 (15.4)	NE (NE, NE)	0.42 (0.16, 1.09)	0.0653	
≥2	6/20 (30.0)	NE (0.49, NE)	8/64 (12.5)	NE (NE, NE)	0.26 (0.09, 0.76)	0.0082	
Prior alloHSCT							0.5980
Yes	7/35 (20.0)	2.85 (1.28, NE)	14/93 (15.1)	NE (NE, NE)	0.41 (0.16, 1.08)	0.0619	
No	17/74 (23.0)	NE (2.59, NE)	21/174 (12.1)	NE (NE, NE)	0.37 (0.19, 0.71)	0.0019	
Race							0.6465
Caucasian	22/90 (24.4)	NE (2.59, NE)	31/226 (13.7)	NE (NE, NE)	0.37 (0.21, 0.64)	0.0003	
Others	2/19 (10.5)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.52 (0.09, 3.07)	0.4660	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1770
<50%	7/27 (25.9)	2.59 (1.28, NE)	8/73 (11.0)	NE (NE, NE)	0.11 (0.03, 0.40)	<0.0001	
≥50%	15/77 (19.5)	NE (2.85, NE)	23/168 (13.7)	NE (NE, NE)	0.53 (0.27, 1.02)	0.0536	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Acute kidney injury							
Overall	8/109 (7.3)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.38 (0.15, 0.97)	0.0363	
Age group 1							0.7427
<35 years	5/50 (10.0)	NE (NE, NE)	6/123 (4.9)	NE (NE, NE)	0.35 (0.11, 1.18)	0.0778	
≥35 years	3/59 (5.1)	NE (2.85, NE)	5/144 (3.5)	NE (NE, NE)	0.41 (0.09, 1.82)	0.2275	
Age group 2							0.9419
<35 years	5/50 (10.0)	NE (NE, NE)	6/124 (4.8)	NE (NE, NE)	0.35 (0.11, 1.18)	0.0778	
35 - 54 years	3/25 (12.0)	2.85 (2.85, NE)	3/77 (3.9)	NE (NE, NE)	0.16 (0.03, 0.88)	0.0183	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.6464	
≥65 years	0/12 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.5127	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8717
Male	5/64 (7.8)	NE (2.85, NE)	7/159 (4.4)	NE (NE, NE)	0.37 (0.12, 1.21)	0.0893	
Female	3/45 (6.7)	NE (NE, NE)	4/108 (3.7)	NE (NE, NE)	0.40 (0.08, 1.87)	0.2286	
Region							0.8490
USA	1/13 (7.7)	-	2/30 (6.7)	-	-	-	
Europe	4/68 (5.9)	-	5/177 (2.8)	-	-	-	
Rest of the world	3/28 (10.7)	-	4/60 (6.7)	-	-	-	
Prior salvage therapy							0.7591
Yes	5/63 (7.9)	NE (2.85, NE)	8/161 (5.0)	NE (NE, NE)	0.40 (0.13, 1.25)	0.1018	
No	3/46 (6.5)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.34 (0.07, 1.73)	0.1730	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7894
0	4/55 (7.3)	-	5/112 (4.5)	-	-	-	
1	2/34 (5.9)	-	4/91 (4.4)	-	-	-	
≥2	2/20 (10.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.1631
Yes	5/35 (14.3)	NE (2.85, NE)	4/93 (4.3)	NE (NE, NE)	0.16 (0.04, 0.67)	0.0048	
No	3/74 (4.1)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.76 (0.19, 2.98)	0.6927	
Race							0.7285
Caucasian	7/90 (7.8)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.35 (0.13, 0.97)	0.0361	
Others	1/19 (5.3)	NE (NE, NE)	2/41 (4.9)	NE (NE, NE)	0.56 (0.05, 6.68)	0.6387	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7351
<50%	2/27 (7.4)	NE (NE, NE)	3/73 (4.1)	NE (NE, NE)	0.32 (0.04, 2.29)	0.2304	
≥50%	5/77 (6.5)	NE (2.85, NE)	7/168 (4.2)	NE (NE, NE)	0.44 (0.14, 1.42)	0.1585	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Reproductive system and breast disorders							
Overall	3/109 (2.8)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	1.18 (0.33, 4.28)	0.8000	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Respiratory, thoracic and mediastinal disorders							
Overall	36/109 (33.0)	NE (2.79, NE)	99/267 (37.1)	5.25 (3.61, 7.15)	0.76 (0.51, 1.13)	0.1715	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Cough							
Overall	6/109 (5.5)	NE (NE, NE)	39/267 (14.6)	NE (NE, NE)	1.74 (0.72, 4.17)	0.2119	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Epistaxis							
Overall	9/109 (8.3)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.61 (0.27, 1.41)	0.2448	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Dyspnoea							
Overall	8/109 (7.3)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.63 (0.27, 1.49)	0.2878	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Oropharyngeal pain							
Overall	7/109 (6.4)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.31 (0.11, 0.86)	0.0178	
Age group 1							0.9844
<35 years	4/50 (8.0)	NE (NE, NE)	7/123 (5.7)	NE (NE, NE)	0.32 (0.08, 1.19)	0.0739	
≥35 years	3/59 (5.1)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.25 (0.05, 1.33)	0.0848	
Age group 2							0.9619
<35 years	4/50 (8.0)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)	0.32 (0.08, 1.19)	0.0733	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	5/77 (6.5)	NE (NE, NE)	0.53 (0.05, 5.37)	0.5815	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	1/33 (3.0)	NE (3.61, NE)	0.00 (0.00, NE)	0.2131	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1266	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4195
Male	3/64 (4.7)	NE (NE, NE)	3/159 (1.9)	NE (NE, NE)	0.23 (0.04, 1.37)	0.0780	
Female	4/45 (8.9)	NE (NE, NE)	10/108 (9.3)	NE (NE, NE)	0.34 (0.10, 1.21)	0.0834	
Region							0.8866
USA	0/13 (0.0)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
Europe	5/68 (7.4)	NE (NE, NE)	10/177 (5.6)	NE (NE, NE)	0.31 (0.10, 1.00)	0.0391	
Rest of the world	2/28 (7.1)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.22 (0.02, 2.47)	0.1808	
Prior salvage therapy							0.3997
Yes	3/63 (4.8)	NE (NE, NE)	3/161 (1.9)	NE (NE, NE)	0.20 (0.04, 1.08)	0.0406	
No	4/46 (8.7)	NE (NE, NE)	10/106 (9.4)	NE (NE, NE)	0.38 (0.10, 1.43)	0.1408	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	6/55 (10.9)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)	0.27 (0.08, 0.89)	0.0241	
1	0/34 (0.0)	NE (NE, NE)	4/91 (4.4)	NE (NE, NE)	NE (NE, NE)	0.5505	
≥2	1/20 (5.0)	NE (NE, NE)	0/64 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0833	
Prior alloHSCT							0.7193
Yes	3/35 (8.6)	NE (NE, NE)	6/93 (6.5)	NE (NE, NE)	0.26 (0.05, 1.22)	0.0690	
No	4/74 (5.4)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.34 (0.09, 1.29)	0.0987	
Race							0.0665
Caucasian	4/90 (4.4)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	0.49 (0.15, 1.65)	0.2440	
Others	3/19 (15.8)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	0.00 (0.00, NE)	0.0064	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7552
<50%	2/27 (7.4)	NE (NE, NE)	6/73 (8.2)	NE (NE, NE)	0.23 (0.03, 1.61)	0.1119	
≥50%	5/77 (6.5)	NE (NE, NE)	6/168 (3.6)	NE (NE, NE)	0.32 (0.09, 1.11)	0.0606	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Productive cough							
Overall	1/109 (0.9)	NE (NE, NE)	11/267 (4.1)	NE (14.23, NE)	1.57 (0.19, 13.10)	0.6751	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Skin and subcutaneous tissue disorders							
Overall	41/109 (37.6)	2.72 (1.25, NE)	89/267 (33.3)	NE (3.84, NE)	0.64 (0.44, 0.94)	0.0218	
Age group 1							0.6134
<35 years	16/50 (32.0)	NE (1.54, NE)	39/123 (31.7)	NE (3.08, NE)	0.71 (0.39, 1.29)	0.2623	
≥35 years	25/59 (42.4)	2.72 (1.05, NE)	50/144 (34.7)	NE (3.28, NE)	0.60 (0.37, 0.98)	0.0394	
Age group 2							0.8041
<35 years	16/50 (32.0)	NE (1.54, NE)	39/124 (31.5)	NE (3.08, NE)	0.71 (0.39, 1.29)	0.2594	
35 - 54 years	9/25 (36.0)	1.25 (0.52, NE)	30/77 (39.0)	3.84 (2.33, NE)	0.68 (0.31, 1.46)	0.3221	
55 - 64 years	11/22 (50.0)	1.08 (0.49, NE)	13/33 (39.4)	NE (1.02, NE)	0.65 (0.29, 1.47)	0.2897	
≥65 years	5/12 (41.7)	NE (0.23, NE)	7/33 (21.2)	NE (2.30, NE)	0.45 (0.14, 1.42)	0.1666	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3226
Male	22/64 (34.4)	2.72 (1.25, NE)	54/159 (34.0)	NE (3.28, NE)	0.75 (0.45, 1.24)	0.2567	
Female	19/45 (42.2)	1.70 (0.52, NE)	35/108 (32.4)	NE (3.25, NE)	0.53 (0.30, 0.95)	0.0295	
Region							0.3748
USA	5/13 (38.5)	1.70 (0.30, NE)	15/30 (50.0)	2.62 (0.62, NE)	1.22 (0.44, 3.38)	0.6933	
Europe	21/68 (30.9)	2.72 (1.25, NE)	44/177 (24.9)	NE (NE, NE)	0.61 (0.36, 1.04)	0.0665	
Rest of the world	15/28 (53.6)	1.05 (0.43, 1.70)	30/60 (50.0)	3.02 (1.48, 6.03)	0.51 (0.26, 1.00)	0.0456	
Prior salvage therapy							0.2797
Yes	21/63 (33.3)	1.70 (1.25, NE)	55/161 (34.2)	6.03 (3.08, NE)	0.75 (0.45, 1.26)	0.2733	
No	20/46 (43.5)	NE (0.59, NE)	34/106 (32.1)	NE (3.74, NE)	0.53 (0.30, 0.93)	0.0264	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6340
0	23/55 (41.8)	NE (0.59, NE)	39/112 (34.8)	NE (3.74, NE)	0.59 (0.34, 0.99)	0.0459	
1	13/34 (38.2)	1.54 (1.05, NE)	31/91 (34.1)	NE (2.62, NE)	0.58 (0.30, 1.15)	0.1165	
≥2	5/20 (25.0)	NE (1.25, NE)	19/64 (29.7)	NE (2.56, NE)	0.98 (0.36, 2.64)	0.9666	
Prior alloHSCT							0.6692
Yes	13/35 (37.1)	1.54 (0.69, NE)	31/93 (33.3)	NE (3.08, NE)	0.52 (0.26, 1.03)	0.0579	
No	28/74 (37.8)	2.72 (1.25, NE)	58/174 (33.3)	NE (3.25, NE)	0.69 (0.44, 1.09)	0.1093	
Race							0.7307
Caucasian	32/90 (35.6)	2.72 (1.25, NE)	73/226 (32.3)	NE (5.87, NE)	0.68 (0.44, 1.04)	0.0723	
Others	9/19 (47.4)	1.70 (0.43, NE)	16/41 (39.0)	6.03 (3.02, NE)	0.53 (0.23, 1.24)	0.1438	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1465
<50%	13/27 (48.1)	1.70 (0.49, NE)	24/73 (32.9)	NE (3.84, NE)	0.36 (0.17, 0.74)	0.0041	
≥50%	27/77 (35.1)	NE (1.25, NE)	56/168 (33.3)	NE (3.02, NE)	0.79 (0.49, 1.25)	0.3105	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Rash							
Overall	13/109 (11.9)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	0.46 (0.22, 0.95)	0.0315	
Age group 1							0.2317
<35 years	8/50 (16.0)	NE (NE, NE)	8/123 (6.5)	NE (NE, NE)	0.32 (0.12, 0.85)	0.0167	
≥35 years	5/59 (8.5)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)	0.69 (0.23, 2.06)	0.5057	
Age group 2							0.4548
<35 years	8/50 (16.0)	NE (NE, NE)	8/124 (6.5)	NE (NE, NE)	0.31 (0.12, 0.85)	0.0164	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	8/77 (10.4)	NE (NE, NE)	1.65 (0.20, 13.73)	0.6377	
55 - 64 years	3/22 (13.6)	NE (NE, NE)	2/33 (6.1)	NE (NE, NE)	0.42 (0.07, 2.53)	0.3377	
≥65 years	1/12 (8.3)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.39 (0.02, 6.29)	0.4942	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8741
Male	8/64 (12.5)	NE (NE, NE)	11/159 (6.9)	NE (NE, NE)	0.46 (0.18, 1.15)	0.0895	
Female	5/45 (11.1)	NE (NE, NE)	8/108 (7.4)	NE (NE, NE)	0.46 (0.14, 1.50)	0.1894	
Region							0.2854
USA	2/13 (15.4)	NE (NE, NE)	4/30 (13.3)	NE (3.28, NE)	0.81 (0.15, 4.43)	0.8029	
Europe	3/68 (4.4)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.99 (0.26, 3.74)	0.9870	
Rest of the world	8/28 (28.6)	NE (1.08, NE)	7/60 (11.7)	NE (NE, NE)	0.19 (0.06, 0.59)	0.0016	
Prior salvage therapy							0.7884
Yes	6/63 (9.5)	NE (NE, NE)	10/161 (6.2)	NE (NE, NE)	0.48 (0.17, 1.36)	0.1613	
No	7/46 (15.2)	NE (NE, NE)	9/106 (8.5)	NE (NE, NE)	0.45 (0.17, 1.24)	0.1140	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1859
0	9/55 (16.4)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)	0.40 (0.15, 1.01)	0.0447	
1	2/34 (5.9)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)	1.28 (0.27, 6.09)	0.7546	
≥2	2/20 (10.0)	NE (NE, NE)	1/64 (1.6)	NE (NE, NE)	0.10 (0.01, 1.20)	0.0292	
Prior alloHSCT							0.0491
Yes	7/35 (20.0)	NE (NE, NE)	5/93 (5.4)	NE (NE, NE)	0.14 (0.04, 0.51)	0.0007	
No	6/74 (8.1)	NE (NE, NE)	14/174 (8.0)	NE (NE, NE)	0.87 (0.33, 2.28)	0.7746	
Race							0.3676
Caucasian	10/90 (11.1)	NE (NE, NE)	17/226 (7.5)	NE (NE, NE)	0.57 (0.26, 1.26)	0.1578	
Others	3/19 (15.8)	NE (1.70, NE)	2/41 (4.9)	NE (NE, NE)	0.10 (0.01, 0.99)	0.0165	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:57) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5889
<50%	2/27 (7.4)	NE (NE, NE)	5/73 (6.8)	NE (NE, NE)	0.42 (0.07, 2.55)	0.3285	
≥50%	11/77 (14.3)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	0.44 (0.19, 1.00)	0.0434	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hyperhidrosis							
Overall	2/109 (1.8)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	1.76 (0.38, 8.16)	0.4618	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Vascular disorders							
Overall	28/109 (25.7)	NE (NE, NE)	62/267 (23.2)	13.38 (10.10, NE)	0.65 (0.41, 1.03)	0.0663	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypotension							
Overall	13/109 (11.9)	NE (NE, NE)	32/267 (12.0)	NE (NE, NE)	0.80 (0.42, 1.55)	0.5152	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypertension							
Overall	9/109 (8.3)	NE (NE, NE)	17/267 (6.4)	NE (13.87, NE)	0.55 (0.24, 1.26)	0.1512	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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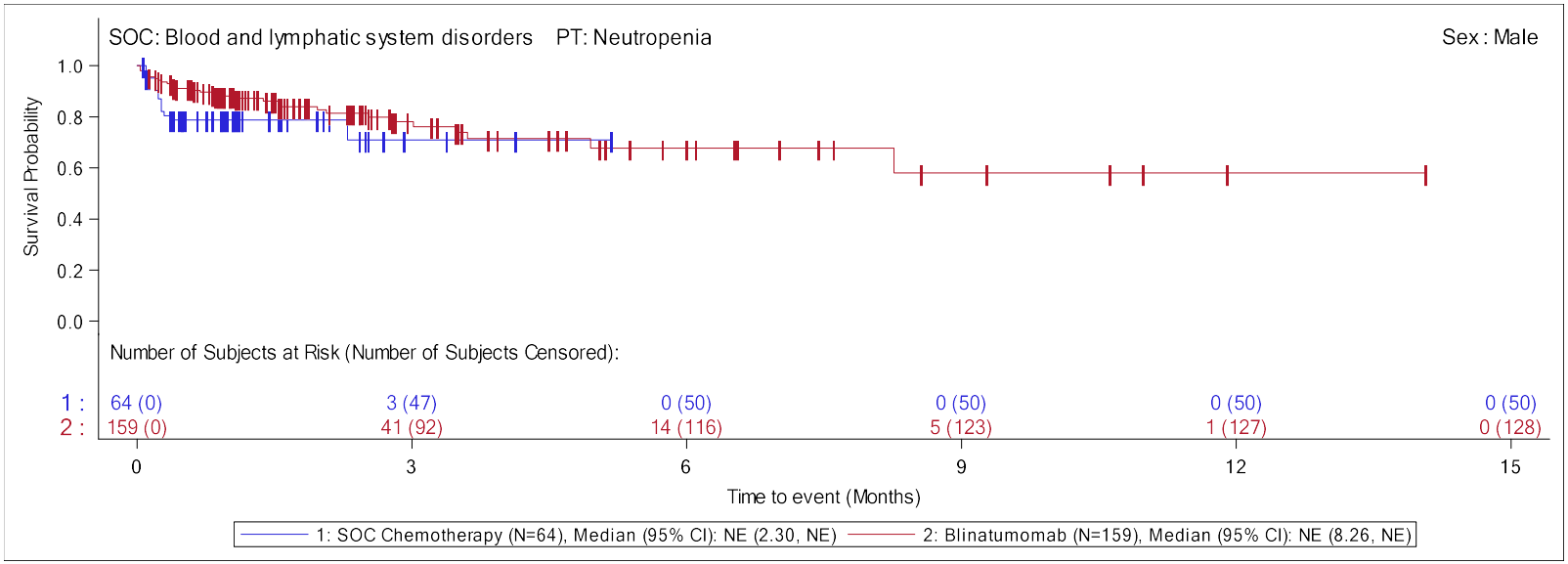
Figure 14-6.2.11. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
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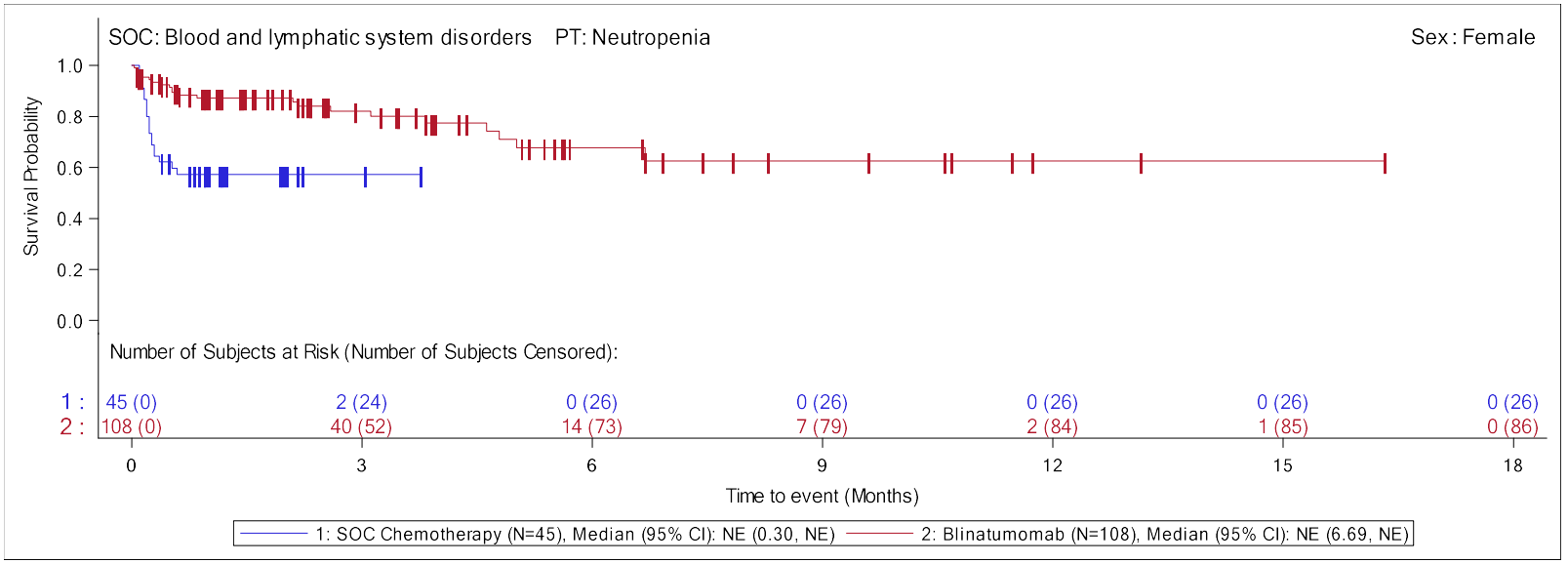

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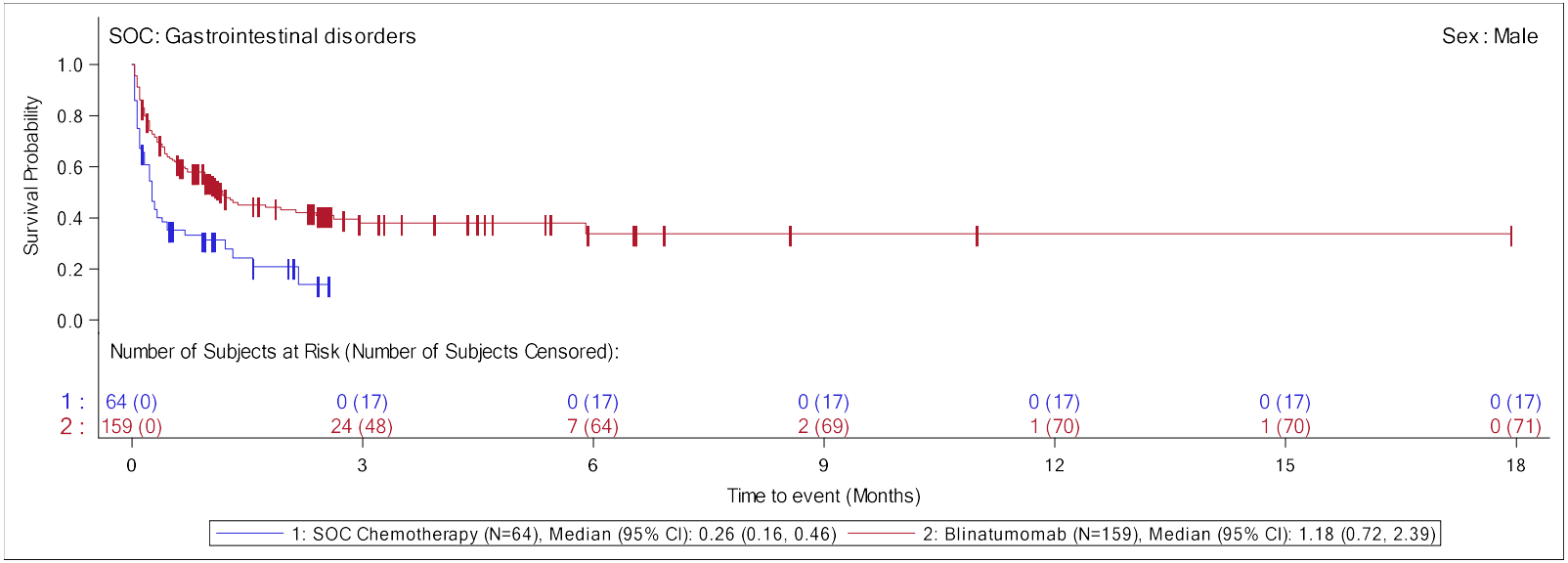

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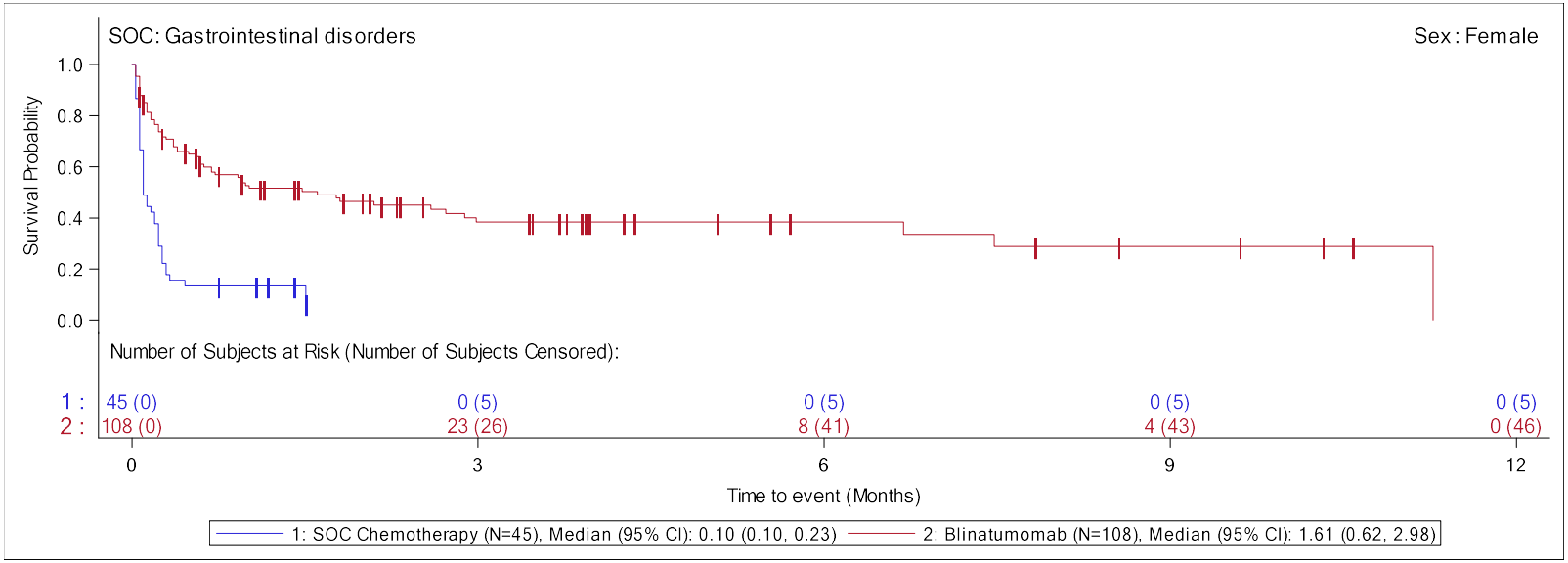

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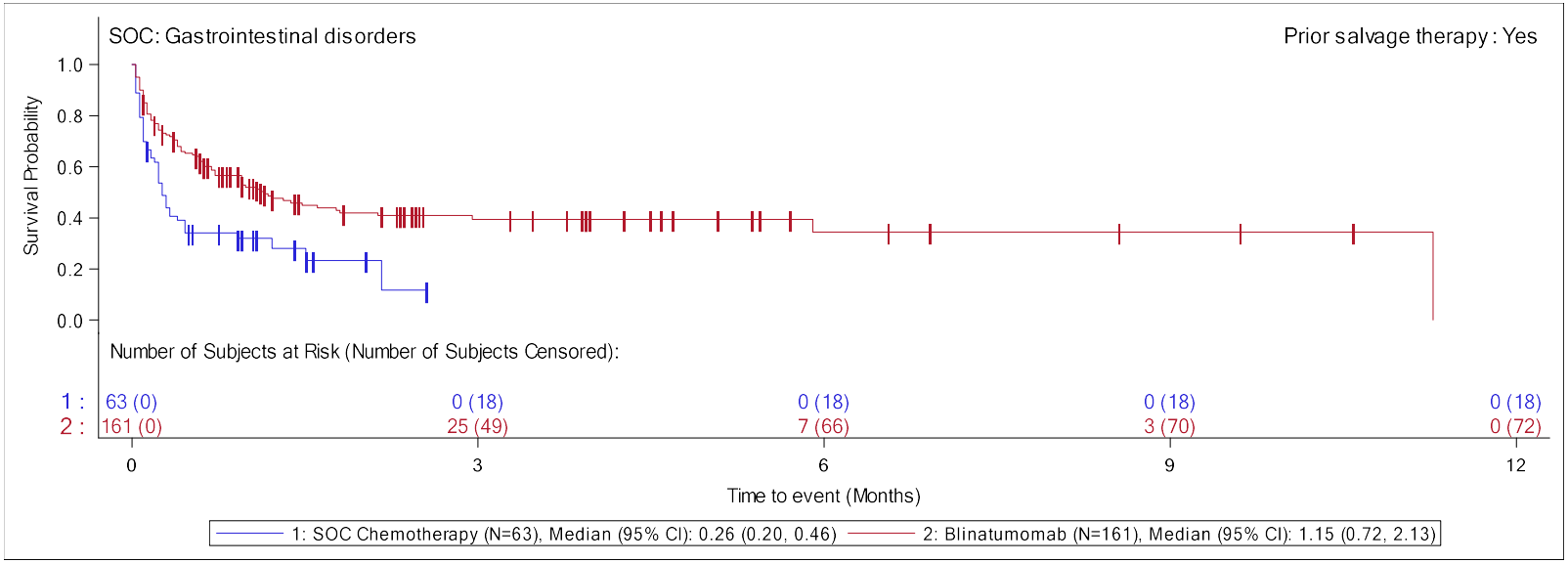

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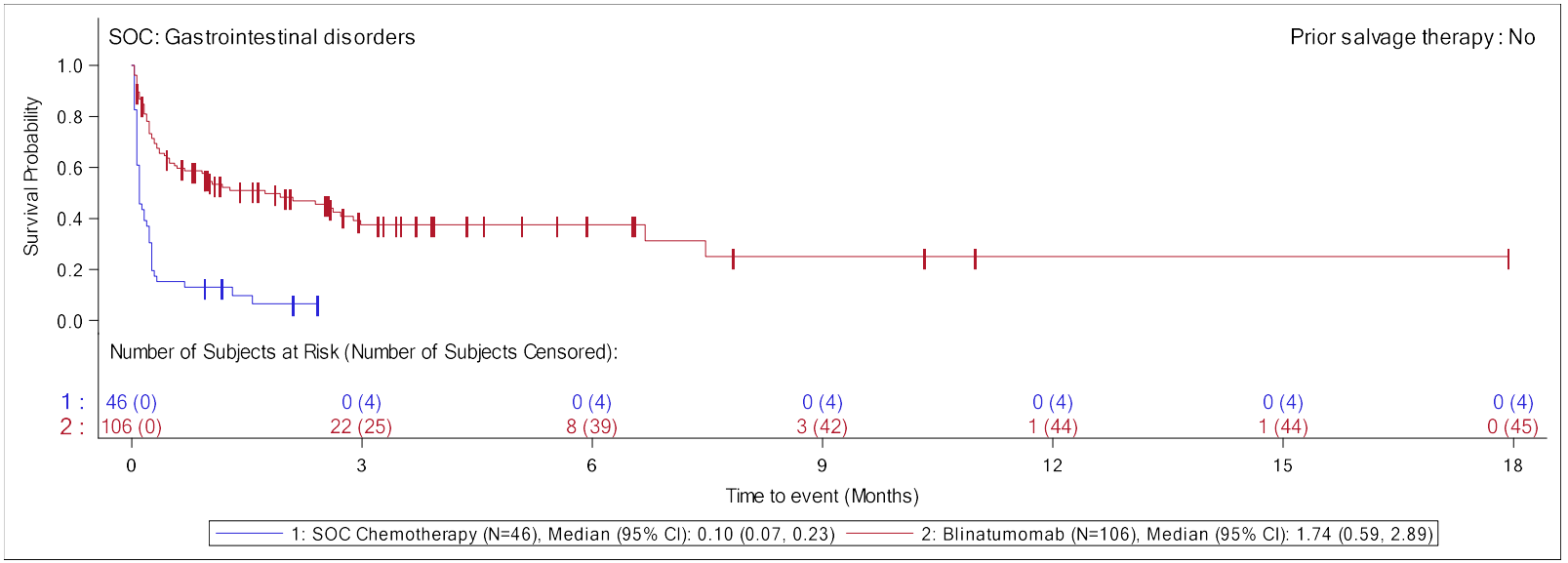

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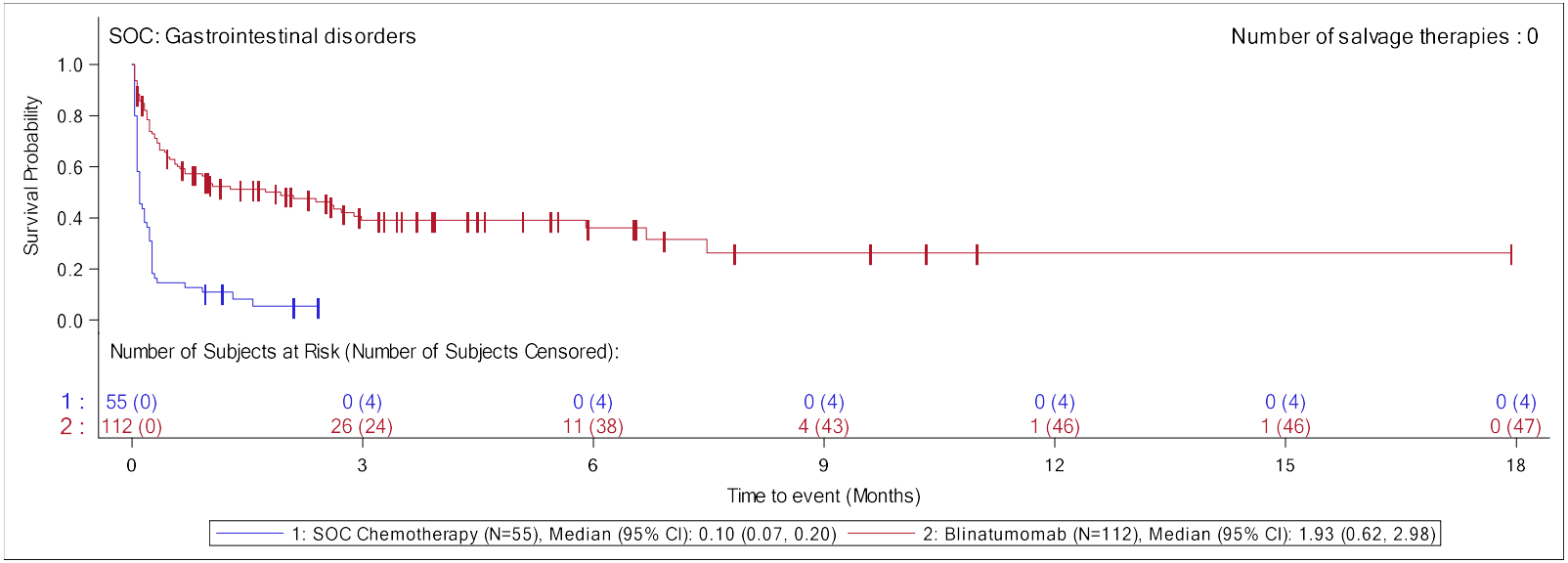

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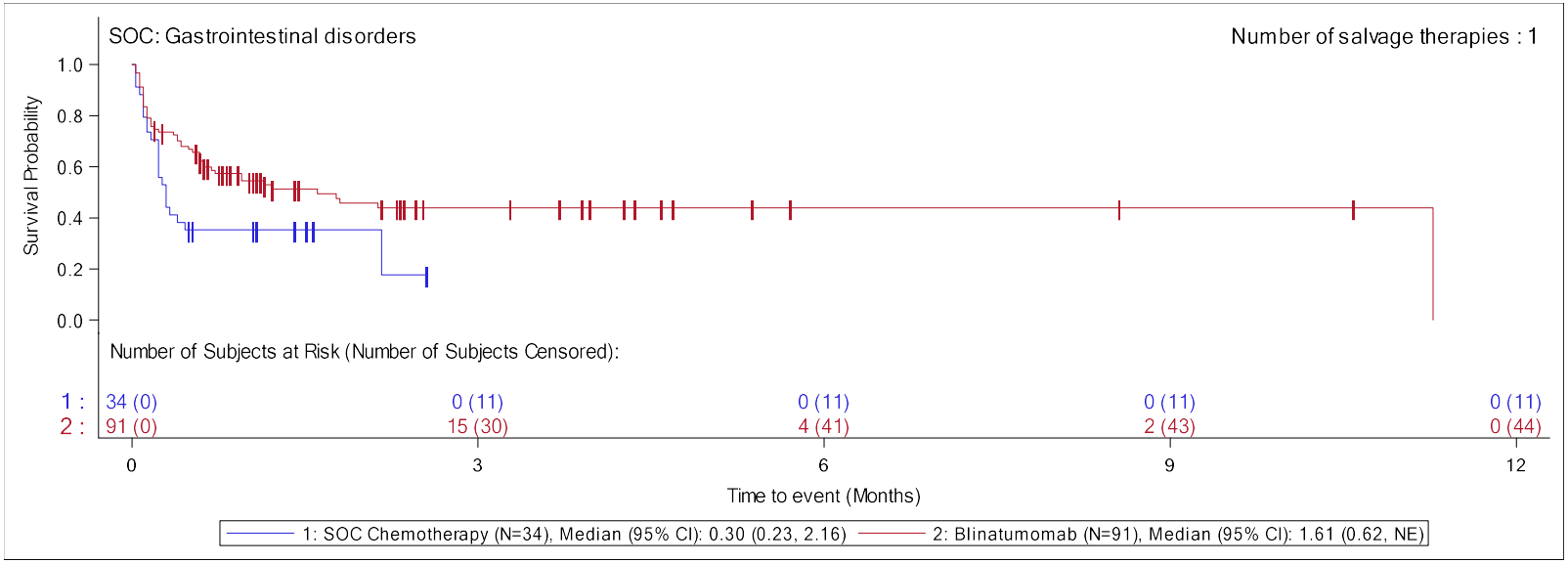

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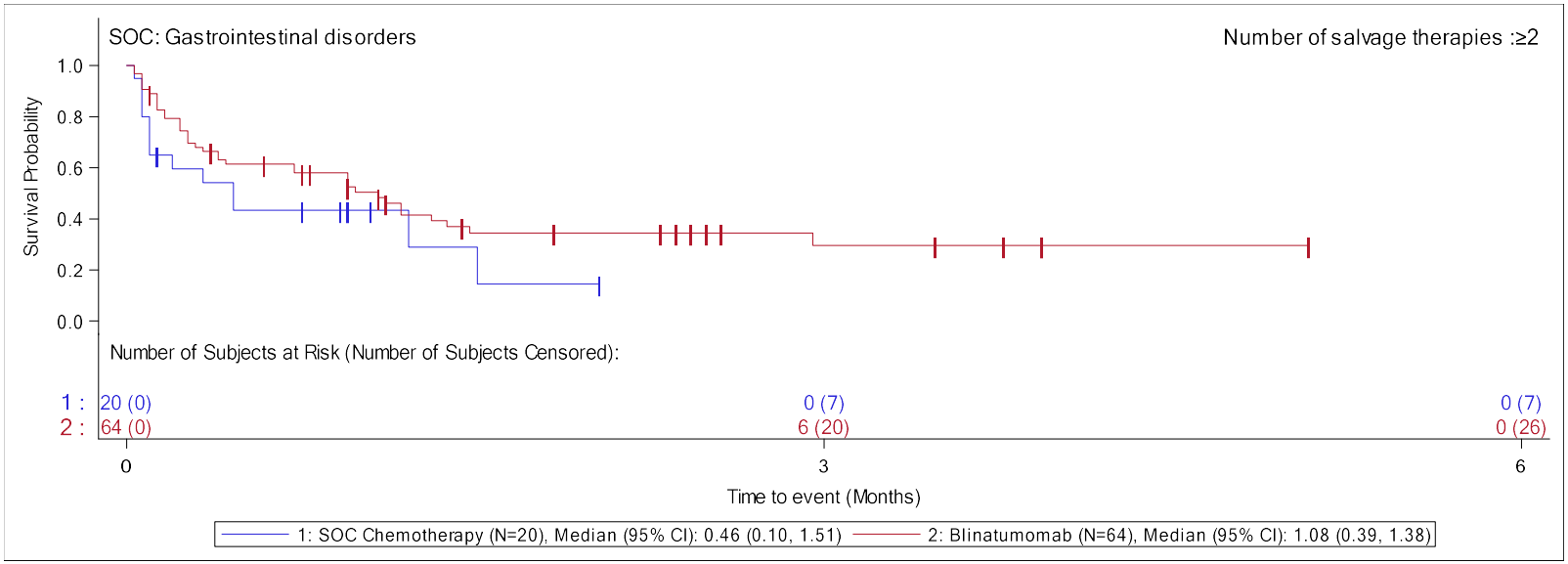

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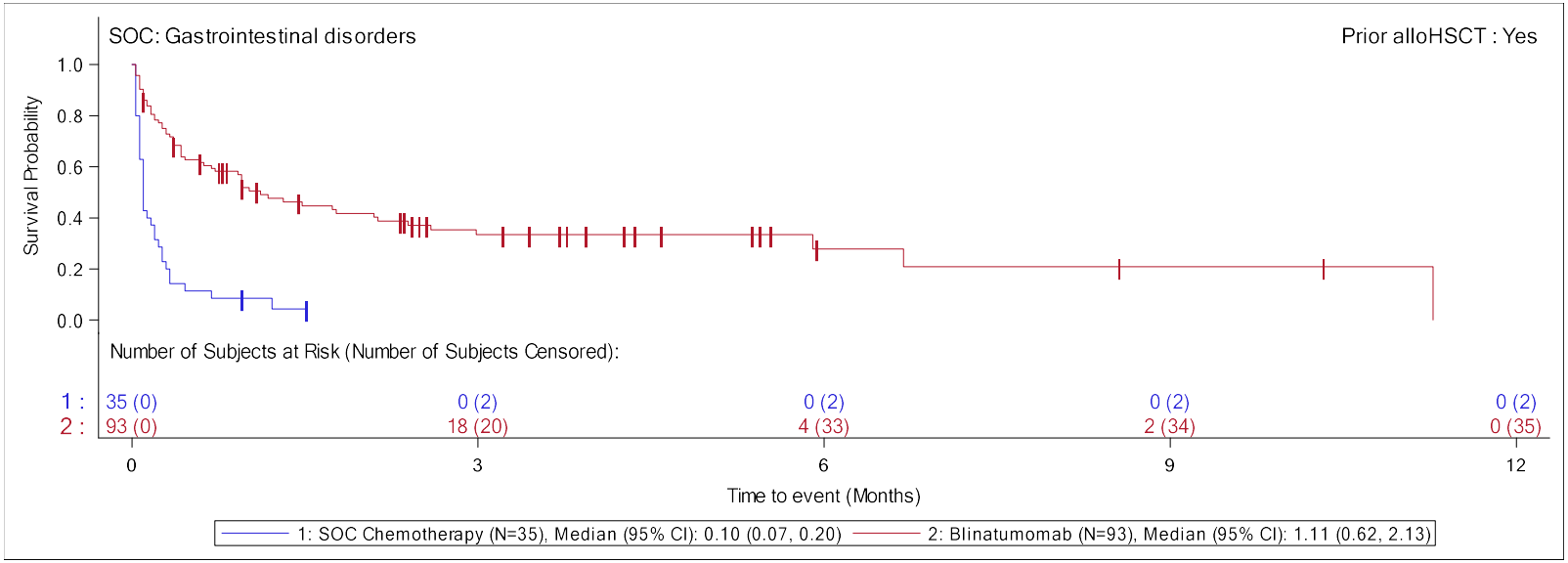

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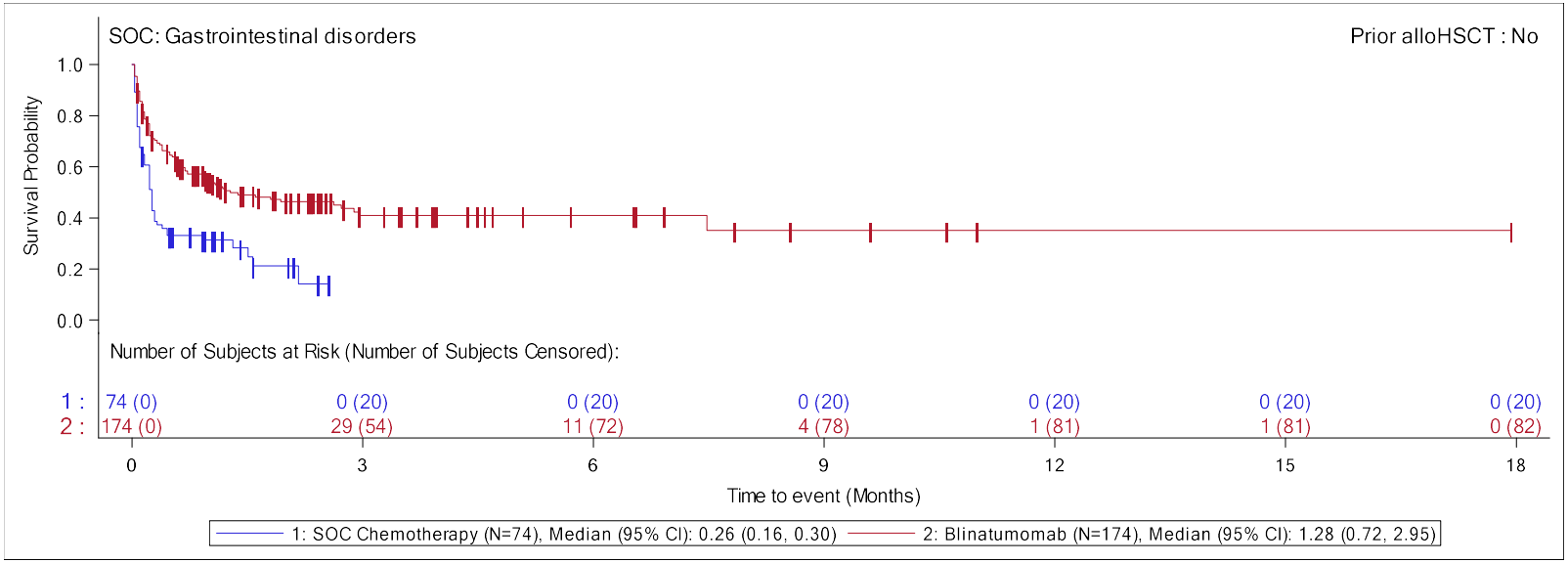

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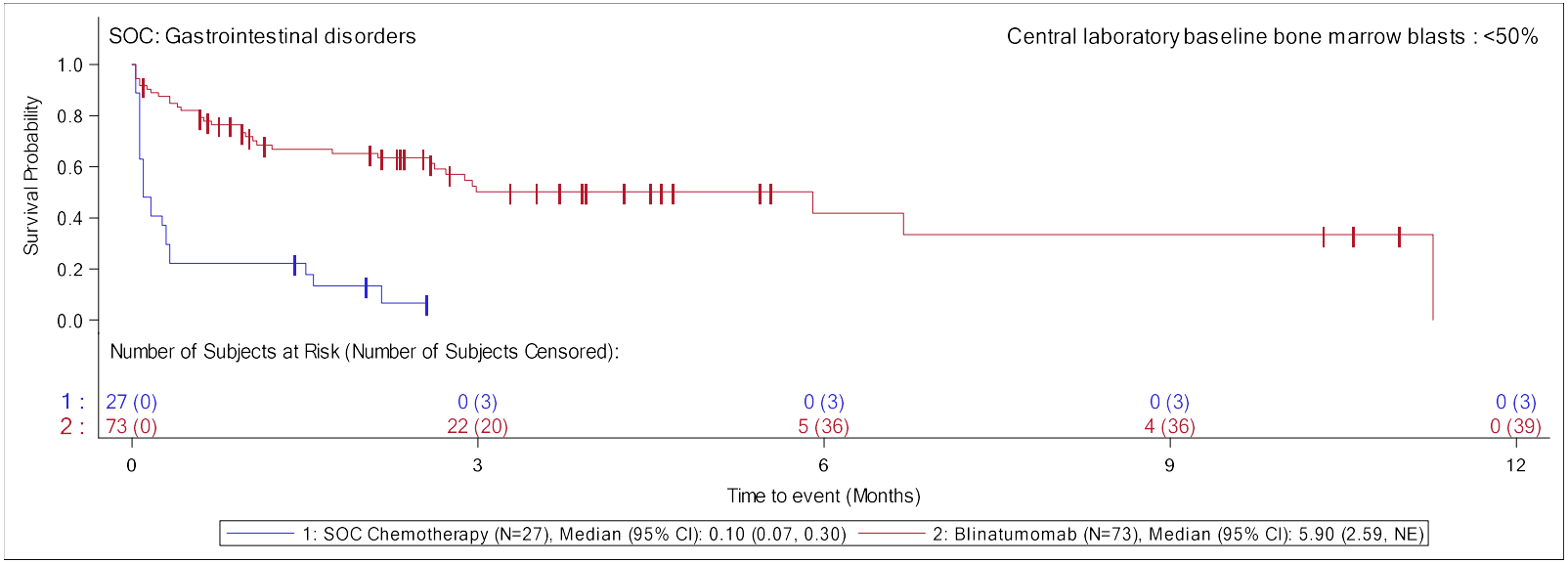

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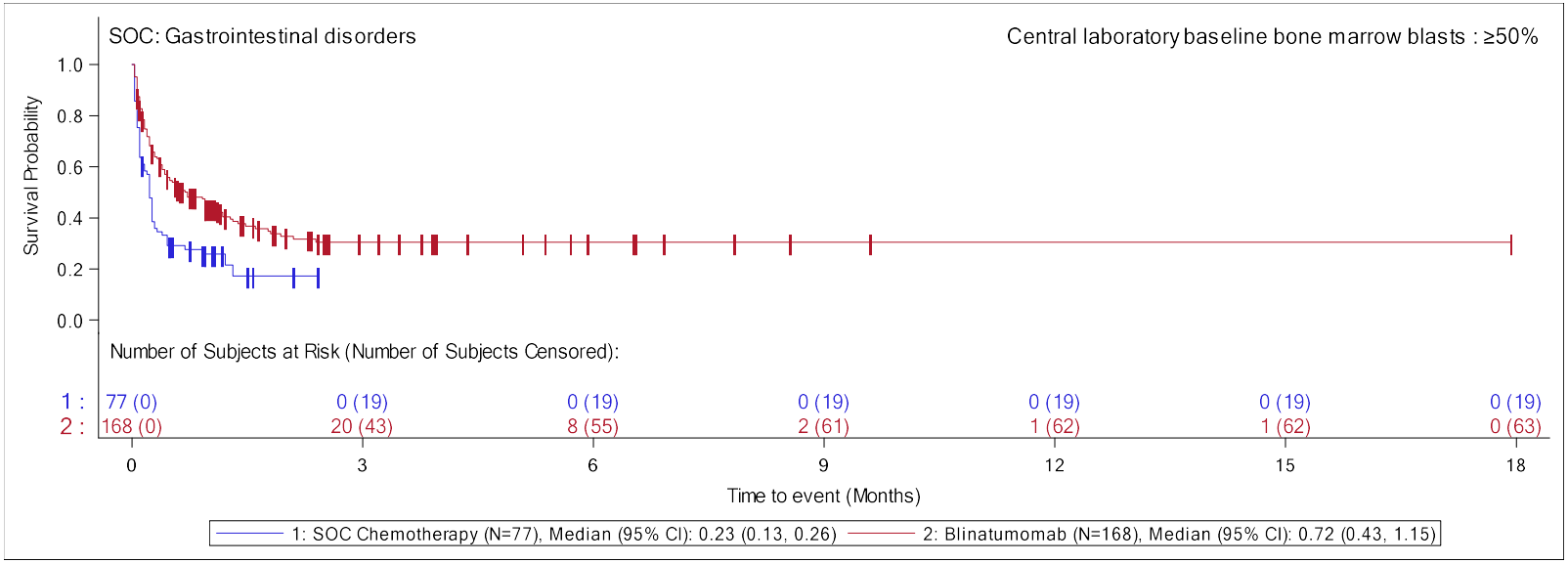

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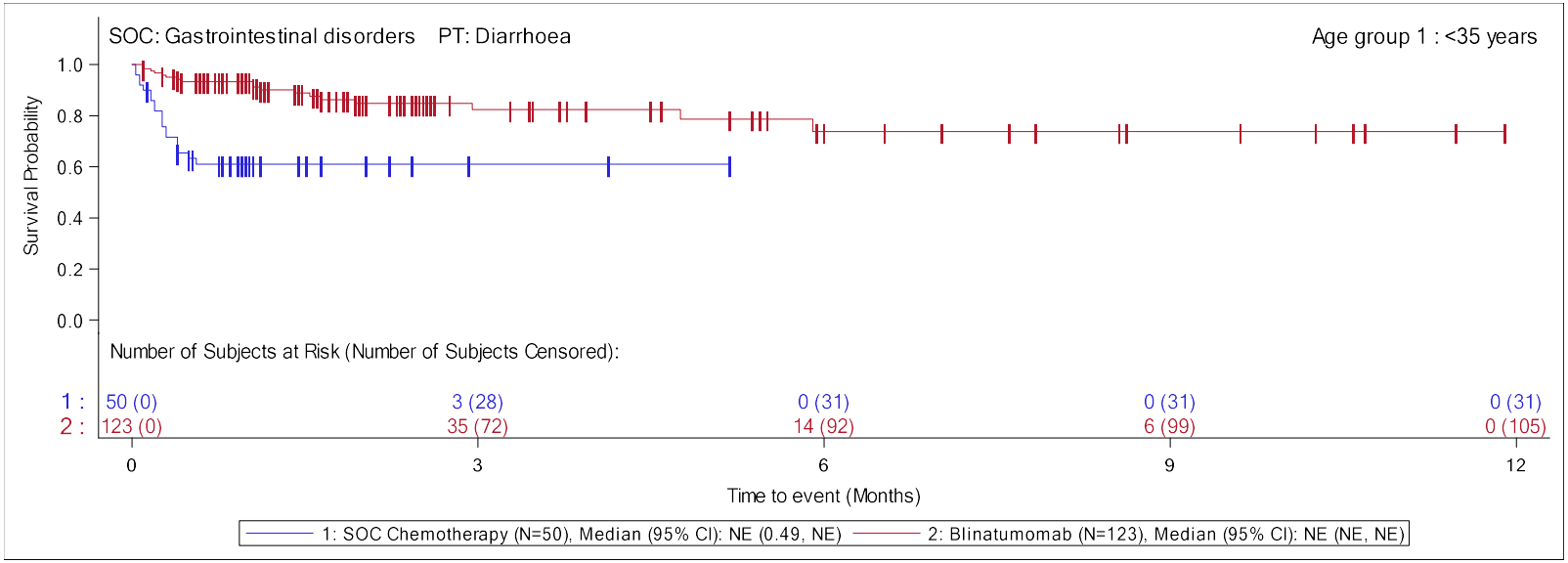

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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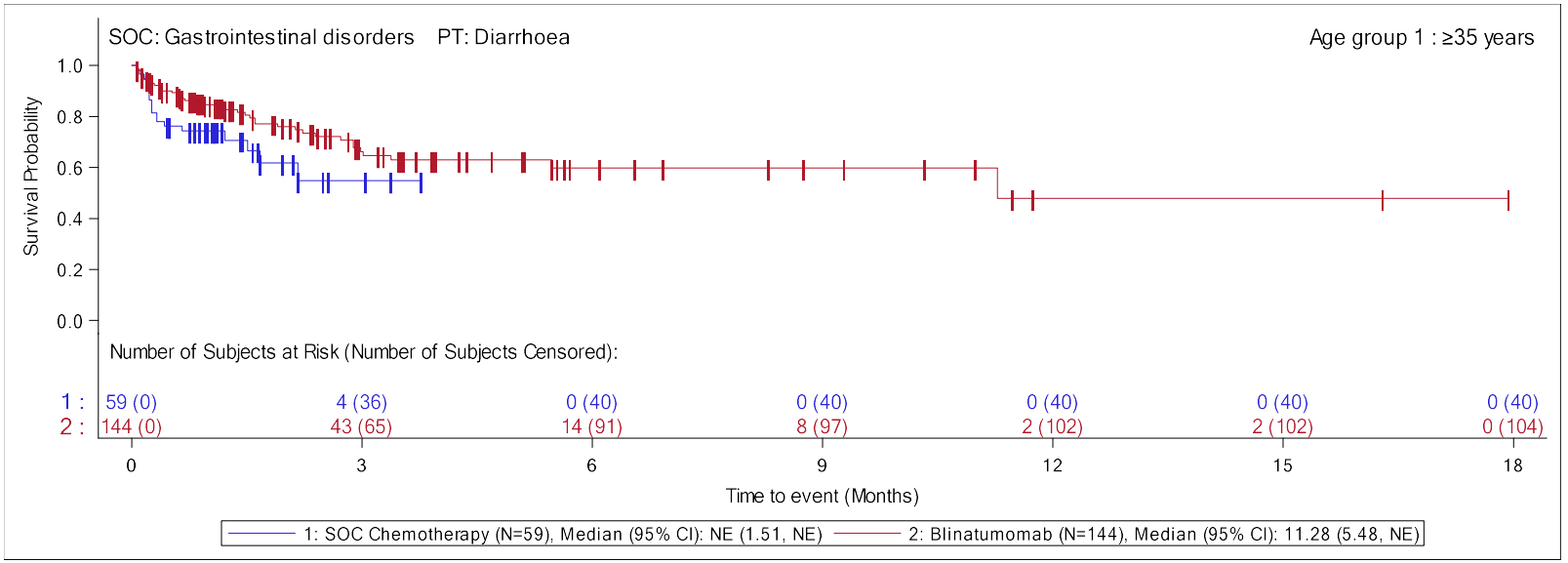

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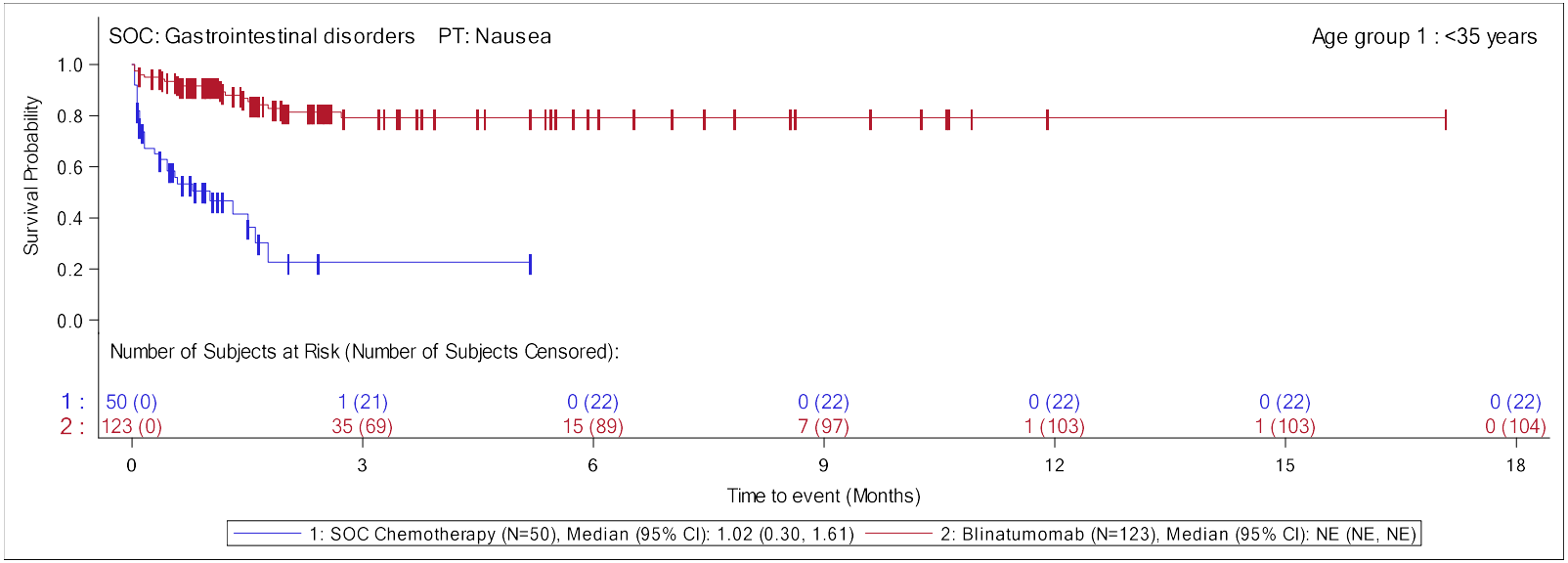

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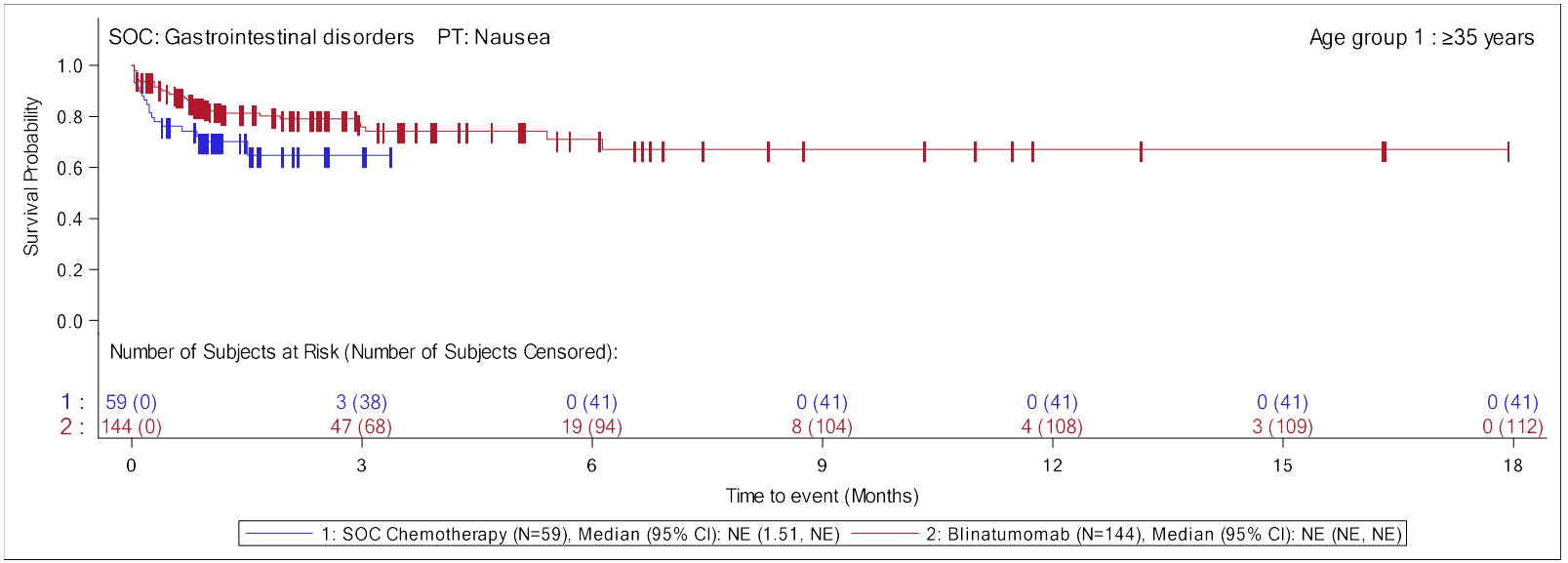

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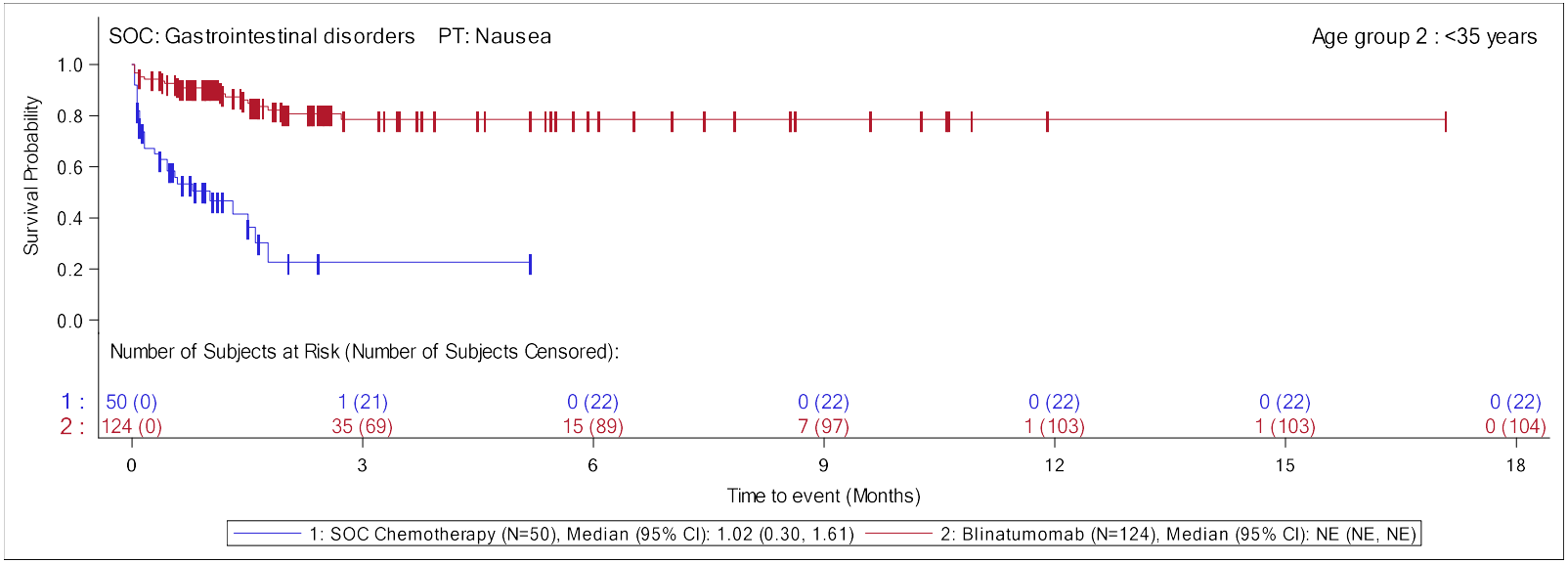

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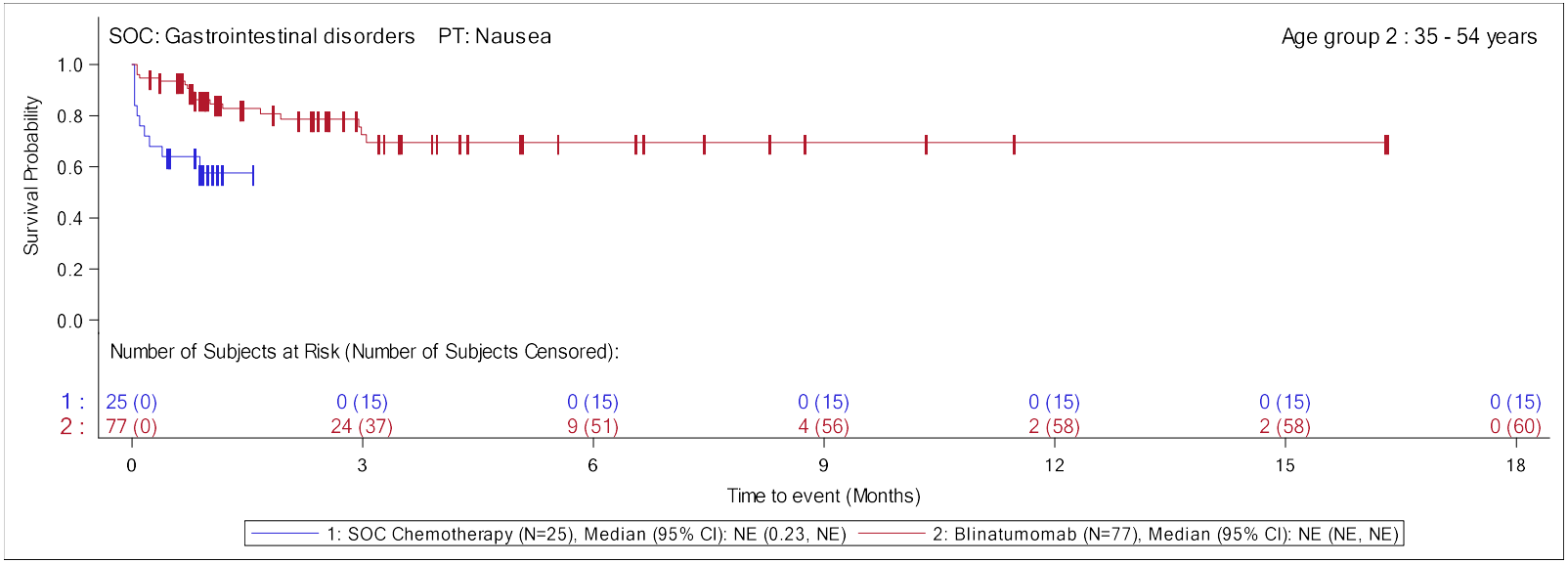

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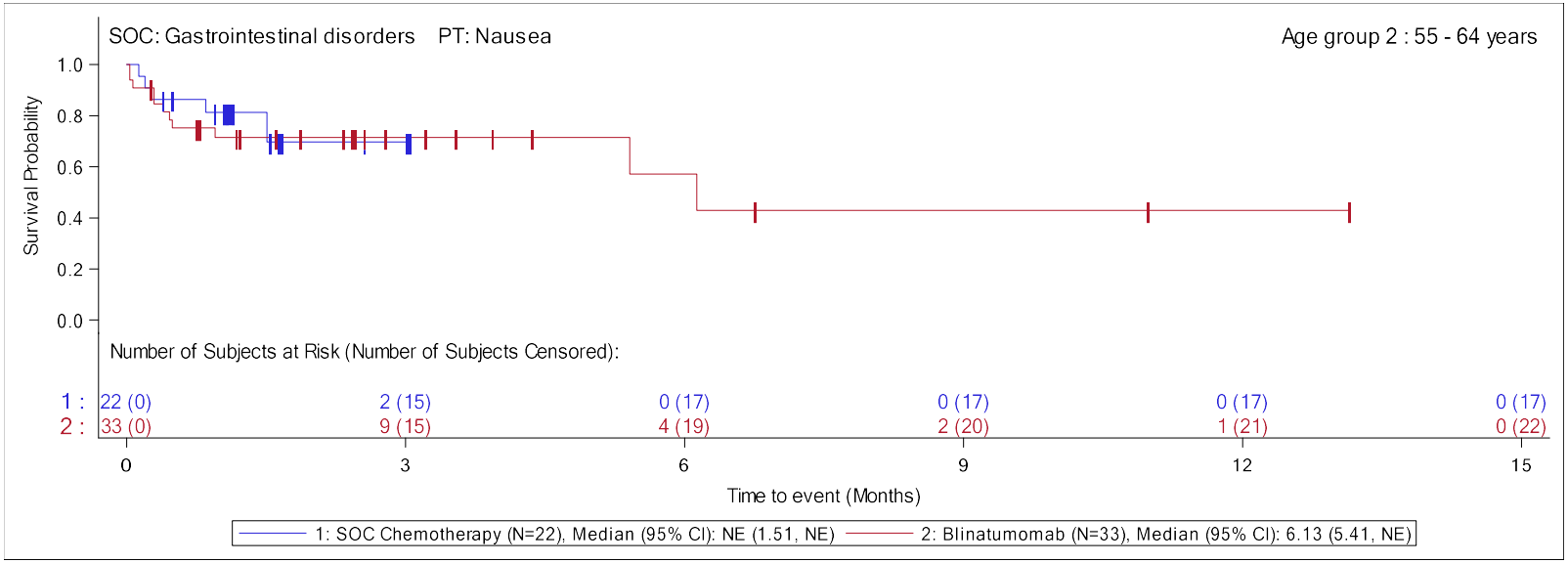

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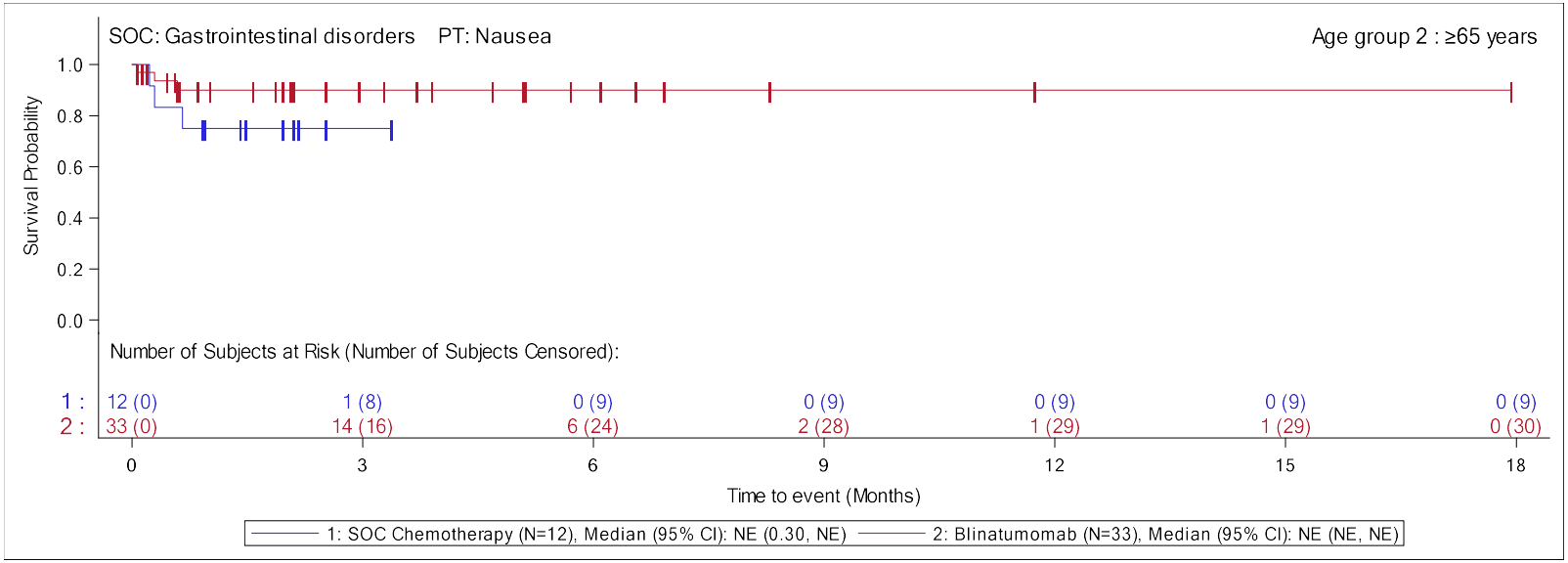

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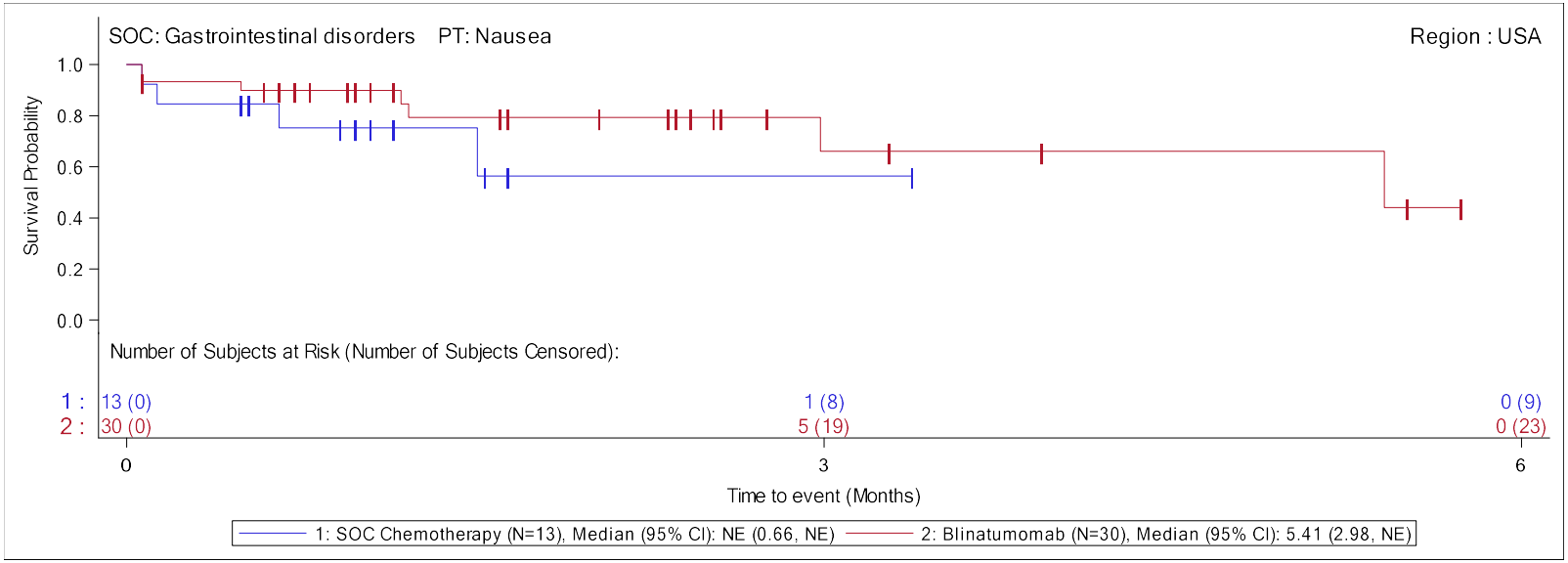

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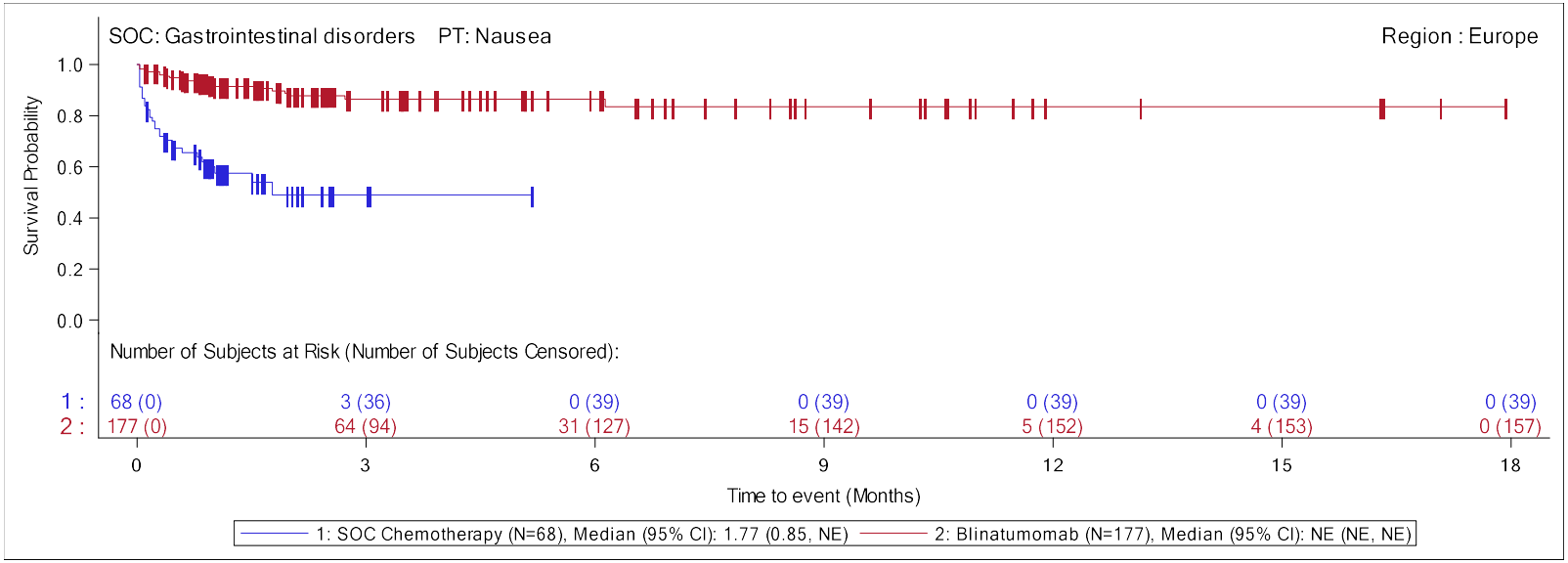

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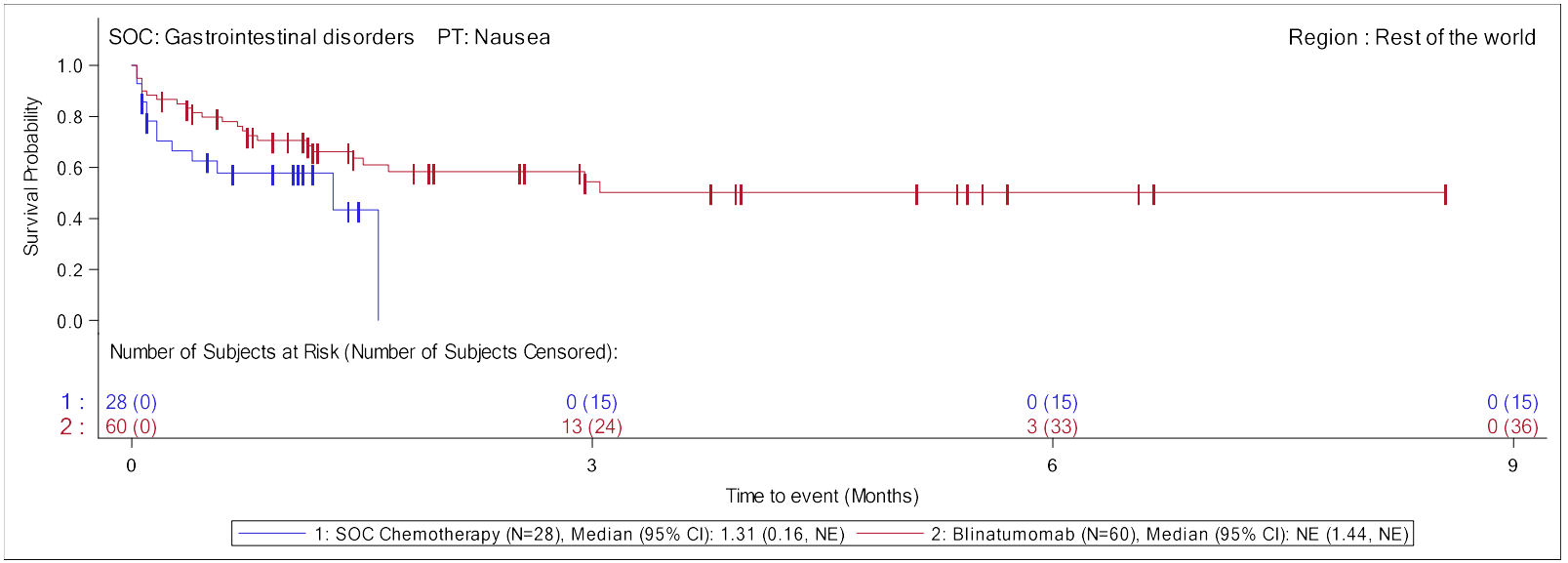

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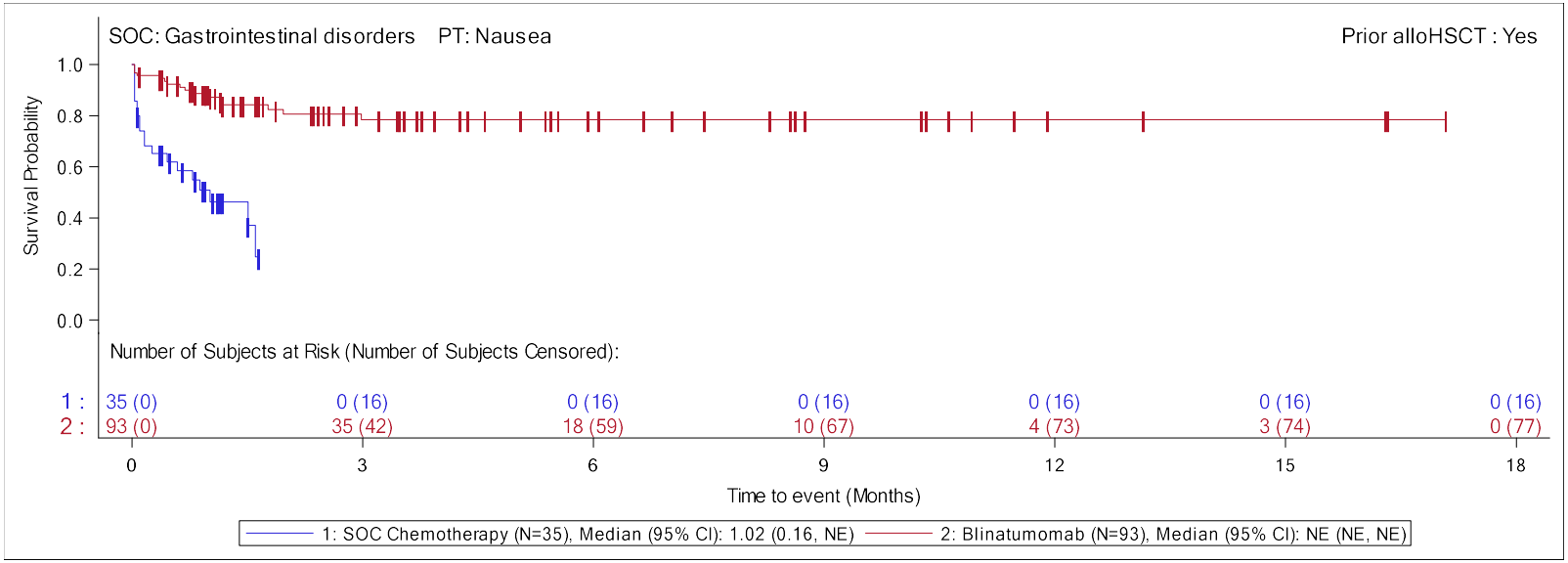

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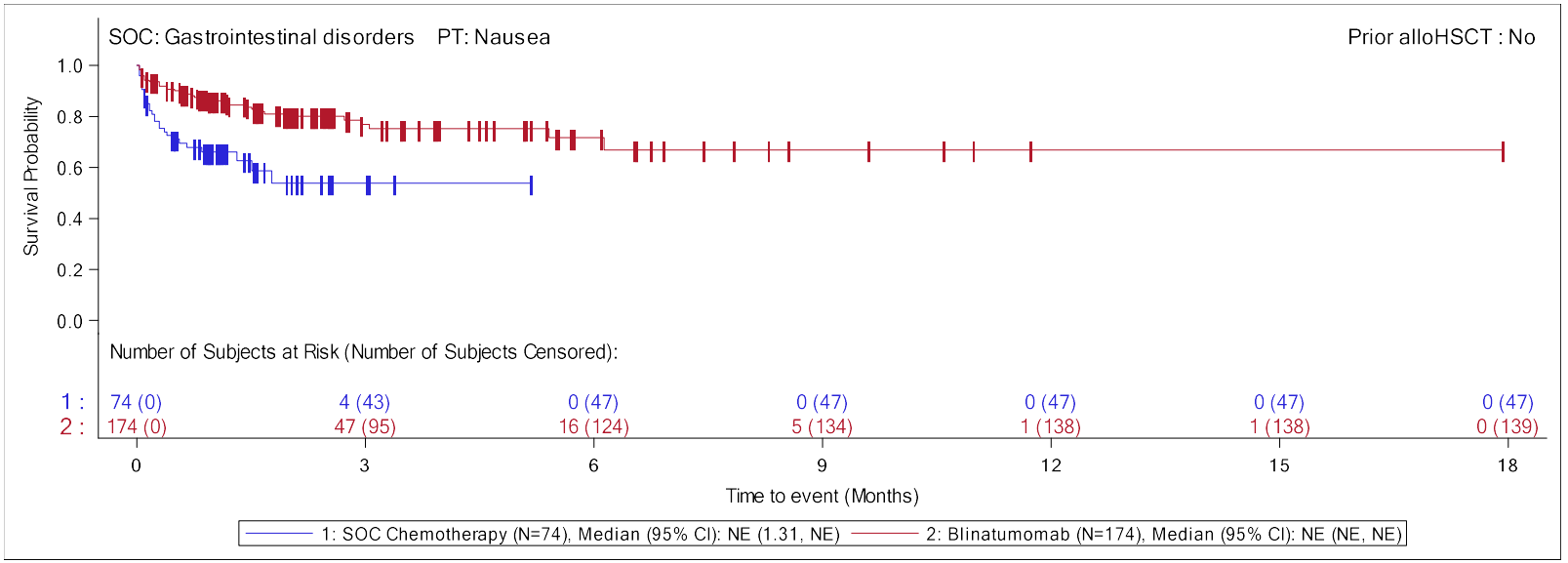

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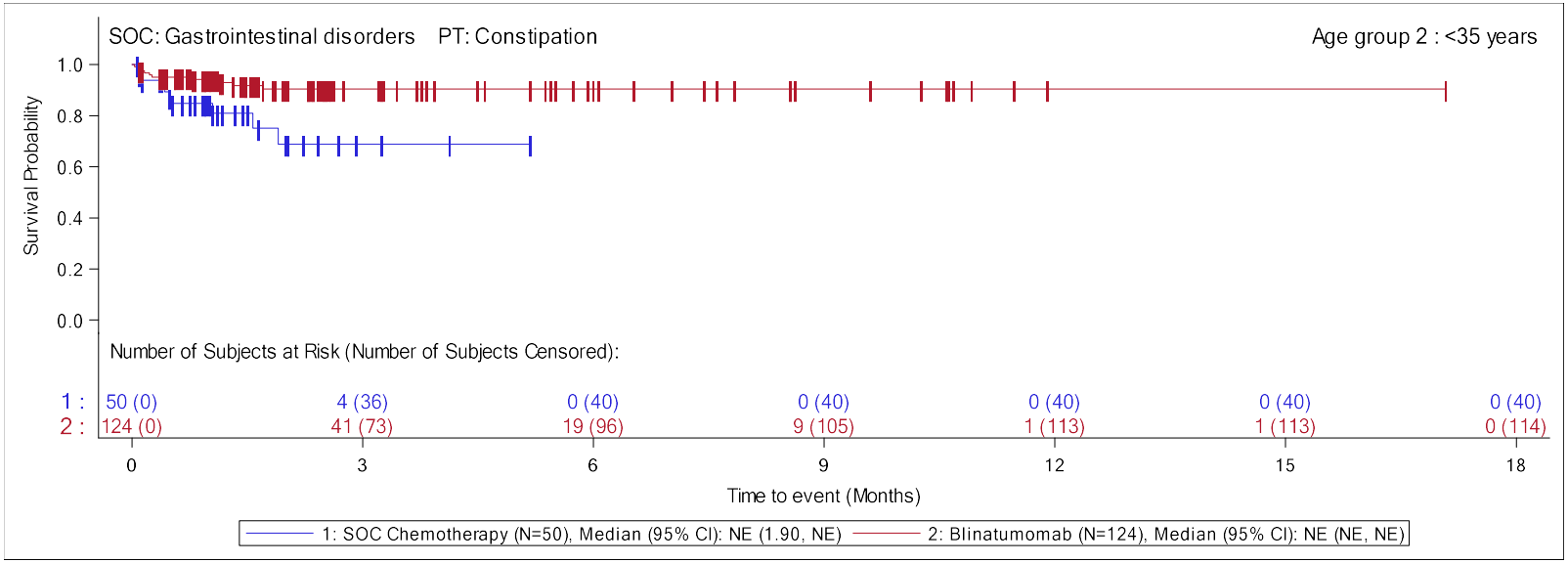

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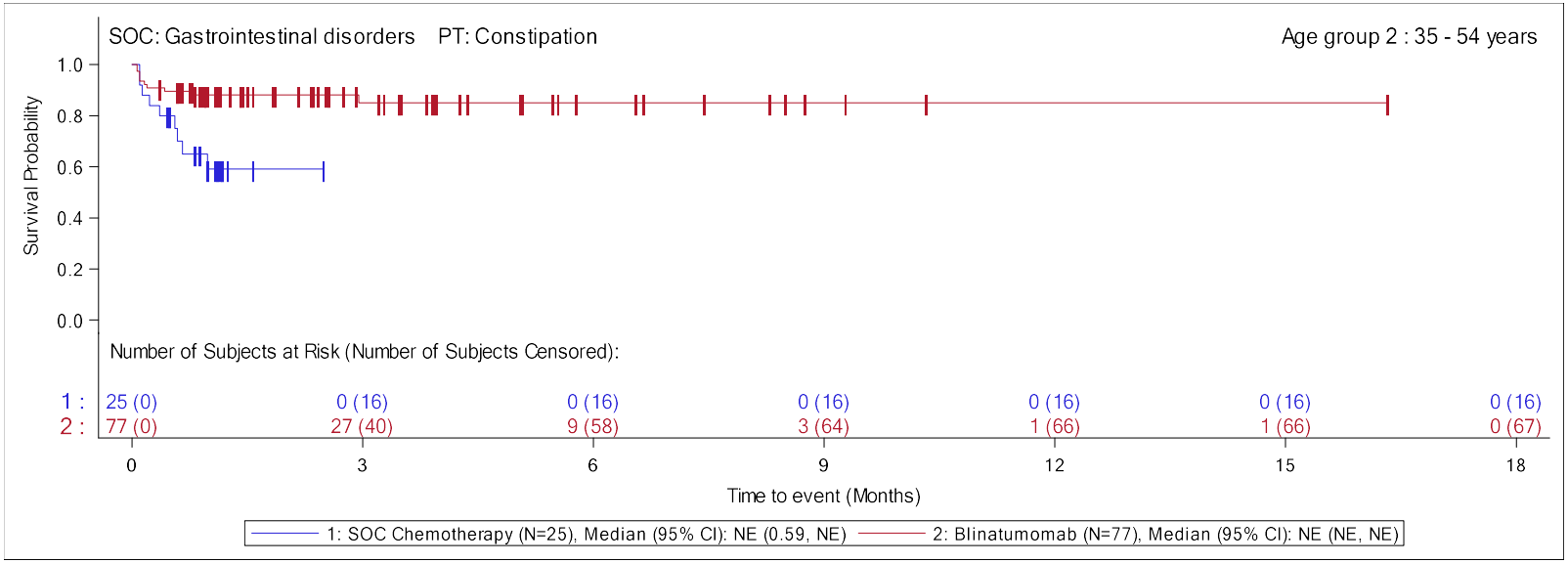

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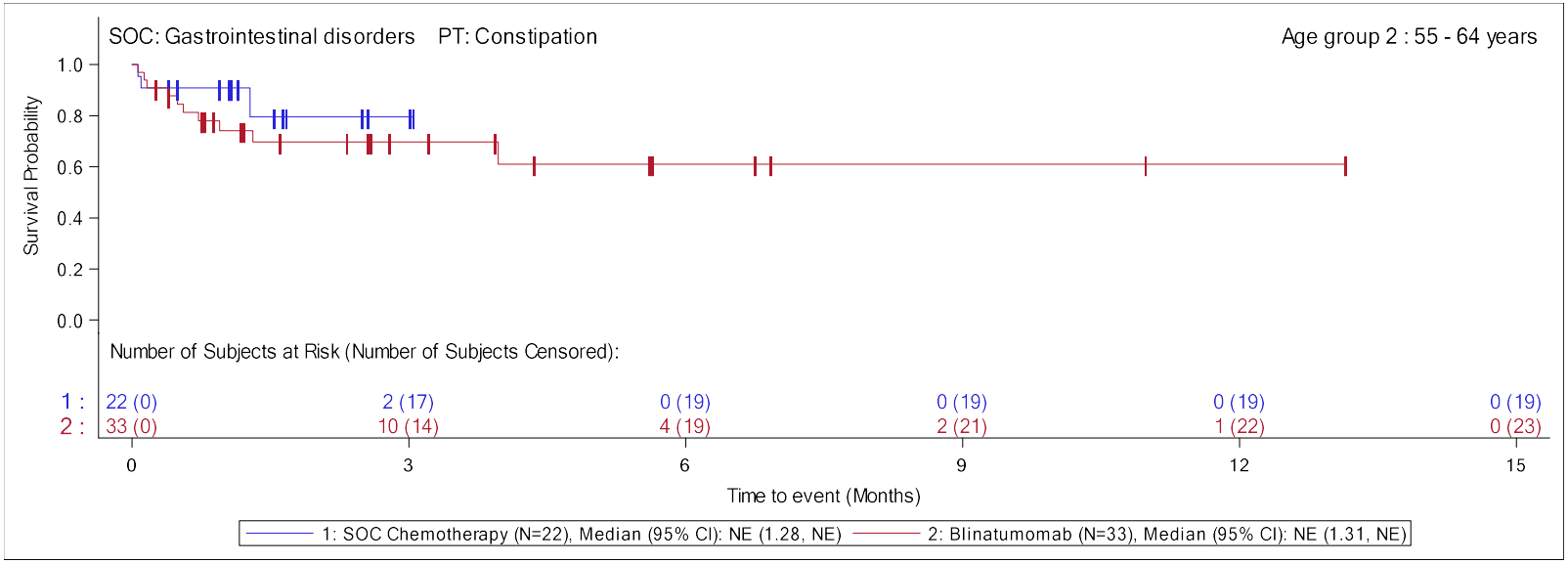

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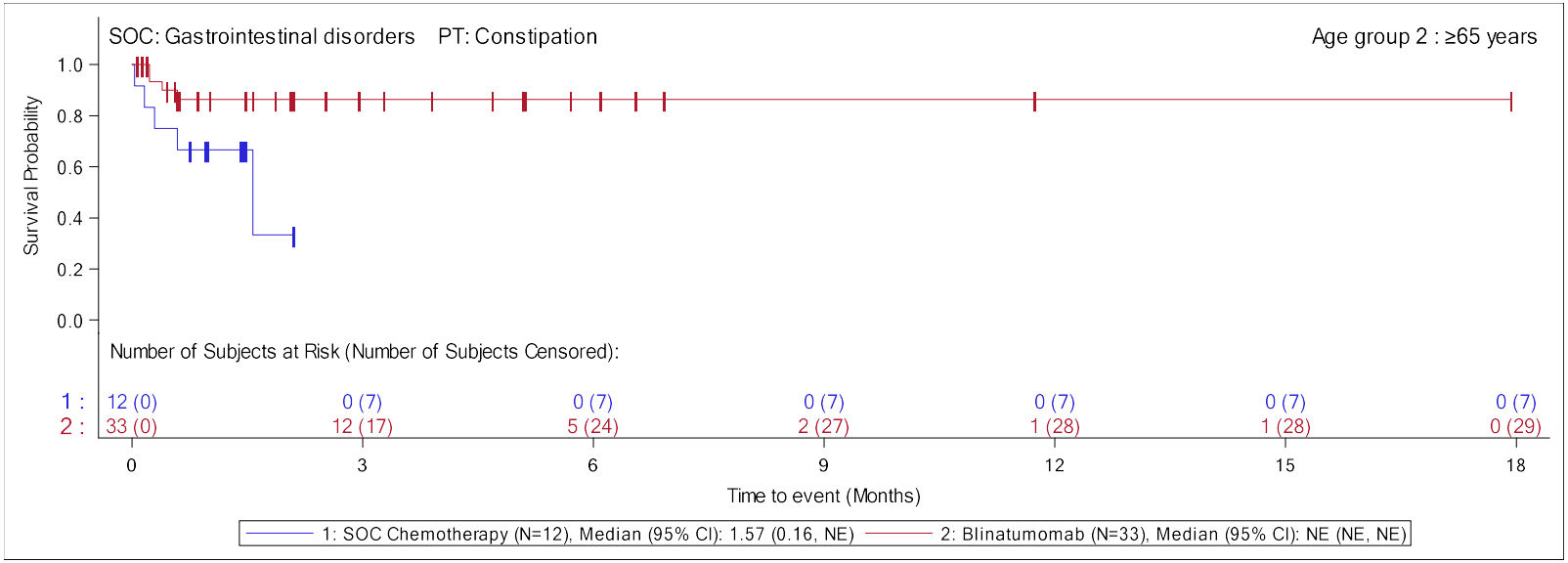

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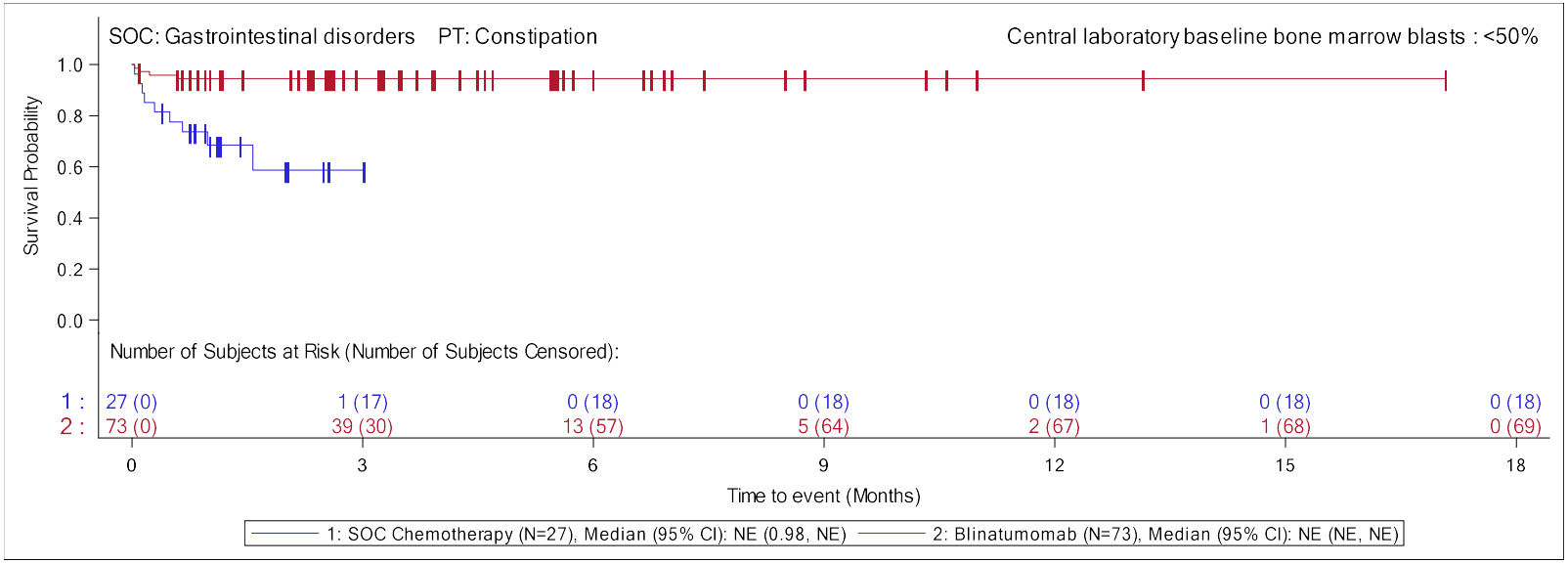

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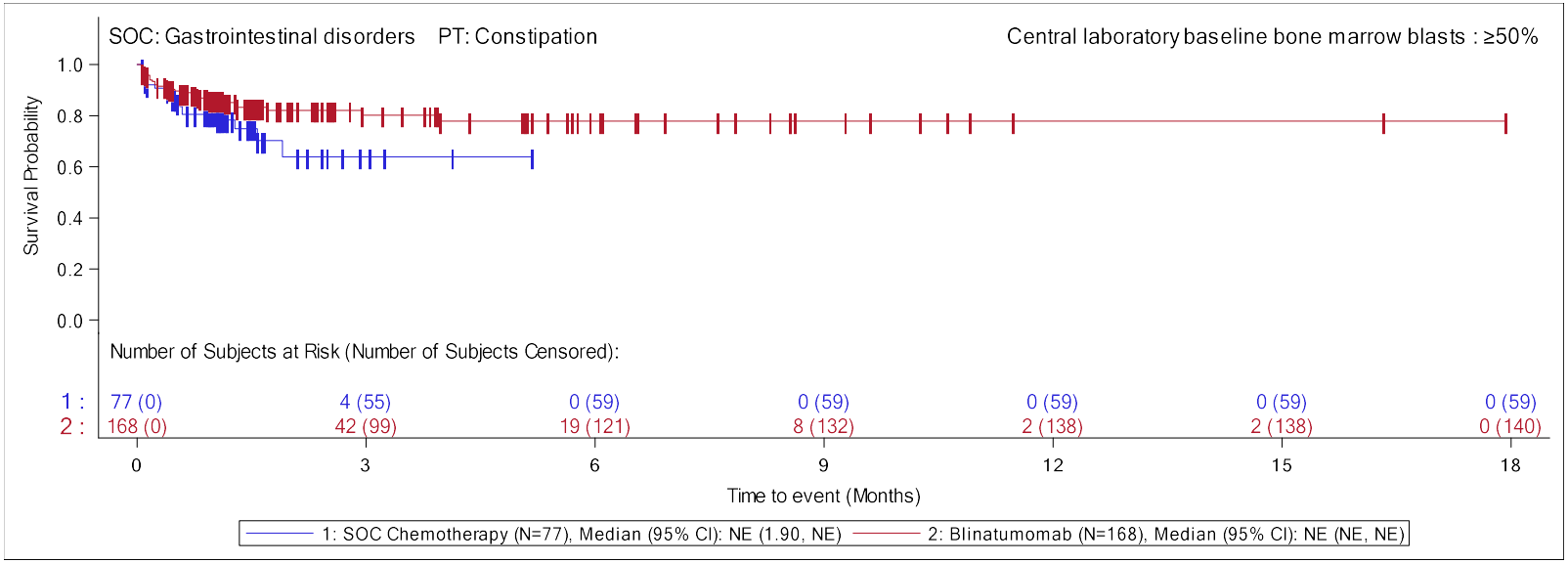

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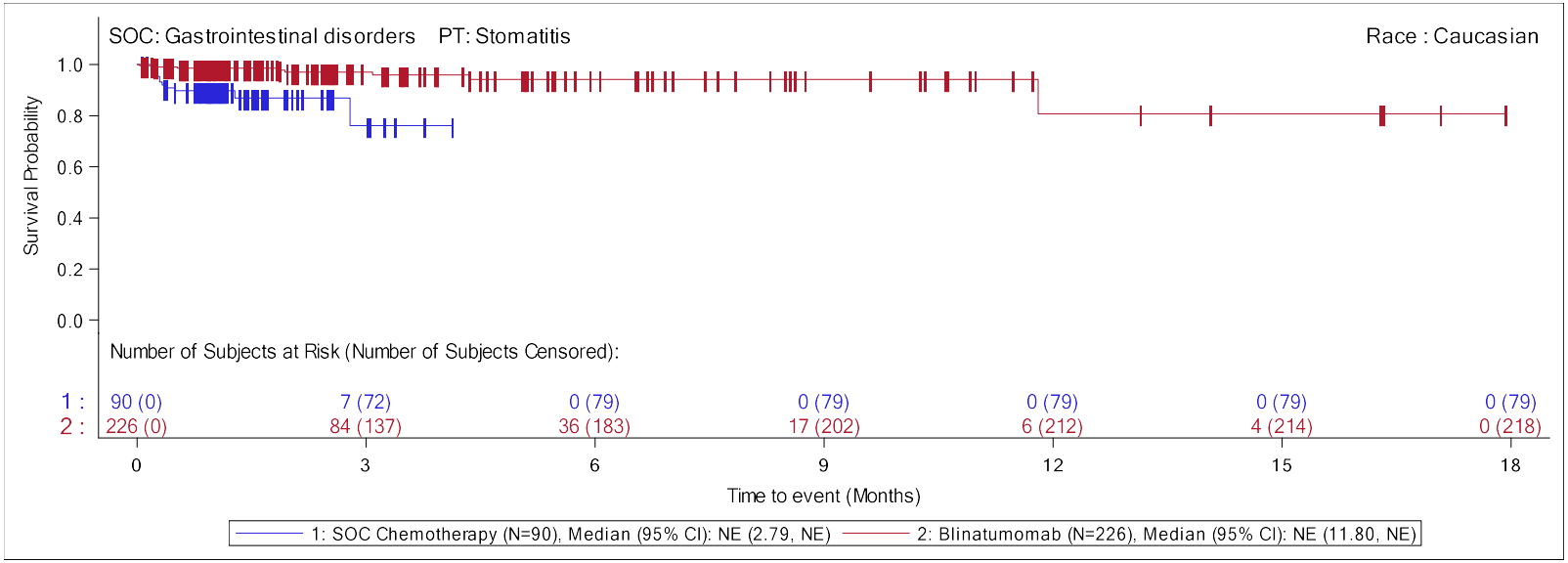

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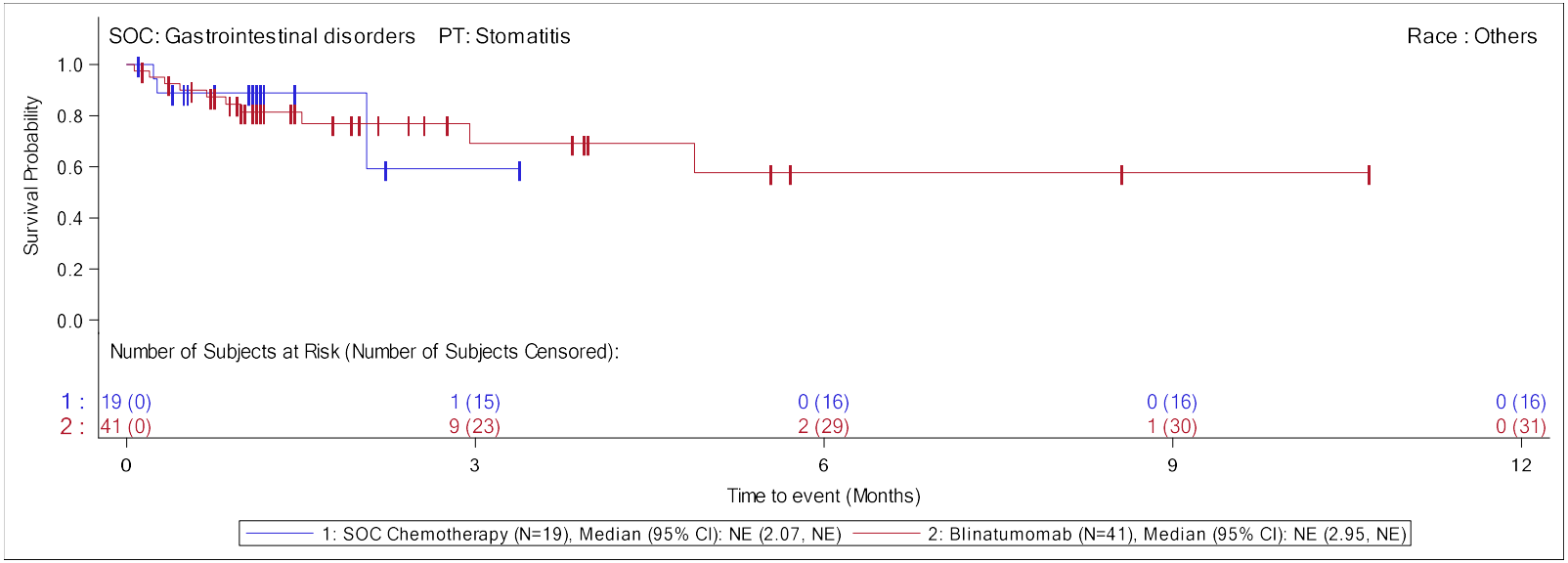

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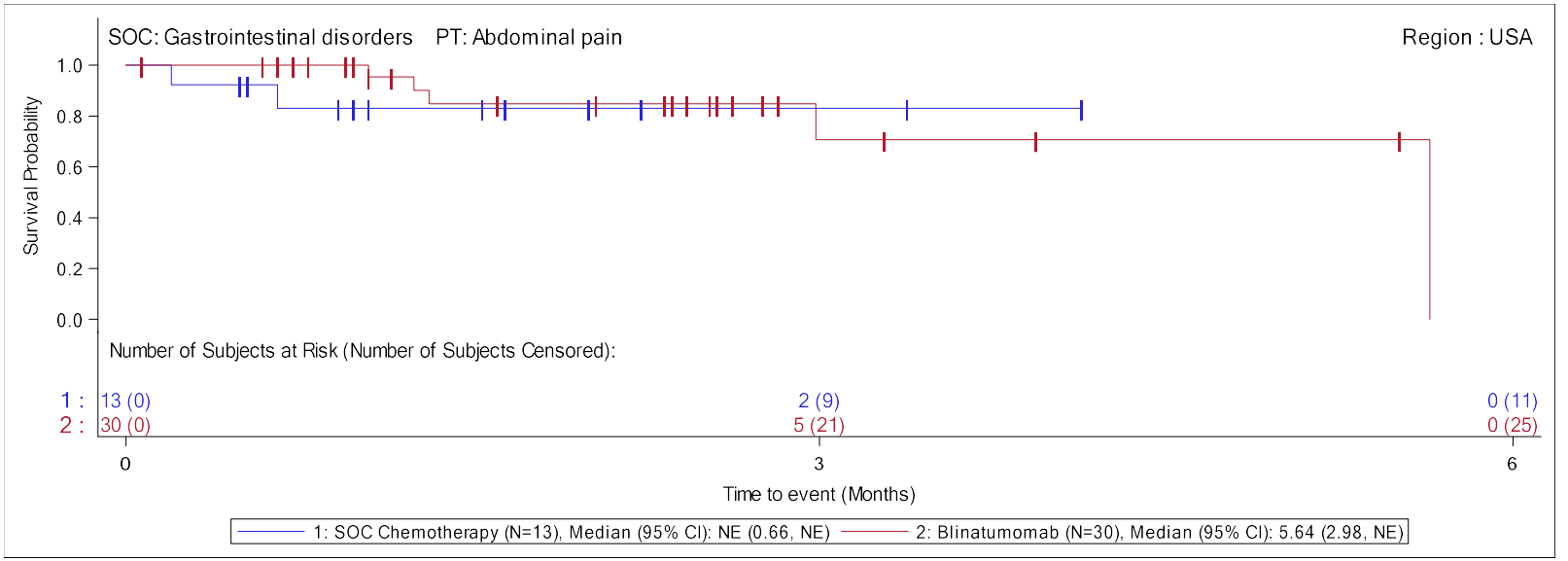

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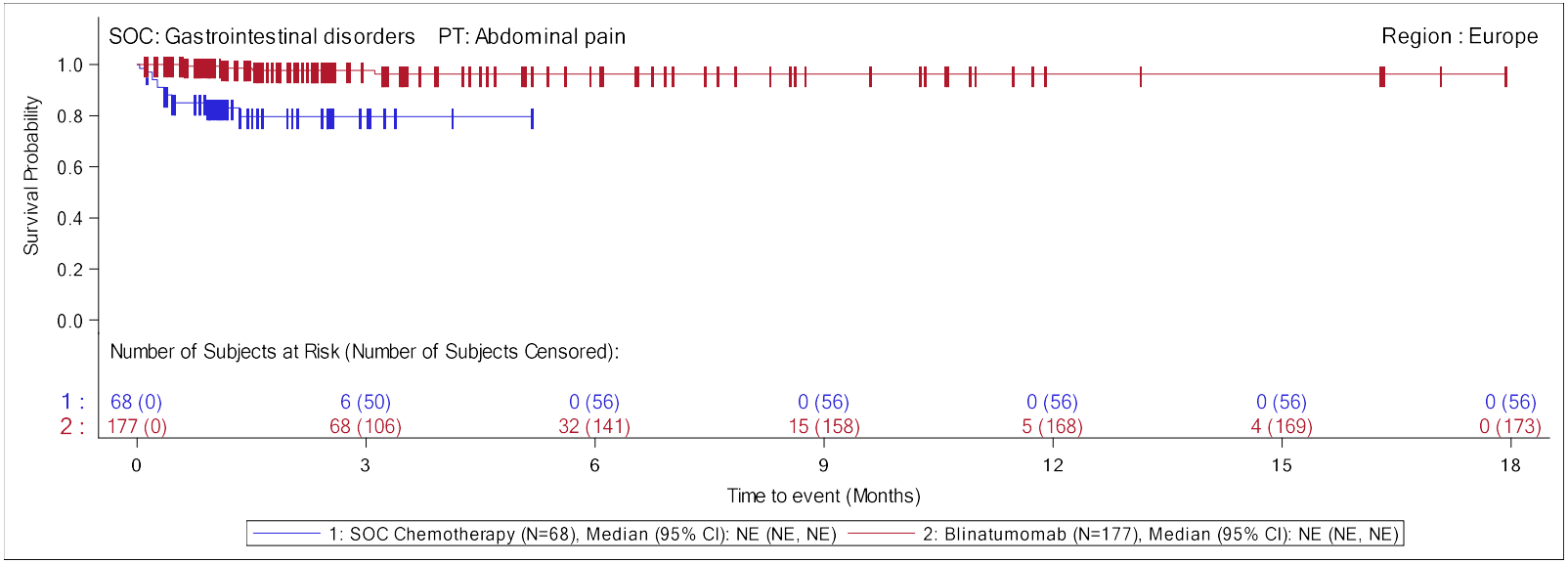

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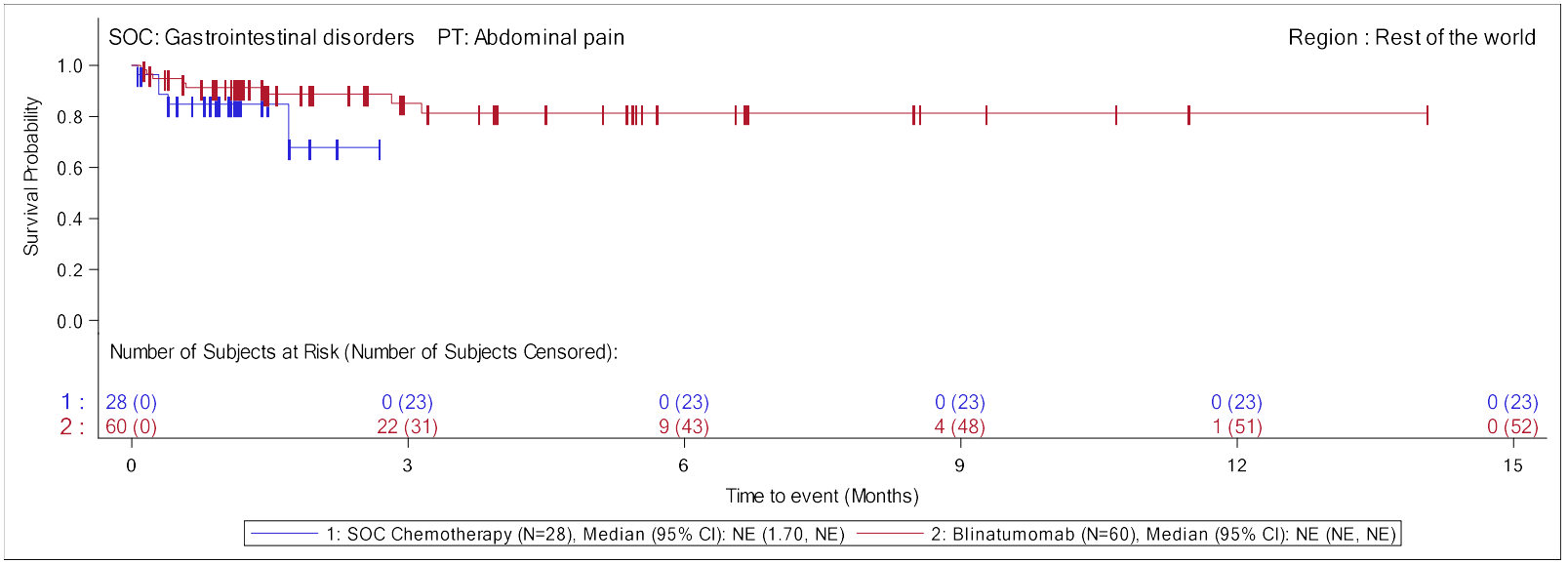
Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-teae-soc-pt-saf.sas
Output: f14-06-002-011-km-sub-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, outtab.t_aette_socpref

Figure 14-6.2.11. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

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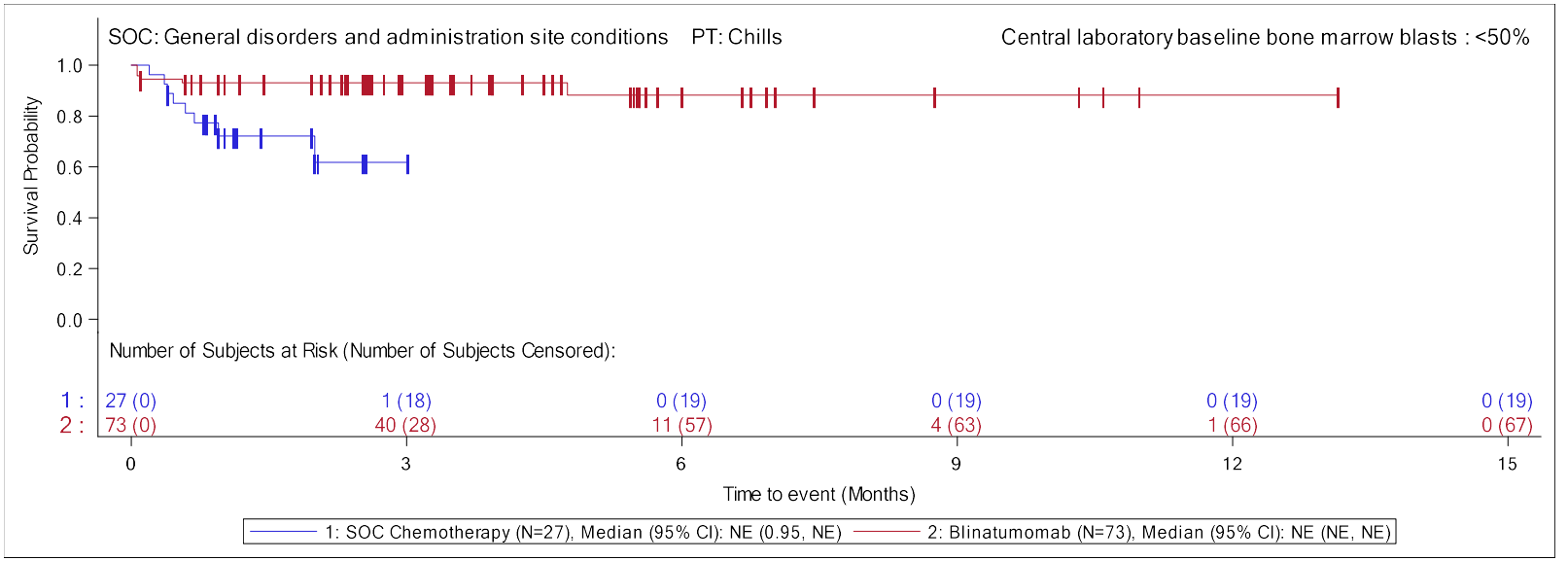

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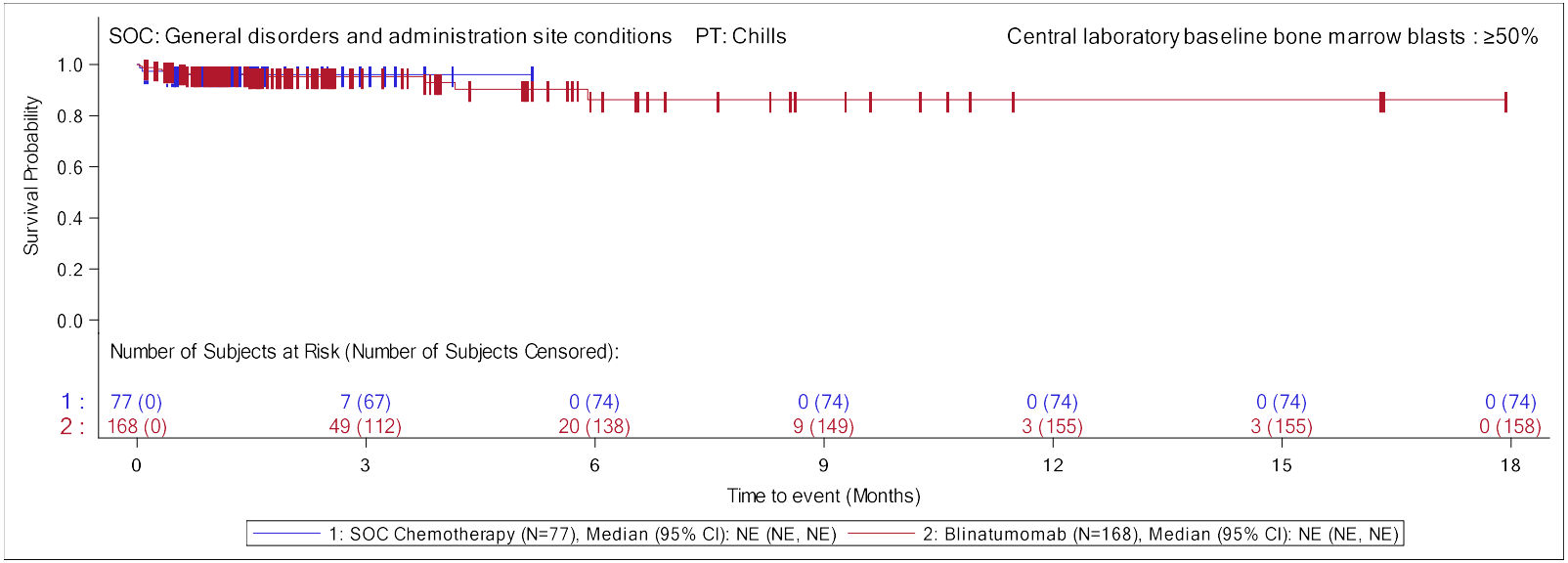

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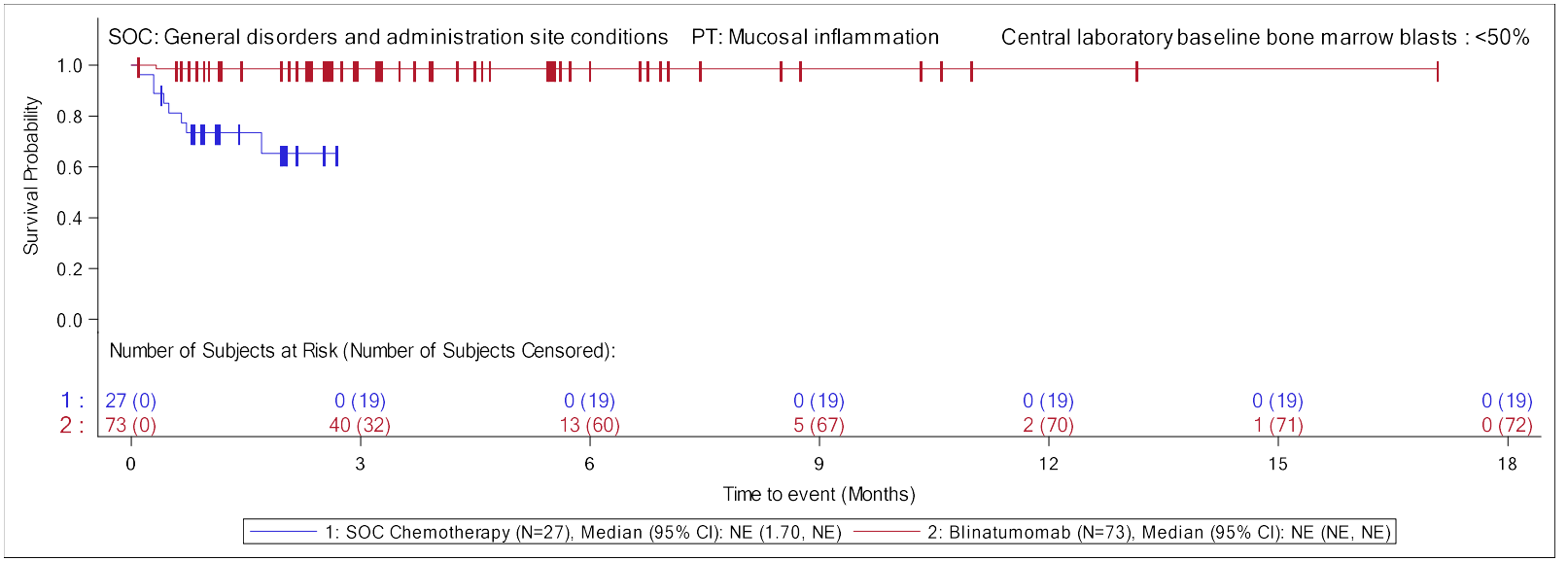

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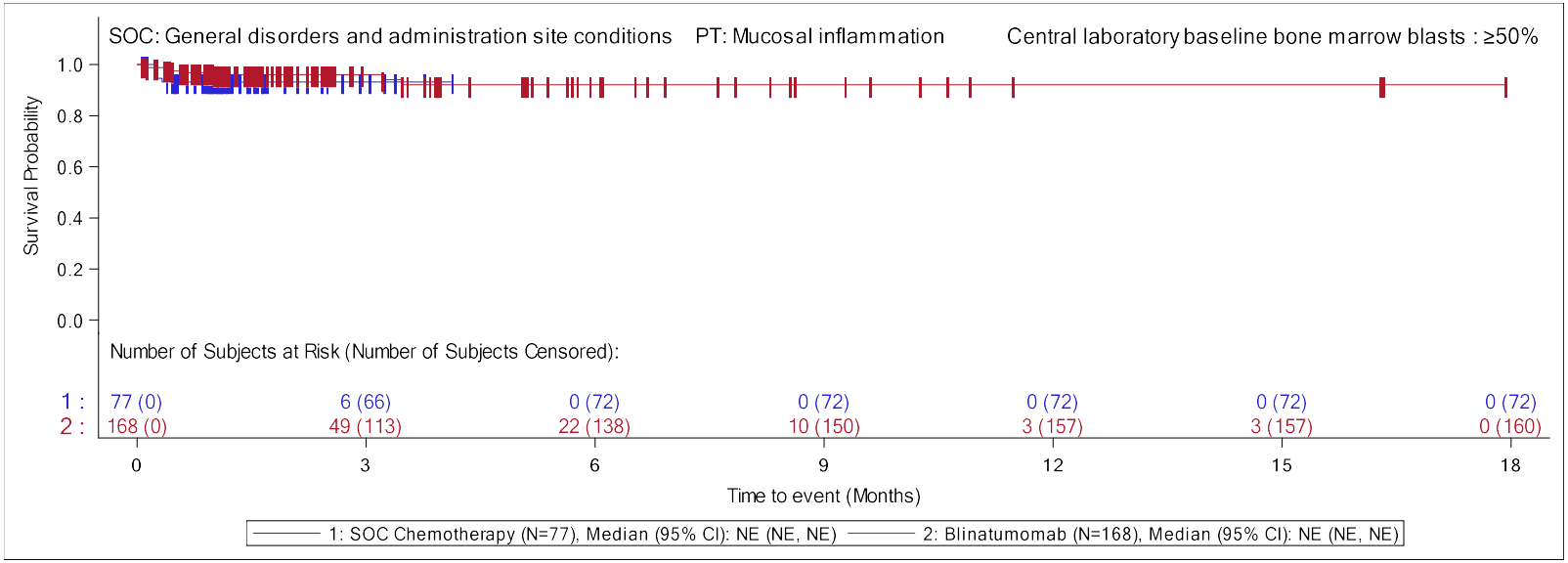

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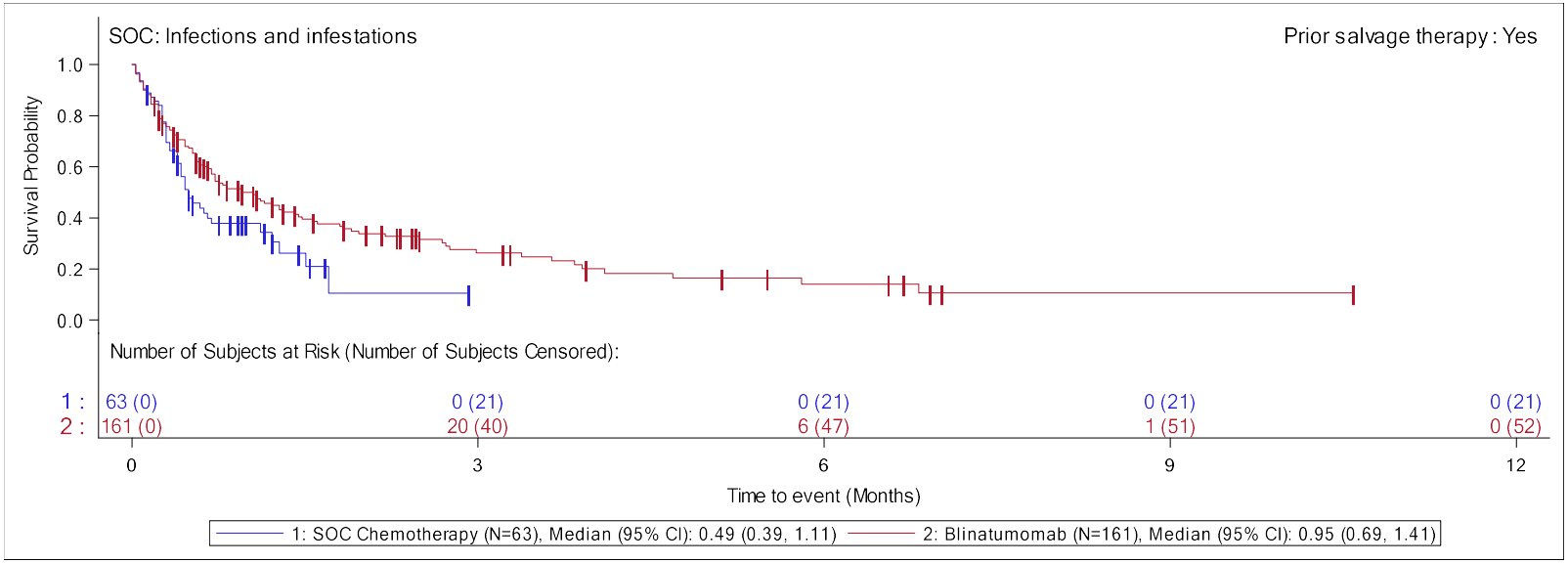

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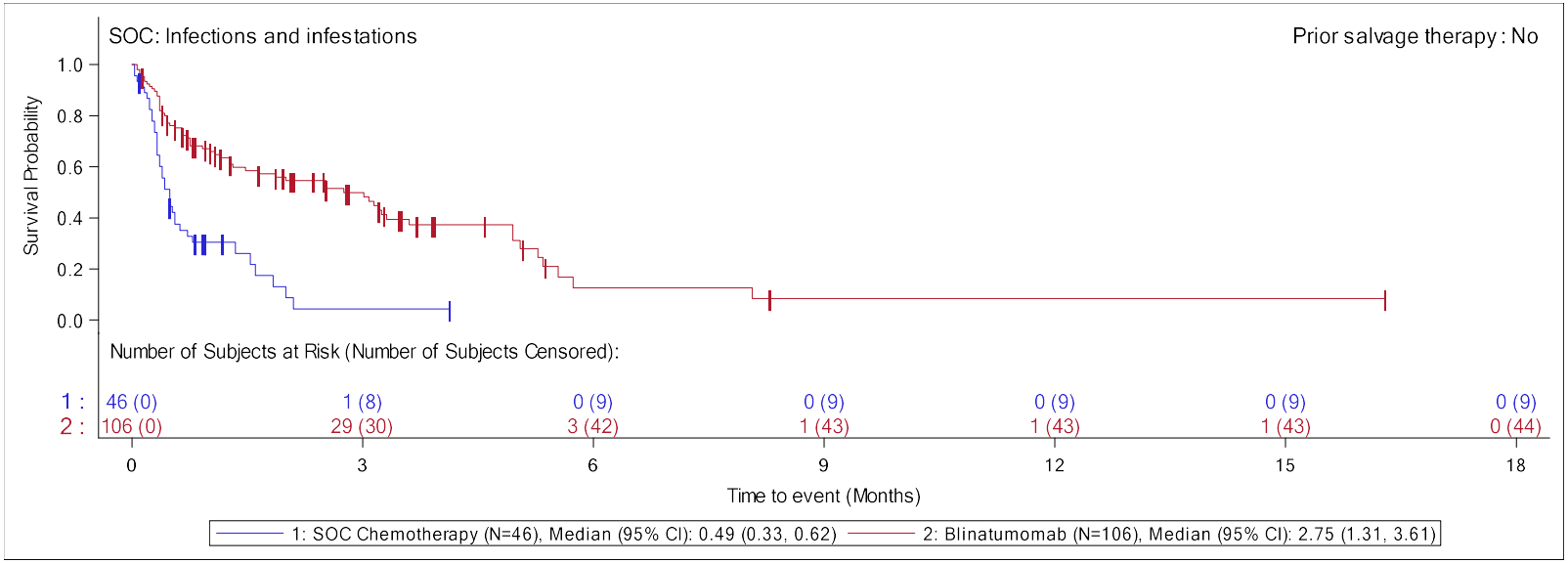

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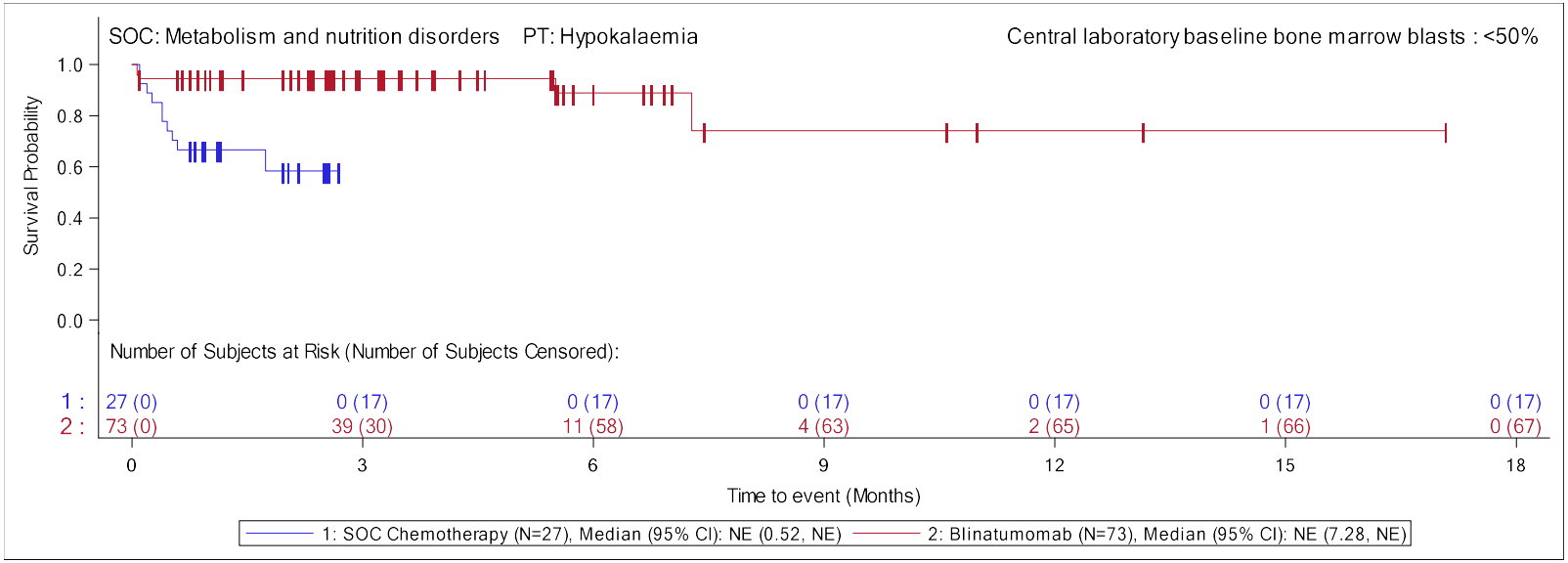

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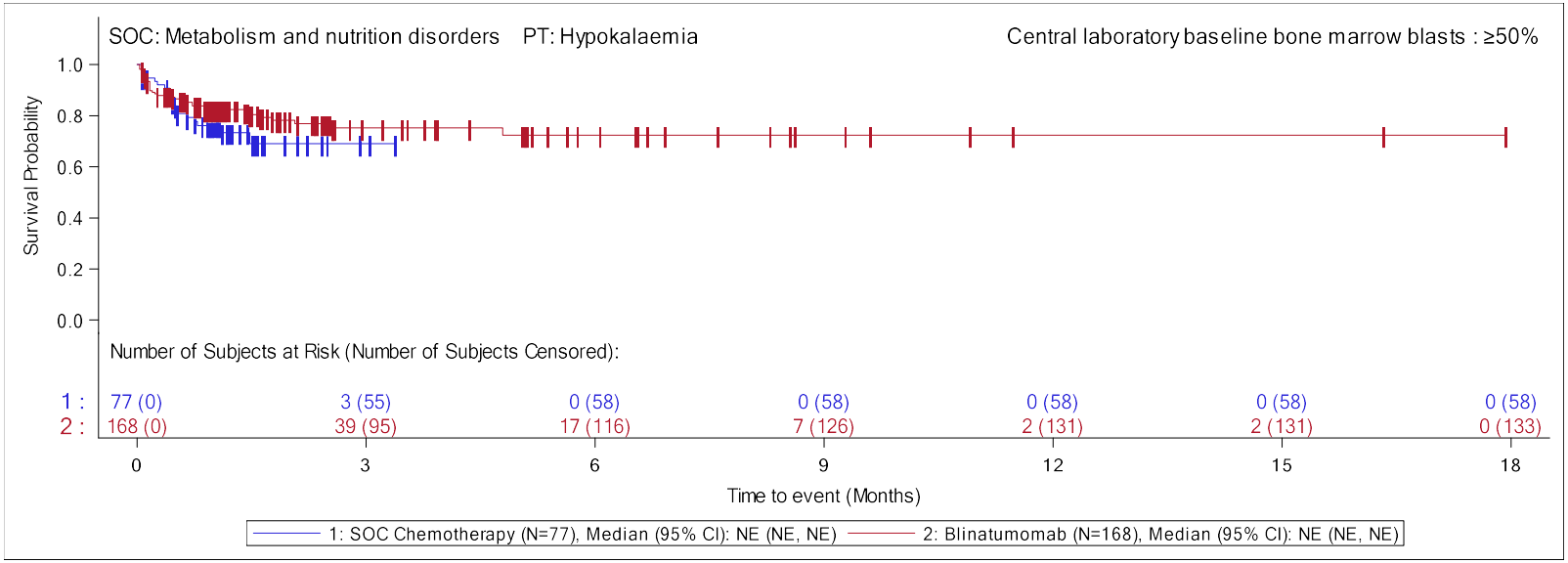

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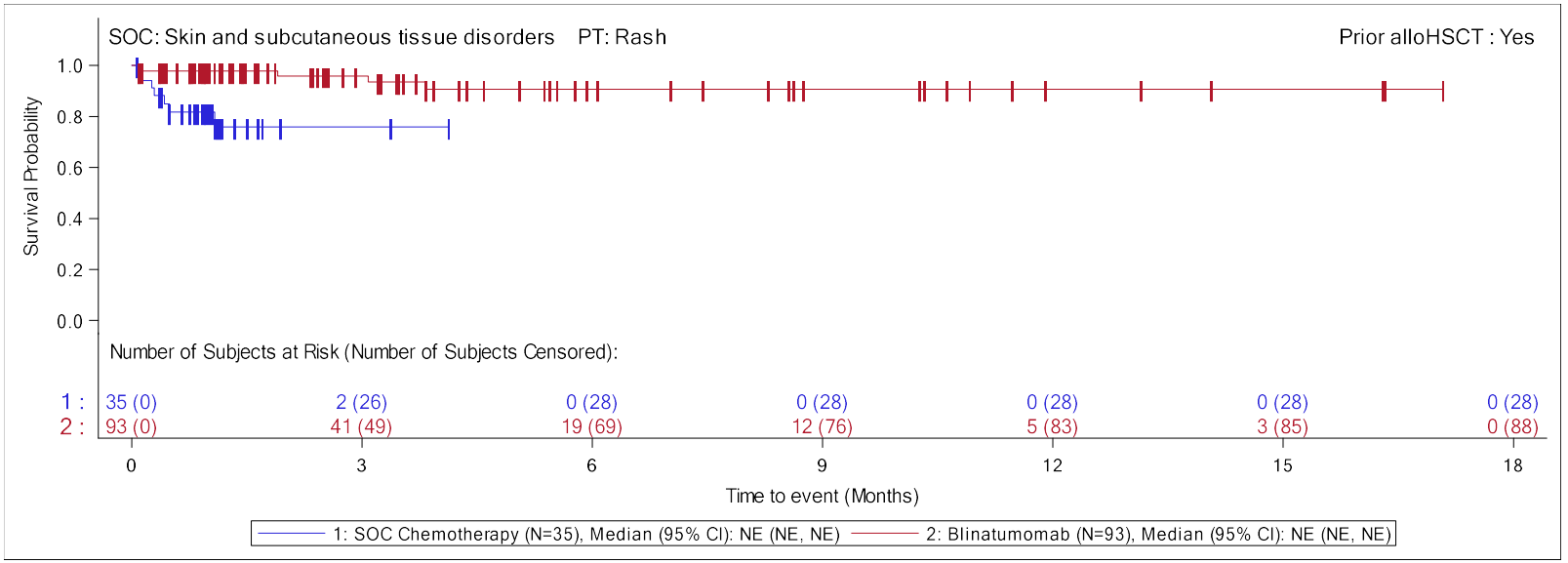

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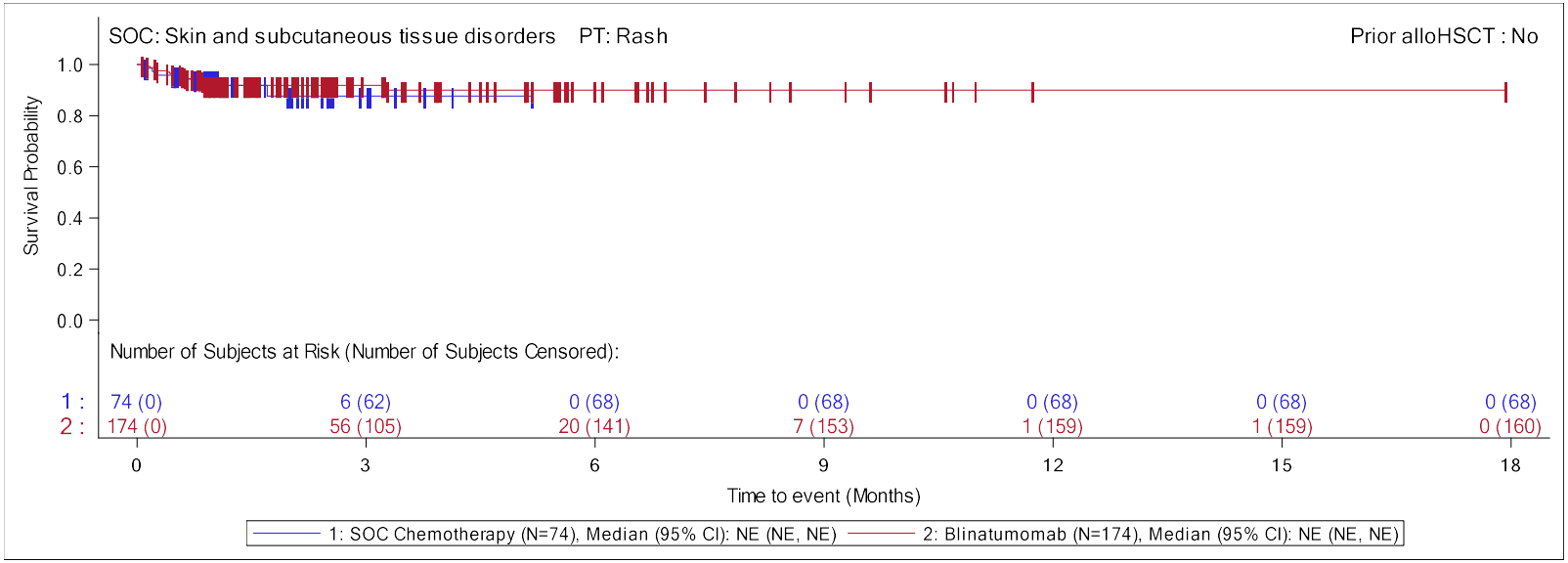

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Anhang 4-G3.7.6: Subgruppenanalysen SUE nach SOC und PT

Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Blood and lymphatic system disorders							
Overall	17/109 (15.6)	NE (2.82, NE)	36/267 (13.5)	NE (NE, NE)	0.55 (0.31, 1.01)	0.0505	
Age group 1							0.7602
<35 years	8/50 (16.0)	NE (2.82, NE)	18/123 (14.6)	NE (NE, NE)	0.64 (0.27, 1.50)	0.2990	
≥35 years	9/59 (15.3)	NE (1.87, NE)	18/144 (12.5)	NE (NE, NE)	0.48 (0.21, 1.11)	0.0801	
Age group 2							0.6435
<35 years	8/50 (16.0)	NE (2.82, NE)	18/124 (14.5)	NE (NE, NE)	0.64 (0.27, 1.49)	0.2977	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	6/77 (7.8)	NE (NE, NE)	0.82 (0.16, 4.06)	0.8099	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	7/33 (21.2)	NE (2.59, NE)	0.97 (0.24, 3.84)	0.9605	
≥65 years	4/12 (33.3)	NE (0.20, NE)	5/33 (15.2)	NE (4.59, NE)	0.07 (0.01, 0.67)	0.0026	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-soc-pt-saf.sas
Output: t14-06-002-012-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_ser_aette_socpref

Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1164
Male	9/64 (14.1)	NE (2.82, NE)	26/159 (16.4)	NE (NE, NE)	0.77 (0.35, 1.67)	0.5036	
Female	8/45 (17.8)	NE (1.77, NE)	10/108 (9.3)	NE (NE, NE)	0.33 (0.12, 0.88)	0.0200	
Region							0.4988
USA	3/13 (23.1)	NE (1.28, NE)	9/30 (30.0)	NE (1.31, NE)	1.08 (0.29, 4.05)	0.9074	
Europe	8/68 (11.8)	NE (2.82, NE)	18/177 (10.2)	NE (NE, NE)	0.52 (0.22, 1.25)	0.1379	
Rest of the world	6/28 (21.4)	1.97 (1.77, NE)	9/60 (15.0)	NE (NE, NE)	0.42 (0.14, 1.27)	0.1159	
Prior salvage therapy							0.0099
Yes	7/63 (11.1)	NE (1.84, NE)	28/161 (17.4)	NE (NE, NE)	1.04 (0.45, 2.43)	0.9199	
No	10/46 (21.7)	2.82 (1.97, NE)	8/106 (7.5)	NE (NE, NE)	0.20 (0.08, 0.55)	0.0005	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1493
0	10/55 (18.2)	NE (2.82, NE)	9/112 (8.0)	NE (NE, NE)	0.25 (0.09, 0.65)	0.0023	
1	3/34 (8.8)	NE (1.77, NE)	14/91 (15.4)	NE (NE, NE)	1.11 (0.31, 3.99)	0.8756	
≥2	4/20 (20.0)	NE (1.84, NE)	13/64 (20.3)	NE (3.87, NE)	0.67 (0.21, 2.11)	0.4918	
Prior alloHSCT							0.0196
Yes	9/35 (25.7)	1.97 (1.28, NE)	10/93 (10.8)	NE (NE, NE)	0.20 (0.08, 0.53)	0.0004	
No	8/74 (10.8)	NE (NE, NE)	26/174 (14.9)	NE (NE, NE)	0.97 (0.43, 2.19)	0.9509	
Race							0.4721
Caucasian	16/90 (17.8)	NE (2.82, NE)	32/226 (14.2)	NE (NE, NE)	0.51 (0.27, 0.95)	0.0307	
Others	1/19 (5.3)	NE (1.84, NE)	4/41 (9.8)	NE (NE, NE)	1.41 (0.16, 12.68)	0.7605	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5602
<50%	4/27 (14.8)	NE (NE, NE)	8/73 (11.0)	NE (NE, NE)	0.46 (0.13, 1.59)	0.2059	
≥50%	13/77 (16.9)	NE (1.97, NE)	27/168 (16.1)	NE (NE, NE)	0.62 (0.31, 1.24)	0.1742	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Febrile neutropenia							
Overall	12/109 (11.0)	NE (2.82, NE)	23/267 (8.6)	NE (NE, NE)	0.50 (0.24, 1.03)	0.0541	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: General disorders and administration site conditions							
Overall	2/109 (1.8)	NE (NE, NE)	27/267 (10.1)	NE (NE, NE)	3.52 (0.83, 15.05)	0.0698	

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Adverse events coded using MedDRA version 18.1.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-ser-teae-soc-pt-saf.sas
Output: t14-06-002-012-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_ser_aette_socpref

Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pyrexia							
Overall	1/109 (0.9)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	4.00 (0.52, 30.82)	0.1499	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1.
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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Immune system disorders							
Overall	0/109 (0.0)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	NE (NE, NE)	0.0567	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Infections and infestations							
Overall	33/109 (30.3)	NE (2.03, NE)	75/267 (28.1)	7.44 (5.80, NE)	0.52 (0.33, 0.80)	0.0023	
Age group 1							0.5382
<35 years	13/50 (26.0)	NE (2.03, NE)	34/123 (27.6)	7.44 (4.59, NE)	0.57 (0.29, 1.12)	0.0972	
≥35 years	20/59 (33.9)	NE (1.57, NE)	41/144 (28.5)	7.25 (5.54, NE)	0.49 (0.28, 0.86)	0.0123	
Age group 2							0.5730
<35 years	13/50 (26.0)	NE (2.03, NE)	34/124 (27.4)	7.44 (4.59, NE)	0.57 (0.29, 1.12)	0.0963	
35 - 54 years	9/25 (36.0)	1.87 (0.66, NE)	19/77 (24.7)	NE (5.05, NE)	0.31 (0.13, 0.72)	0.0046	
55 - 64 years	7/22 (31.8)	NE (0.62, NE)	11/33 (33.3)	8.07 (1.84, NE)	0.61 (0.22, 1.69)	0.3403	
≥65 years	4/12 (33.3)	NE (0.75, NE)	11/33 (33.3)	6.10 (4.79, NE)	0.80 (0.24, 2.68)	0.7208	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1949
Male	19/64 (29.7)	NE (2.03, NE)	50/159 (31.4)	6.10 (5.54, 9.97)	0.62 (0.35, 1.07)	0.0830	
Female	14/45 (31.1)	NE (1.87, NE)	25/108 (23.1)	NE (5.80, NE)	0.39 (0.19, 0.80)	0.0076	
Region							0.2846
USA	2/13 (15.4)	NE (1.21, NE)	7/30 (23.3)	5.74 (2.46, NE)	1.10 (0.22, 5.52)	0.9097	
Europe	18/68 (26.5)	NE (2.03, NE)	45/177 (25.4)	8.07 (6.10, NE)	0.54 (0.30, 0.96)	0.0334	
Rest of the world	13/28 (46.4)	1.11 (0.39, NE)	23/60 (38.3)	4.79 (2.56, NE)	0.36 (0.17, 0.77)	0.0059	
Prior salvage therapy							0.2200
Yes	17/63 (27.0)	NE (1.57, NE)	46/161 (28.6)	7.44 (4.79, NE)	0.68 (0.38, 1.21)	0.1856	
No	16/46 (34.8)	NE (1.87, NE)	29/106 (27.4)	8.07 (5.74, NE)	0.34 (0.17, 0.67)	0.0013	

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Data cut-off date: 04JAN2016

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Output: t14-06-002-012-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_ser_aette_socpref

Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3410
0	16/55 (29.1)	NE (2.03, NE)	30/112 (26.8)	8.07 (6.10, NE)	0.45 (0.23, 0.89)	0.0179	
1	13/34 (38.2)	1.57 (0.98, NE)	25/91 (27.5)	5.80 (4.59, NE)	0.37 (0.18, 0.75)	0.0044	
≥2	4/20 (20.0)	NE (1.21, NE)	20/64 (31.3)	6.07 (4.03, NE)	1.06 (0.35, 3.16)	0.9257	
Prior alloHSCT							0.1940
Yes	14/35 (40.0)	NE (0.56, NE)	31/93 (33.3)	7.25 (5.05, NE)	0.36 (0.18, 0.71)	0.0022	
No	19/74 (25.7)	NE (2.03, NE)	44/174 (25.3)	7.44 (5.74, NE)	0.62 (0.36, 1.10)	0.0985	
Race							0.4219
Caucasian	28/90 (31.1)	NE (1.87, NE)	62/226 (27.4)	7.57 (6.07, NE)	0.49 (0.31, 0.79)	0.0030	
Others	5/19 (26.3)	NE (0.89, NE)	13/41 (31.7)	4.79 (2.56, NE)	0.66 (0.22, 1.96)	0.4469	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3164
<50%	10/27 (37.0)	2.10 (1.57, NE)	19/73 (26.0)	7.25 (5.54, NE)	0.21 (0.08, 0.54)	0.0004	
≥50%	22/77 (28.6)	NE (2.03, NE)	46/168 (27.4)	7.44 (5.54, NE)	0.57 (0.33, 0.97)	0.0368	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sepsis							
Overall	7/109 (6.4)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.44 (0.17, 1.16)	0.0883	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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Data cut-off date: 04JAN2016

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pneumonia							
Overall	2/109 (1.8)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	1.22 (0.25, 5.96)	0.8009	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Injury, poisoning and procedural complications							
Overall	1/109 (0.9)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	5.69 (0.75, 43.23)	0.0573	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Metabolism and nutrition disorders							
Overall	2/109 (1.8)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	1.82 (0.40, 8.36)	0.4330	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1.
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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Nervous system disorders							
Overall	4/109 (3.7)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	1.41 (0.47, 4.20)	0.5395	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Respiratory, thoracic and mediastinal disorders							
Overall	4/109 (3.7)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	1.19 (0.39, 3.64)	0.7602	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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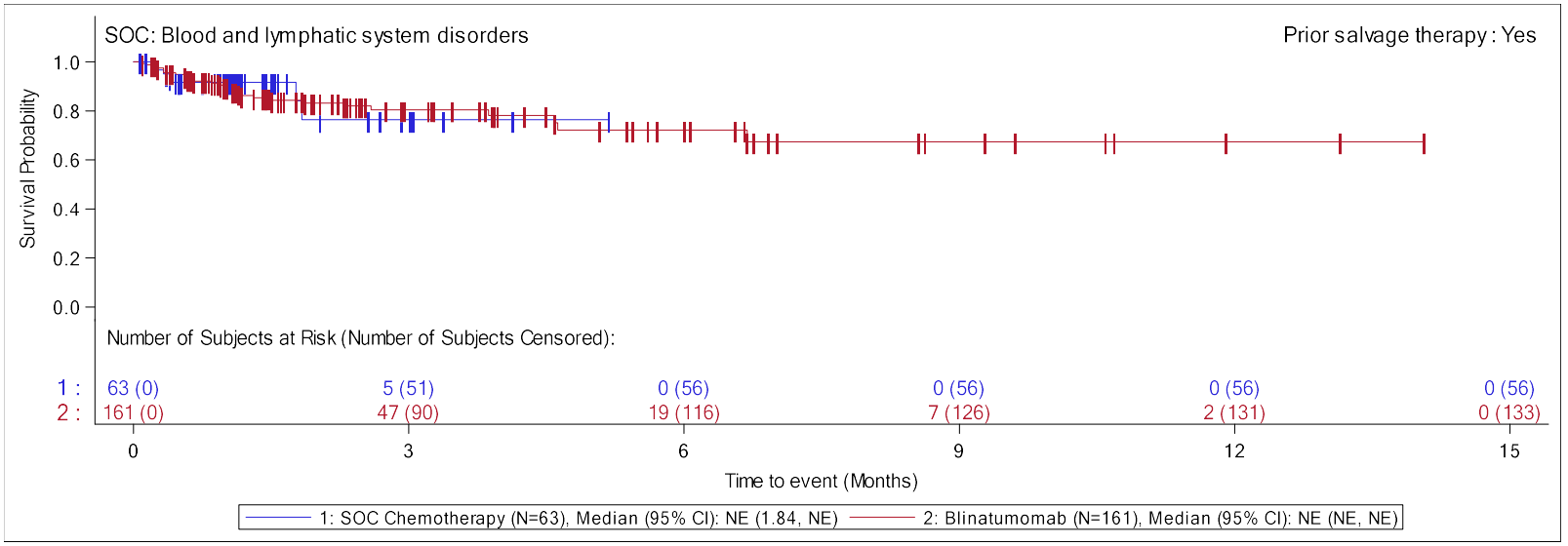
Output: t14-06-002-012-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_ser_aette_socpref

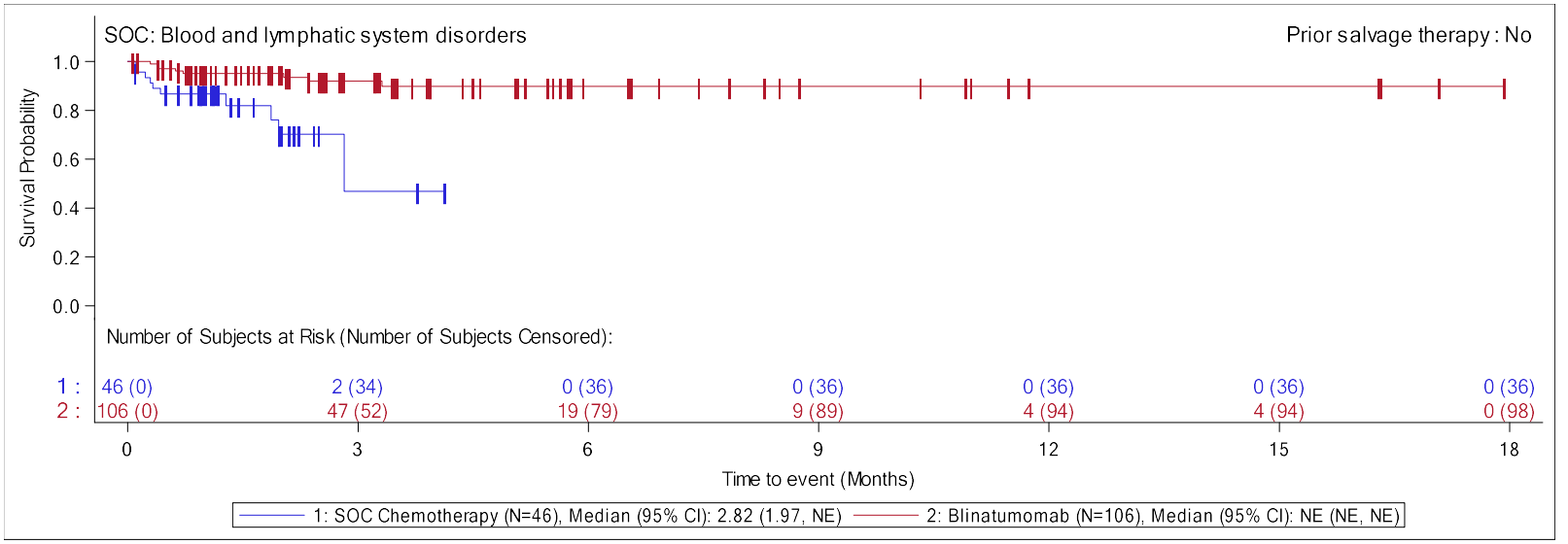
Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-soc-pt-saf.sas
Output: f14-06-002-012-km-sub-ser-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, outtab.t_ser_aette_socpref

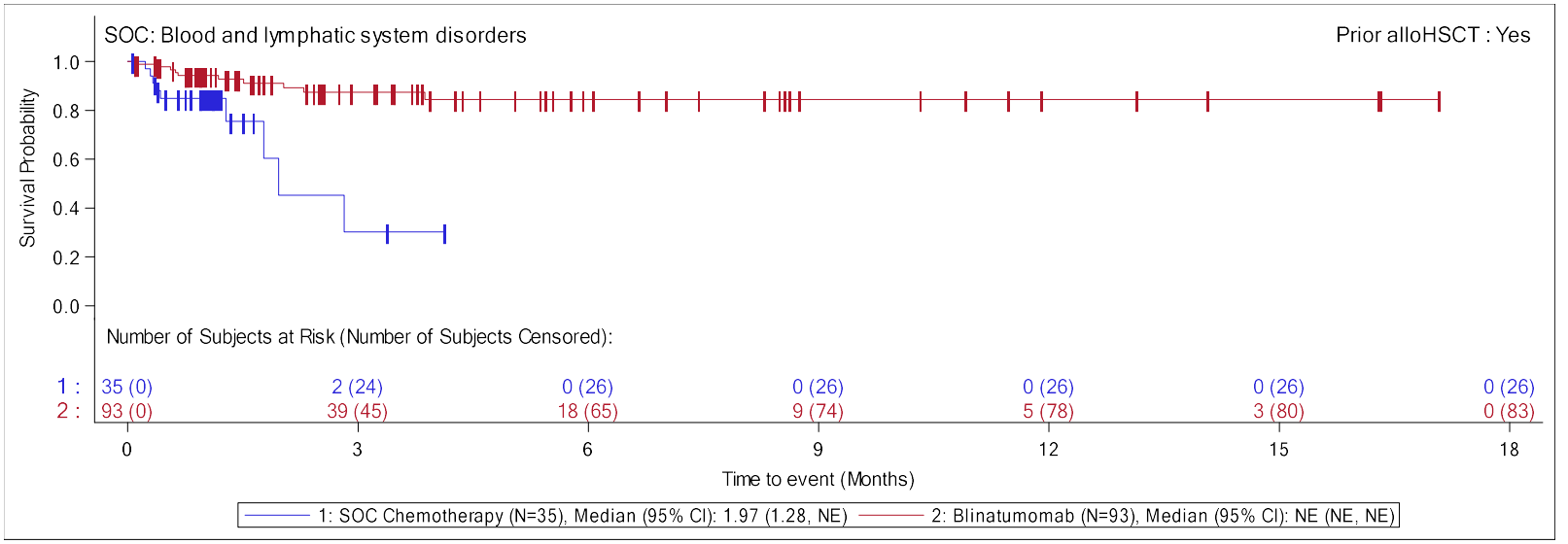
Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-soc-pt-saf.sas
Output: f14-06-002-012-km-sub-ser-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, outtab.t_ser_aette_socpref

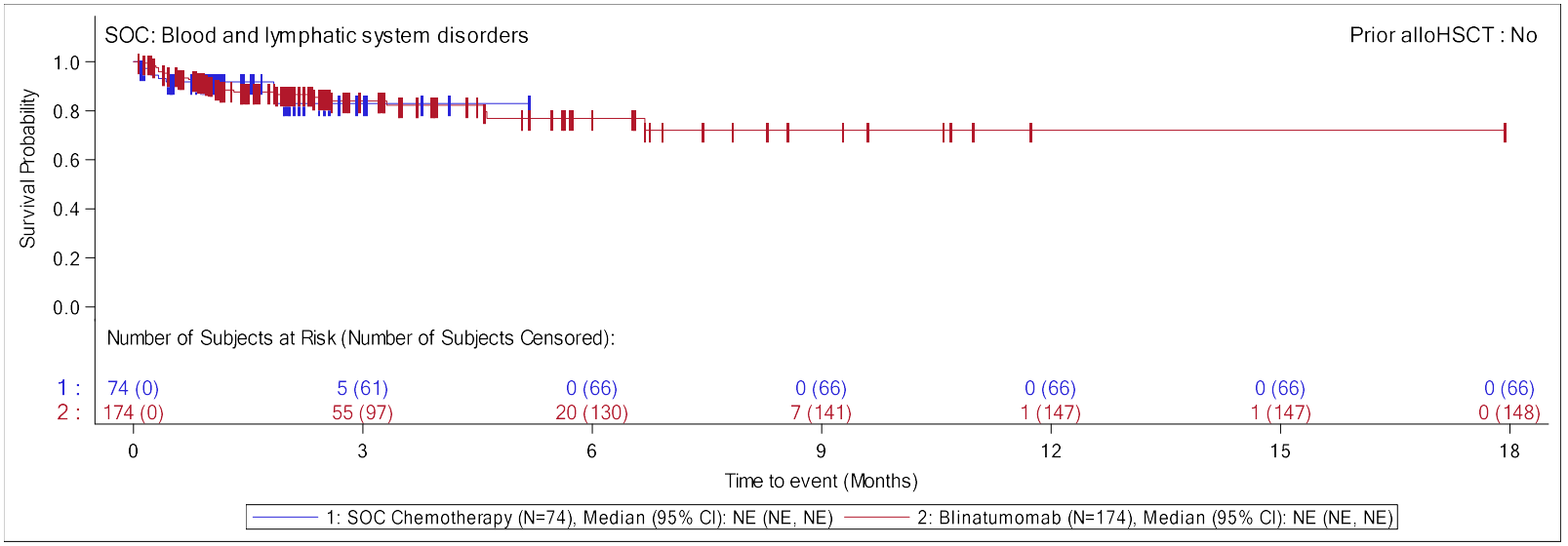
Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-soc-pt-saf.sas
Output: f14-06-002-012-km-sub-ser-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, outtab.t_ser_aette_socpref

Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 18.1.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/figures/f-km-sub-ser-teae-soc-pt-saf.sas
Output: f14-06-002-012-km-sub-ser-teae-soc-pt-saf.rtf (Date Generated: 19OCT25 22:32) Source Data: adam_pa.adsl, adam_pa.adbase, outtab.t_ser_aette_socpref

Anhang 4-G3.7.7: Subgruppenanalysen schwerer UE nach SOC und PT

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Blood and lymphatic system disorders							
Overall	75/109 (68.8)	0.30 (0.26, 0.36)	154/267 (57.7)	1.31 (0.75, 2.20)	0.59 (0.45, 0.78)	0.0002	
Age group 1							0.3316
<35 years	28/50 (56.0)	0.39 (0.26, NE)	67/123 (54.5)	2.03 (0.92, 3.57)	0.68 (0.43, 1.06)	0.0854	
≥35 years	47/59 (79.7)	0.26 (0.20, 0.33)	87/144 (60.4)	0.75 (0.46, 2.20)	0.54 (0.37, 0.78)	0.0007	
Age group 2							0.7600
<35 years	28/50 (56.0)	0.39 (0.26, NE)	67/124 (54.0)	2.03 (0.92, 3.57)	0.67 (0.43, 1.05)	0.0825	
35 - 54 years	21/25 (84.0)	0.26 (0.16, 0.33)	47/77 (61.0)	0.72 (0.39, 2.36)	0.50 (0.29, 0.85)	0.0088	
55 - 64 years	19/22 (86.4)	0.26 (0.16, 0.43)	23/33 (69.7)	0.46 (0.10, 1.44)	0.62 (0.33, 1.16)	0.1276	
≥65 years	7/12 (58.3)	0.30 (0.03, NE)	17/33 (51.5)	4.62 (0.33, 4.95)	0.50 (0.19, 1.29)	0.1400	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2958
Male	39/64 (60.9)	0.33 (0.26, 0.59)	92/159 (57.9)	1.54 (0.72, 2.52)	0.66 (0.45, 0.96)	0.0295	
Female	36/45 (80.0)	0.26 (0.23, 0.33)	62/108 (57.4)	0.92 (0.46, 2.59)	0.52 (0.34, 0.80)	0.0022	
Region							0.2790
USA	8/13 (61.5)	0.39 (0.16, NE)	21/30 (70.0)	0.52 (0.33, 1.15)	0.94 (0.41, 2.14)	0.8776	
Europe	46/68 (67.6)	0.26 (0.23, 0.43)	99/177 (55.9)	1.64 (0.62, 3.57)	0.62 (0.43, 0.88)	0.0070	
Rest of the world	21/28 (75.0)	0.26 (0.16, 0.43)	34/60 (56.7)	2.10 (0.59, 3.87)	0.38 (0.22, 0.69)	0.0009	
Prior salvage therapy							0.0564
Yes	39/63 (61.9)	0.36 (0.26, 1.05)	96/161 (59.6)	1.18 (0.59, 2.10)	0.71 (0.48, 1.03)	0.0678	
No	36/46 (78.3)	0.26 (0.20, 0.26)	58/106 (54.7)	1.54 (0.46, 6.85)	0.47 (0.31, 0.73)	0.0005	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5121
0	39/55 (70.9)	0.26 (0.23, 0.33)	62/112 (55.4)	2.03 (0.59, 4.95)	0.54 (0.36, 0.82)	0.0030	
1	23/34 (67.6)	0.34 (0.20, 0.59)	52/91 (57.1)	1.64 (0.72, 3.11)	0.54 (0.32, 0.90)	0.0153	
≥2	13/20 (65.0)	0.39 (0.20, 1.93)	40/64 (62.5)	0.59 (0.33, 2.07)	0.78 (0.41, 1.46)	0.4101	
Prior alloHSCT							0.8542
Yes	26/35 (74.3)	0.30 (0.23, 0.49)	55/93 (59.1)	1.44 (0.39, 2.59)	0.58 (0.36, 0.95)	0.0237	
No	49/74 (66.2)	0.30 (0.23, 0.43)	99/174 (56.9)	1.15 (0.62, 3.02)	0.60 (0.42, 0.85)	0.0036	
Race							0.9221
Caucasian	63/90 (70.0)	0.26 (0.23, 0.36)	132/226 (58.4)	1.44 (0.62, 2.36)	0.59 (0.44, 0.81)	0.0007	
Others	12/19 (63.2)	0.43 (0.26, NE)	22/41 (53.7)	1.08 (0.46, NE)	0.58 (0.28, 1.18)	0.1350	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1944
<50%	19/27 (70.4)	0.26 (0.13, 1.93)	39/73 (53.4)	2.59 (1.15, 6.85)	0.41 (0.23, 0.74)	0.0023	
≥50%	53/77 (68.8)	0.30 (0.26, 0.43)	98/168 (58.3)	0.75 (0.46, 1.74)	0.66 (0.47, 0.93)	0.0140	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Febrile neutropenia							
Overall	38/109 (34.9)	NE (1.77, NE)	57/267 (21.3)	NE (NE, NE)	0.48 (0.32, 0.73)	0.0004	
Age group 1							0.9800
<35 years	17/50 (34.0)	2.82 (1.77, NE)	26/123 (21.1)	NE (6.69, NE)	0.45 (0.24, 0.84)	0.0098	
≥35 years	21/59 (35.6)	NE (0.59, NE)	31/144 (21.5)	NE (NE, NE)	0.52 (0.30, 0.91)	0.0208	
Age group 2							0.8719
<35 years	17/50 (34.0)	2.82 (1.77, NE)	26/124 (21.0)	NE (6.69, NE)	0.45 (0.24, 0.83)	0.0097	
35 - 54 years	10/25 (40.0)	NE (0.33, NE)	16/77 (20.8)	NE (NE, NE)	0.46 (0.21, 1.02)	0.0520	
55 - 64 years	8/22 (36.4)	NE (0.43, NE)	9/33 (27.3)	NE (NE, NE)	0.66 (0.25, 1.72)	0.3903	
≥65 years	3/12 (25.0)	NE (0.33, NE)	6/33 (18.2)	NE (4.59, NE)	0.49 (0.11, 2.18)	0.3395	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6759
Male	24/64 (37.5)	2.82 (0.59, NE)	39/159 (24.5)	NE (6.69, NE)	0.48 (0.29, 0.81)	0.0048	
Female	14/45 (31.1)	NE (1.77, NE)	18/108 (16.7)	NE (NE, NE)	0.48 (0.24, 0.97)	0.0386	
Region							0.7684
USA	6/13 (46.2)	NE (0.33, NE)	12/30 (40.0)	NE (0.72, NE)	0.61 (0.23, 1.64)	0.3320	
Europe	18/68 (26.5)	NE (2.82, NE)	28/177 (15.8)	NE (NE, NE)	0.49 (0.27, 0.89)	0.0162	
Rest of the world	14/28 (50.0)	0.59 (0.36, NE)	17/60 (28.3)	NE (3.87, NE)	0.41 (0.20, 0.86)	0.0150	
Prior salvage therapy							0.0285
Yes	20/63 (31.7)	NE (1.77, NE)	42/161 (26.1)	NE (6.69, NE)	0.67 (0.39, 1.15)	0.1394	
No	18/46 (39.1)	2.82 (0.46, NE)	15/106 (14.2)	NE (NE, NE)	0.27 (0.14, 0.55)	<0.0001	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4083
0	18/55 (32.7)	NE (2.82, NE)	17/112 (15.2)	NE (NE, NE)	0.35 (0.18, 0.69)	0.0017	
1	12/34 (35.3)	1.77 (0.59, NE)	26/91 (28.6)	NE (4.59, NE)	0.63 (0.32, 1.27)	0.1935	
≥2	8/20 (40.0)	NE (0.39, NE)	14/64 (21.9)	NE (NE, NE)	0.44 (0.18, 1.06)	0.0592	
Prior alloHSCT							0.1363
Yes	14/35 (40.0)	1.77 (0.56, NE)	15/93 (16.1)	NE (NE, NE)	0.28 (0.13, 0.59)	0.0004	
No	24/74 (32.4)	NE (NE, NE)	42/174 (24.1)	NE (NE, NE)	0.61 (0.37, 1.01)	0.0539	
Race							0.2353
Caucasian	28/90 (31.1)	NE (2.82, NE)	47/226 (20.8)	NE (NE, NE)	0.54 (0.33, 0.87)	0.0095	
Others	10/19 (52.6)	0.56 (0.30, NE)	10/41 (24.4)	NE (NE, NE)	0.30 (0.12, 0.73)	0.0051	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1656
<50%	9/27 (33.3)	NE (0.46, NE)	10/73 (13.7)	NE (NE, NE)	0.30 (0.12, 0.77)	0.0079	
≥50%	29/77 (37.7)	2.82 (1.77, NE)	44/168 (26.2)	NE (6.69, NE)	0.57 (0.35, 0.91)	0.0182	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Anaemia							
Overall	38/109 (34.9)	NE (1.93, NE)	53/267 (19.9)	NE (11.90, NE)	0.49 (0.32, 0.75)	0.0008	
Age group 1							0.2328
<35 years	18/50 (36.0)	NE (0.66, NE)	20/123 (16.3)	11.90 (11.90, NE)	0.35 (0.18, 0.67)	0.0010	
≥35 years	20/59 (33.9)	NE (1.15, NE)	33/144 (22.9)	NE (NE, NE)	0.64 (0.37, 1.12)	0.1105	
Age group 2							0.7392
<35 years	18/50 (36.0)	NE (0.66, NE)	20/124 (16.1)	11.90 (11.90, NE)	0.35 (0.18, 0.67)	0.0009	
35 - 54 years	9/25 (36.0)	NE (0.95, NE)	20/77 (26.0)	NE (NE, NE)	0.67 (0.30, 1.46)	0.3053	
55 - 64 years	7/22 (31.8)	NE (0.49, NE)	6/33 (18.2)	NE (NE, NE)	0.59 (0.20, 1.77)	0.3344	
≥65 years	4/12 (33.3)	NE (0.10, NE)	7/33 (21.2)	NE (NE, NE)	0.57 (0.17, 1.96)	0.3701	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4795
Male	20/64 (31.3)	NE (1.15, NE)	26/159 (16.4)	NE (11.90, NE)	0.42 (0.24, 0.77)	0.0034	
Female	18/45 (40.0)	1.93 (0.59, NE)	27/108 (25.0)	NE (NE, NE)	0.60 (0.33, 1.09)	0.0845	
Region							0.0575
USA	6/13 (46.2)	NE (0.26, NE)	6/30 (20.0)	NE (NE, NE)	0.41 (0.13, 1.29)	0.1147	
Europe	19/68 (27.9)	NE (NE, NE)	39/177 (22.0)	NE (11.90, NE)	0.73 (0.42, 1.26)	0.2512	
Rest of the world	13/28 (46.4)	1.08 (0.36, NE)	8/60 (13.3)	NE (NE, NE)	0.21 (0.09, 0.51)	0.0002	
Prior salvage therapy							0.9046
Yes	19/63 (30.2)	NE (1.15, NE)	28/161 (17.4)	11.90 (11.90, NE)	0.49 (0.27, 0.88)	0.0153	
No	19/46 (41.3)	NE (0.43, NE)	25/106 (23.6)	NE (NE, NE)	0.51 (0.28, 0.93)	0.0250	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9541
0	21/55 (38.2)	NE (0.52, NE)	27/112 (24.1)	NE (NE, NE)	0.56 (0.32, 0.99)	0.0438	
1	11/34 (32.4)	NE (1.08, NE)	16/91 (17.6)	NE (NE, NE)	0.51 (0.23, 1.09)	0.0765	
≥2	6/20 (30.0)	1.93 (0.59, NE)	10/64 (15.6)	11.90 (NE, NE)	0.39 (0.14, 1.10)	0.0652	
Prior alloHSCT							0.5168
Yes	16/35 (45.7)	1.15 (0.46, NE)	21/93 (22.6)	NE (11.90, NE)	0.40 (0.20, 0.77)	0.0046	
No	22/74 (29.7)	NE (1.93, NE)	32/174 (18.4)	NE (NE, NE)	0.56 (0.32, 0.96)	0.0330	
Race							0.7083
Caucasian	33/90 (36.7)	NE (1.93, NE)	48/226 (21.2)	NE (11.90, NE)	0.51 (0.32, 0.79)	0.0023	
Others	5/19 (26.3)	NE (1.15, NE)	5/41 (12.2)	NE (NE, NE)	0.40 (0.11, 1.40)	0.1414	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4398
<50%	12/27 (44.4)	1.93 (0.39, NE)	14/73 (19.2)	NE (NE, NE)	0.37 (0.17, 0.80)	0.0088	
≥50%	24/77 (31.2)	NE (NE, NE)	31/168 (18.5)	NE (NE, NE)	0.54 (0.31, 0.92)	0.0200	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutropenia							
Overall	29/109 (26.6)	NE (NE, NE)	47/267 (17.6)	NE (NE, NE)	0.41 (0.25, 0.66)	0.0002	
Age group 1							0.7360
<35 years	12/50 (24.0)	NE (2.30, NE)	21/123 (17.1)	NE (NE, NE)	0.45 (0.22, 0.95)	0.0314	
≥35 years	17/59 (28.8)	NE (NE, NE)	26/144 (18.1)	NE (6.69, NE)	0.38 (0.19, 0.72)	0.0026	
Age group 2							0.7601
<35 years	12/50 (24.0)	NE (2.30, NE)	21/124 (16.9)	NE (NE, NE)	0.45 (0.22, 0.94)	0.0309	
35 - 54 years	7/25 (28.0)	NE (NE, NE)	16/77 (20.8)	NE (6.69, NE)	0.46 (0.18, 1.15)	0.0899	
55 - 64 years	8/22 (36.4)	NE (0.26, NE)	5/33 (15.2)	NE (NE, NE)	0.32 (0.10, 1.00)	0.0404	
≥65 years	2/12 (16.7)	NE (0.36, NE)	5/33 (15.2)	8.26 (4.75, NE)	0.19 (0.02, 2.08)	0.1267	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0703
Male	12/64 (18.8)	NE (NE, NE)	27/159 (17.0)	NE (8.26, NE)	0.57 (0.28, 1.16)	0.1173	
Female	17/45 (37.8)	NE (0.36, NE)	20/108 (18.5)	NE (NE, NE)	0.30 (0.15, 0.60)	0.0003	
Region							0.2397
USA	1/13 (7.7)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)	1.80 (0.20, 16.11)	0.5889	
Europe	18/68 (26.5)	NE (2.30, NE)	33/177 (18.6)	NE (8.26, NE)	0.45 (0.25, 0.83)	0.0086	
Rest of the world	10/28 (35.7)	NE (0.30, NE)	10/60 (16.7)	NE (4.95, NE)	0.18 (0.07, 0.51)	0.0003	
Prior salvage therapy							0.9942
Yes	13/63 (20.6)	NE (NE, NE)	21/161 (13.0)	NE (NE, NE)	0.36 (0.17, 0.74)	0.0039	
No	16/46 (34.8)	NE (2.30, NE)	26/106 (24.5)	NE (6.69, NE)	0.47 (0.24, 0.90)	0.0207	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7901
0	17/55 (30.9)	NE (2.30, NE)	25/112 (22.3)	NE (8.26, NE)	0.45 (0.23, 0.86)	0.0145	
1	8/34 (23.5)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)	0.30 (0.11, 0.80)	0.0113	
≥2	4/20 (20.0)	NE (NE, NE)	10/64 (15.6)	NE (3.61, NE)	0.52 (0.16, 1.70)	0.2668	
Prior alloHSCT							0.0777
Yes	15/35 (42.9)	NE (0.26, NE)	19/93 (20.4)	NE (4.52, NE)	0.23 (0.11, 0.49)	<0.0001	
No	14/74 (18.9)	NE (NE, NE)	28/174 (16.1)	NE (8.26, NE)	0.58 (0.30, 1.14)	0.1117	
Race							0.4446
Caucasian	27/90 (30.0)	NE (2.30, NE)	42/226 (18.6)	NE (8.26, NE)	0.36 (0.22, 0.61)	<0.0001	
Others	2/19 (10.5)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	1.07 (0.21, 5.52)	0.9349	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5478
<50%	6/27 (22.2)	NE (NE, NE)	16/73 (21.9)	NE (6.69, NE)	0.49 (0.18, 1.34)	0.1561	
≥50%	21/77 (27.3)	NE (2.30, NE)	28/168 (16.7)	NE (8.26, NE)	0.43 (0.24, 0.77)	0.0037	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Thrombocytopenia							
Overall	30/109 (27.5)	NE (NE, NE)	39/267 (14.6)	NE (NE, NE)	0.46 (0.29, 0.75)	0.0014	
Age group 1							0.4719
<35 years	14/50 (28.0)	NE (2.03, NE)	16/123 (13.0)	NE (NE, NE)	0.36 (0.17, 0.74)	0.0042	
≥35 years	16/59 (27.1)	NE (NE, NE)	23/144 (16.0)	NE (NE, NE)	0.58 (0.31, 1.10)	0.0921	
Age group 2							0.7913
<35 years	14/50 (28.0)	NE (2.03, NE)	16/124 (12.9)	NE (NE, NE)	0.36 (0.17, 0.74)	0.0040	
35 - 54 years	6/25 (24.0)	NE (NE, NE)	14/77 (18.2)	NE (NE, NE)	0.75 (0.29, 1.94)	0.5465	
55 - 64 years	7/22 (31.8)	NE (0.36, NE)	5/33 (15.2)	NE (NE, NE)	0.46 (0.14, 1.44)	0.1728	
≥65 years	3/12 (25.0)	NE (0.16, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.11, 2.16)	0.3270	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8720
Male	16/64 (25.0)	NE (NE, NE)	21/159 (13.2)	NE (NE, NE)	0.45 (0.23, 0.87)	0.0143	
Female	14/45 (31.1)	NE (2.03, NE)	18/108 (16.7)	NE (NE, NE)	0.49 (0.24, 1.00)	0.0450	
Region							0.3090
USA	1/13 (7.7)	NE (2.03, NE)	4/30 (13.3)	NE (NE, NE)	1.61 (0.18, 14.53)	0.6709	
Europe	24/68 (35.3)	NE (NE, NE)	32/177 (18.1)	NE (NE, NE)	0.44 (0.26, 0.75)	0.0021	
Rest of the world	5/28 (17.9)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.26 (0.06, 1.09)	0.0481	
Prior salvage therapy							0.9353
Yes	14/63 (22.2)	NE (NE, NE)	19/161 (11.8)	NE (NE, NE)	0.48 (0.24, 0.97)	0.0361	
No	16/46 (34.8)	NE (2.03, NE)	20/106 (18.9)	NE (NE, NE)	0.46 (0.24, 0.90)	0.0203	

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Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6364
0	19/55 (34.5)	NE (2.03, NE)	20/112 (17.9)	NE (NE, NE)	0.43 (0.23, 0.81)	0.0074	
1	8/34 (23.5)	NE (NE, NE)	10/91 (11.0)	NE (NE, NE)	0.41 (0.16, 1.07)	0.0575	
≥2	3/20 (15.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)	0.89 (0.24, 3.28)	0.8519	
Prior alloHSCT							0.7388
Yes	10/35 (28.6)	NE (NE, NE)	16/93 (17.2)	NE (NE, NE)	0.52 (0.23, 1.16)	0.1007	
No	20/74 (27.0)	NE (NE, NE)	23/174 (13.2)	NE (NE, NE)	0.44 (0.24, 0.80)	0.0059	
Race							0.5968
Caucasian	29/90 (32.2)	NE (2.03, NE)	37/226 (16.4)	NE (NE, NE)	0.44 (0.27, 0.72)	0.0008	
Others	1/19 (5.3)	NE (NE, NE)	2/41 (4.9)	NE (NE, NE)	0.91 (0.08, 10.00)	0.9365	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0306
<50%	14/27 (51.9)	0.39 (0.26, NE)	10/73 (13.7)	NE (6.85, NE)	0.19 (0.08, 0.44)	<0.0001	
≥50%	15/77 (19.5)	NE (NE, NE)	24/168 (14.3)	NE (NE, NE)	0.71 (0.37, 1.35)	0.2859	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Cardiac disorders							
Overall	4/109 (3.7)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	0.90 (0.28, 2.87)	0.8542	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Gastrointestinal disorders							
Overall	15/109 (13.8)	NE (NE, NE)	19/267 (7.1)	NE (11.80, NE)	0.28 (0.13, 0.59)	0.0004	
Age group 1							0.3764
<35 years	10/50 (20.0)	NE (1.87, NE)	10/123 (8.1)	11.80 (9.64, NE)	0.20 (0.07, 0.52)	0.0003	
≥35 years	5/59 (8.5)	NE (NE, NE)	9/144 (6.3)	NE (NE, NE)	0.47 (0.15, 1.52)	0.1983	
Age group 2							0.7626
<35 years	10/50 (20.0)	NE (1.87, NE)	10/124 (8.1)	11.80 (9.64, NE)	0.20 (0.07, 0.52)	0.0003	
35 - 54 years	5/25 (20.0)	NE (NE, NE)	3/77 (3.9)	NE (NE, NE)	0.17 (0.04, 0.71)	0.0059	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	4/33 (12.1)	NE (5.64, NE)	NE (NE, NE)	0.2100	
≥65 years	0/12 (0.0)	NE (NE, NE)	2/33 (6.1)	NE (7.48, NE)	NE (NE, NE)	0.6080	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8703
Male	8/64 (12.5)	NE (NE, NE)	10/159 (6.3)	NE (11.80, NE)	0.33 (0.13, 0.89)	0.0208	
Female	7/45 (15.6)	NE (NE, NE)	9/108 (8.3)	NE (9.64, NE)	0.21 (0.06, 0.69)	0.0049	
Region							0.5504
USA	2/13 (15.4)	NE (1.21, NE)	2/30 (6.7)	5.64 (5.64, NE)	0.21 (0.02, 2.30)	0.1574	
Europe	11/68 (16.2)	NE (NE, NE)	12/177 (6.8)	NE (11.80, NE)	0.26 (0.11, 0.64)	0.0015	
Rest of the world	2/28 (7.1)	NE (1.87, NE)	5/60 (8.3)	NE (9.64, NE)	0.35 (0.05, 2.20)	0.2375	
Prior salvage therapy							0.4301
Yes	7/63 (11.1)	NE (NE, NE)	11/161 (6.8)	NE (9.64, NE)	0.39 (0.14, 1.07)	0.0587	
No	8/46 (17.4)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	0.18 (0.06, 0.58)	0.0013	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3170
0	9/55 (16.4)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	0.19 (0.06, 0.59)	0.0015	
1	5/34 (14.7)	NE (NE, NE)	5/91 (5.5)	NE (9.64, NE)	0.24 (0.06, 0.92)	0.0241	
≥2	1/20 (5.0)	NE (1.21, NE)	6/64 (9.4)	11.80 (NE, NE)	1.00 (0.11, 8.80)	0.9980	
Prior alloHSCT							0.0460
Yes	7/35 (20.0)	NE (1.87, NE)	5/93 (5.4)	NE (11.80, NE)	0.14 (0.04, 0.50)	0.0005	
No	8/74 (10.8)	NE (NE, NE)	14/174 (8.0)	NE (9.64, NE)	0.41 (0.16, 1.05)	0.0565	
Race							0.5836
Caucasian	14/90 (15.6)	NE (NE, NE)	17/226 (7.5)	NE (11.80, NE)	0.29 (0.14, 0.63)	0.0008	
Others	1/19 (5.3)	NE (NE, NE)	2/41 (4.9)	9.64 (5.64, NE)	0.00 (0.00, NE)	0.1360	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2737
<50%	1/27 (3.7)	NE (NE, NE)	4/73 (5.5)	NE (NE, NE)	0.36 (0.03, 4.99)	0.4254	
≥50%	14/77 (18.2)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.26 (0.11, 0.58)	0.0005	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: General disorders and administration site conditions							
Overall	16/109 (14.7)	NE (NE, NE)	46/267 (17.2)	NE (NE, NE)	0.92 (0.51, 1.65)	0.7755	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pyrexia							
Overall	5/109 (4.6)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	1.24 (0.46, 3.39)	0.6717	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Hepatobiliary disorders							
Overall	6/109 (5.5)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.73 (0.28, 1.94)	0.5307	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Immune system disorders							
Overall	0/109 (0.0)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	NE (NE, NE)	0.0232	
Age group 1							0.9998
<35 years	0/50 (0.0)	NE (NE, NE)	11/123 (8.9)	NE (NE, NE)	NE (NE, NE)	0.0770	
≥35 years	0/59 (0.0)	NE (NE, NE)	7/144 (4.9)	NE (NE, NE)	NE (NE, NE)	0.1548	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	11/124 (8.9)	NE (NE, NE)	NE (NE, NE)	0.0777	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	4/77 (5.2)	NE (NE, NE)	NE (NE, NE)	0.3702	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥65 years	0/12 (0.0)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	NE (NE, NE)	0.3644	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	NE (NE, NE)	10/159 (6.3)	NE (NE, NE)	NE (NE, NE)	0.1104	
Female	0/45 (0.0)	NE (NE, NE)	8/108 (7.4)	NE (NE, NE)	NE (NE, NE)	0.1097	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	3/30 (10.0)	NE (3.02, NE)	NE (NE, NE)	0.2850	
Europe	0/68 (0.0)	NE (NE, NE)	12/177 (6.8)	NE (NE, NE)	NE (NE, NE)	0.0674	
Rest of the world	0/28 (0.0)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	NE (NE, NE)	0.3981	
Prior salvage therapy							0.9997
Yes	0/63 (0.0)	NE (NE, NE)	13/161 (8.1)	NE (NE, NE)	NE (NE, NE)	0.0749	
No	0/46 (0.0)	NE (NE, NE)	5/106 (4.7)	NE (NE, NE)	NE (NE, NE)	0.1522	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)	NE (NE, NE)	0.1585	
1	0/34 (0.0)	NE (NE, NE)	11/91 (12.1)	NE (NE, NE)	NE (NE, NE)	0.0915	
≥2	0/20 (0.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	NE (NE, NE)	0.6304	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	NE (NE, NE)	7/93 (7.5)	NE (NE, NE)	NE (NE, NE)	0.2635	
No	0/74 (0.0)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	NE (NE, NE)	0.0488	
Race							>0.9999
Caucasian	0/90 (0.0)	NE (NE, NE)	15/226 (6.6)	NE (NE, NE)	NE (NE, NE)	0.0344	
Others	0/19 (0.0)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	NE (NE, NE)	0.4216	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	NE (NE, NE)	4/73 (5.5)	NE (NE, NE)	NE (NE, NE)	0.6508	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0244	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Infections and infestations							
Overall	57/109 (52.3)	1.11 (0.62, 2.03)	91/267 (34.1)	6.10 (5.54, NE)	0.33 (0.23, 0.48)	<0.0001	
Age group 1							0.1698
<35 years	21/50 (42.0)	2.00 (0.62, NE)	41/123 (33.3)	6.07 (4.36, NE)	0.40 (0.23, 0.70)	0.0010	
≥35 years	36/59 (61.0)	0.66 (0.43, 1.51)	50/144 (34.7)	7.25 (5.05, NE)	0.30 (0.19, 0.47)	<0.0001	
Age group 2							0.6259
<35 years	21/50 (42.0)	2.00 (0.62, NE)	41/124 (33.1)	6.07 (4.36, NE)	0.40 (0.23, 0.70)	0.0010	
35 - 54 years	14/25 (56.0)	0.66 (0.36, NE)	25/77 (32.5)	7.25 (2.75, NE)	0.25 (0.13, 0.52)	<0.0001	
55 - 64 years	14/22 (63.6)	0.67 (0.30, NE)	13/33 (39.4)	5.80 (1.84, NE)	0.31 (0.13, 0.71)	0.0037	
≥65 years	8/12 (66.7)	0.62 (0.26, NE)	12/33 (36.4)	6.10 (1.48, NE)	0.40 (0.16, 1.02)	0.0465	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9286
Male	35/64 (54.7)	1.11 (0.52, 2.03)	57/159 (35.8)	6.07 (4.59, 8.07)	0.33 (0.21, 0.52)	<0.0001	
Female	22/45 (48.9)	1.34 (0.49, NE)	34/108 (31.5)	7.25 (4.79, NE)	0.35 (0.20, 0.62)	0.0002	
Region							0.2684
USA	5/13 (38.5)	NE (0.33, NE)	11/30 (36.7)	5.74 (1.48, NE)	0.62 (0.21, 1.86)	0.3896	
Europe	33/68 (48.5)	1.51 (0.62, NE)	55/177 (31.1)	7.44 (5.87, NE)	0.34 (0.22, 0.55)	<0.0001	
Rest of the world	19/28 (67.9)	0.49 (0.39, 0.69)	25/60 (41.7)	4.36 (2.10, NE)	0.21 (0.11, 0.42)	<0.0001	
Prior salvage therapy							0.1184
Yes	32/63 (50.8)	1.11 (0.49, NE)	62/161 (38.5)	5.80 (2.75, 7.57)	0.42 (0.27, 0.65)	<0.0001	
No	25/46 (54.3)	1.34 (0.49, 2.10)	29/106 (27.4)	8.07 (5.74, NE)	0.22 (0.12, 0.40)	<0.0001	

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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1179
0	28/55 (50.9)	1.34 (0.52, NE)	33/112 (29.5)	8.07 (5.87, NE)	0.26 (0.15, 0.46)	<0.0001	
1	22/34 (64.7)	0.59 (0.33, 1.11)	33/91 (36.3)	4.79 (2.69, 7.57)	0.27 (0.15, 0.47)	<0.0001	
≥2	7/20 (35.0)	NE (0.49, NE)	25/64 (39.1)	5.05 (1.61, NE)	0.70 (0.30, 1.68)	0.4250	
Prior alloHSCT							0.6087
Yes	19/35 (54.3)	0.72 (0.46, NE)	34/93 (36.6)	6.07 (4.59, NE)	0.28 (0.15, 0.52)	<0.0001	
No	38/74 (51.4)	1.34 (0.62, 2.10)	57/174 (32.8)	7.44 (4.36, NE)	0.36 (0.23, 0.55)	<0.0001	
Race							0.5744
Caucasian	47/90 (52.2)	1.34 (0.59, 2.10)	73/226 (32.3)	7.25 (5.80, NE)	0.33 (0.22, 0.48)	<0.0001	
Others	10/19 (52.6)	0.89 (0.33, NE)	18/41 (43.9)	3.38 (1.31, NE)	0.35 (0.15, 0.83)	0.0128	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4672
<50%	14/27 (51.9)	1.51 (0.43, NE)	23/73 (31.5)	5.87 (5.54, NE)	0.14 (0.06, 0.33)	<0.0001	
≥50%	41/77 (53.2)	0.89 (0.52, 2.03)	59/168 (35.1)	6.10 (4.30, NE)	0.38 (0.25, 0.58)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sepsis							
Overall	7/109 (6.4)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.41 (0.16, 1.08)	0.0629	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Device related infection							
Overall	5/109 (4.6)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.49 (0.15, 1.55)	0.2152	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pneumonia							
Overall	11/109 (10.1)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.30 (0.12, 0.72)	0.0042	
Age group 1							0.1651
<35 years	6/50 (12.0)	NE (NE, NE)	3/123 (2.4)	NE (NE, NE)	0.19 (0.05, 0.75)	0.0077	
≥35 years	5/59 (8.5)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)	0.42 (0.13, 1.41)	0.1483	
Age group 2							0.5302
<35 years	6/50 (12.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	2/25 (8.0)	-	5/77 (6.5)	-	-	-	
55 - 64 years	3/22 (13.6)	-	3/33 (9.1)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6992
Male	7/64 (10.9)	NE (NE, NE)	6/159 (3.8)	NE (NE, NE)	0.25 (0.08, 0.79)	0.0107	
Female	4/45 (8.9)	NE (NE, NE)	5/108 (4.6)	NE (NE, NE)	0.40 (0.10, 1.59)	0.1767	
Region							0.9620
USA	0/13 (0.0)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	NE (NE, NE)	0.5032	
Europe	7/68 (10.3)	NE (NE, NE)	7/177 (4.0)	NE (NE, NE)	0.24 (0.08, 0.76)	0.0088	
Rest of the world	4/28 (14.3)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.32 (0.07, 1.43)	0.1163	
Prior salvage therapy							0.5970
Yes	9/63 (14.3)	NE (NE, NE)	8/161 (5.0)	NE (NE, NE)	0.29 (0.11, 0.77)	0.0082	
No	2/46 (4.3)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.22 (0.02, 2.41)	0.1719	

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Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3050
0	4/55 (7.3)	-	4/112 (3.6)	-	-	-	
1	6/34 (17.6)	-	3/91 (3.3)	-	-	-	
≥2	1/20 (5.0)	-	4/64 (6.3)	-	-	-	
Prior alloHSCT							0.3642
Yes	4/35 (11.4)	NE (NE, NE)	7/93 (7.5)	NE (NE, NE)	0.38 (0.10, 1.45)	0.1423	
No	7/74 (9.5)	NE (NE, NE)	4/174 (2.3)	NE (NE, NE)	0.22 (0.06, 0.76)	0.0087	
Race							0.5999
Caucasian	9/90 (10.0)	NE (NE, NE)	8/226 (3.5)	NE (NE, NE)	0.24 (0.08, 0.67)	0.0032	
Others	2/19 (10.5)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.63 (0.11, 3.78)	0.6046	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.8381
<50%	3/27 (11.1)	NE (1.57, NE)	3/73 (4.1)	NE (8.30, NE)	0.20 (0.03, 1.24)	0.0566	
≥50%	8/77 (10.4)	NE (NE, NE)	7/168 (4.2)	NE (NE, NE)	0.32 (0.11, 0.92)	0.0261	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Bacteraemia							
Overall	6/109 (5.5)	NE (NE, NE)	2/267 (0.7)	NE (NE, NE)	0.11 (0.02, 0.54)	0.0011	
Age group 1							0.9846
<35 years	3/50 (6.0)	-	1/123 (0.8)	-	-	-	
≥35 years	3/59 (5.1)	-	1/144 (0.7)	-	-	-	
Age group 2							0.9815
<35 years	3/50 (6.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	1/25 (4.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	1/22 (4.5)	-	0/33 (0.0)	-	-	-	
≥65 years	1/12 (8.3)	-	0/33 (0.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9953
Male	5/64 (7.8)	-	2/159 (1.3)	-	-	-	
Female	1/45 (2.2)	-	0/108 (0.0)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	3/68 (4.4)	-	1/177 (0.6)	-	-	-	
Rest of the world	3/28 (10.7)	-	0/60 (0.0)	-	-	-	
Prior salvage therapy							0.5746
Yes	4/63 (6.3)	-	1/161 (0.6)	-	-	-	
No	2/46 (4.3)	-	1/106 (0.9)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	2/55 (3.6)	-	0/112 (0.0)	-	-	-	
1	3/34 (8.8)	-	0/91 (0.0)	-	-	-	
≥2	1/20 (5.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.9950
Yes	1/35 (2.9)	-	0/93 (0.0)	-	-	-	
No	5/74 (6.8)	-	2/174 (1.1)	-	-	-	
Race							0.3462
Caucasian	5/90 (5.6)	-	1/226 (0.4)	-	-	-	
Others	1/19 (5.3)	-	1/41 (2.4)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9943
<50%	3/27 (11.1)	-	0/73 (0.0)	-	-	-	
≥50%	2/77 (2.6)	-	2/168 (1.2)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Investigations							
Overall	28/109 (25.7)	NE (NE, NE)	60/267 (22.5)	NE (NE, NE)	0.74 (0.47, 1.16)	0.1830	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Alanine aminotransferase increased							
Overall	9/109 (8.3)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.60 (0.26, 1.38)	0.2211	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: White blood cell count decreased							
Overall	6/109 (5.5)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	0.72 (0.27, 1.92)	0.5014	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Platelet count decreased							
Overall	13/109 (11.9)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.29 (0.13, 0.65)	0.0015	
Age group 1							0.9645
<35 years	6/50 (12.0)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	0.29 (0.09, 0.94)	0.0285	
≥35 years	7/59 (11.9)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.28 (0.09, 0.90)	0.0221	
Age group 2							0.6245
<35 years	6/50 (12.0)	NE (NE, NE)	5/124 (4.0)	NE (NE, NE)	0.28 (0.09, 0.94)	0.0280	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	2/77 (2.6)	NE (NE, NE)	0.15 (0.01, 1.63)	0.0702	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.16 (0.02, 1.41)	0.0573	
≥65 years	1/12 (8.3)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	1.13 (0.12, 10.89)	0.9142	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4012
Male	7/64 (10.9)	NE (NE, NE)	4/159 (2.5)	NE (NE, NE)	0.16 (0.04, 0.59)	0.0019	
Female	6/45 (13.3)	NE (NE, NE)	7/108 (6.5)	NE (NE, NE)	0.47 (0.16, 1.39)	0.1622	
Region							0.9476
USA	4/13 (30.8)	NE (0.30, NE)	3/30 (10.0)	NE (NE, NE)	0.31 (0.07, 1.38)	0.0998	
Europe	4/68 (5.9)	NE (NE, NE)	3/177 (1.7)	NE (NE, NE)	0.26 (0.06, 1.18)	0.0614	
Rest of the world	5/28 (17.9)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)	0.32 (0.09, 1.20)	0.0743	
Prior salvage therapy							0.2326
Yes	5/63 (7.9)	NE (NE, NE)	7/161 (4.3)	NE (NE, NE)	0.44 (0.14, 1.45)	0.1660	
No	8/46 (17.4)	NE (NE, NE)	4/106 (3.8)	NE (NE, NE)	0.19 (0.06, 0.64)	0.0026	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.8959
0	7/55 (12.7)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0189	
1	4/34 (11.8)	NE (NE, NE)	3/91 (3.3)	NE (NE, NE)	0.27 (0.06, 1.20)	0.0647	
≥2	2/20 (10.0)	NE (1.31, NE)	3/64 (4.7)	NE (NE, NE)	0.41 (0.07, 2.49)	0.3138	
Prior alloHSCT							0.1927
Yes	5/35 (14.3)	NE (1.31, NE)	2/93 (2.2)	NE (NE, NE)	0.12 (0.02, 0.63)	0.0031	
No	8/74 (10.8)	NE (NE, NE)	9/174 (5.2)	NE (NE, NE)	0.41 (0.15, 1.07)	0.0605	
Race							0.4344
Caucasian	11/90 (12.2)	NE (NE, NE)	8/226 (3.5)	NE (NE, NE)	0.26 (0.11, 0.65)	0.0020	
Others	2/19 (10.5)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.41 (0.06, 2.96)	0.3645	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

Program: /userdata/stat/amg103/onc/mt103_311/analysis/primary_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:05:53) Source data: adam_pa.adsl, adam_pa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9881
<50%	3/27 (11.1)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0039	
≥50%	10/77 (13.0)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.29 (0.11, 0.76)	0.0076	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutrophil count decreased							
Overall	11/109 (10.1)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.27 (0.11, 0.67)	0.0023	
Age group 1							0.8079
<35 years	6/50 (12.0)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0185	
≥35 years	5/59 (8.5)	NE (NE, NE)	5/144 (3.5)	NE (NE, NE)	0.27 (0.07, 1.06)	0.0455	
Age group 2							0.9989
<35 years	6/50 (12.0)	NE (NE, NE)	5/124 (4.0)	NE (NE, NE)	0.26 (0.08, 0.86)	0.0182	
35 - 54 years	3/25 (12.0)	NE (NE, NE)	4/77 (5.2)	NE (NE, NE)	0.24 (0.04, 1.24)	0.0643	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0797	
≥65 years	0/12 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.5403	

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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3021
Male	7/64 (10.9)	NE (NE, NE)	4/159 (2.5)	NE (NE, NE)	0.13 (0.03, 0.51)	0.0006	
Female	4/45 (8.9)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	0.58 (0.16, 2.07)	0.3928	
Region							0.8133
USA	4/13 (30.8)	NE (0.26, NE)	2/30 (6.7)	NE (NE, NE)	0.19 (0.03, 1.05)	0.0332	
Europe	2/68 (2.9)	NE (NE, NE)	2/177 (1.1)	NE (NE, NE)	0.29 (0.04, 2.09)	0.1912	
Rest of the world	5/28 (17.9)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.29 (0.08, 1.10)	0.0523	
Prior salvage therapy							0.0505
Yes	5/63 (7.9)	NE (NE, NE)	9/161 (5.6)	NE (NE, NE)	0.56 (0.18, 1.73)	0.3070	
No	6/46 (13.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	0.05 (0.01, 0.44)	0.0002	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4139
0	7/55 (12.7)	NE (NE, NE)	3/112 (2.7)	NE (NE, NE)	0.11 (0.02, 0.52)	0.0008	
1	3/34 (8.8)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)	0.53 (0.13, 2.27)	0.3867	
≥2	1/20 (5.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.63 (0.06, 6.94)	0.6980	
Prior alloHSCT							0.5314
Yes	4/35 (11.4)	NE (NE, NE)	3/93 (3.2)	NE (NE, NE)	0.21 (0.05, 1.01)	0.0338	
No	7/74 (9.5)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.31 (0.10, 0.94)	0.0281	
Race							0.3001
Caucasian	8/90 (8.9)	NE (NE, NE)	5/226 (2.2)	NE (NE, NE)	0.20 (0.06, 0.62)	0.0021	
Others	3/19 (15.8)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	0.48 (0.10, 2.20)	0.3299	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9918
<50%	3/27 (11.1)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0040	
≥50%	8/77 (10.4)	NE (NE, NE)	9/168 (5.4)	NE (NE, NE)	0.40 (0.15, 1.07)	0.0592	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Metabolism and nutrition disorders							
Overall	26/109 (23.9)	NE (NE, NE)	38/267 (14.2)	NE (NE, NE)	0.48 (0.29, 0.80)	0.0038	
Age group 1							0.3621
<35 years	9/50 (18.0)	NE (2.33, NE)	17/123 (13.8)	NE (NE, NE)	0.61 (0.27, 1.39)	0.2372	
≥35 years	17/59 (28.8)	NE (1.74, NE)	21/144 (14.6)	NE (NE, NE)	0.41 (0.21, 0.78)	0.0052	
Age group 2							0.4175
<35 years	9/50 (18.0)	NE (2.33, NE)	17/124 (13.7)	NE (NE, NE)	0.61 (0.27, 1.39)	0.2348	
35 - 54 years	8/25 (32.0)	1.74 (0.79, NE)	9/77 (11.7)	NE (NE, NE)	0.24 (0.09, 0.66)	0.0028	
55 - 64 years	6/22 (27.3)	NE (0.66, NE)	8/33 (24.2)	NE (NE, NE)	0.74 (0.25, 2.17)	0.5759	
≥65 years	3/12 (25.0)	NE (0.46, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.11, 2.15)	0.3281	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1042
Male	13/64 (20.3)	NE (NE, NE)	26/159 (16.4)	NE (NE, NE)	0.68 (0.35, 1.33)	0.2571	
Female	13/45 (28.9)	NE (1.74, NE)	12/108 (11.1)	NE (NE, NE)	0.28 (0.12, 0.62)	0.0009	
Region							0.1457
USA	4/13 (30.8)	NE (0.46, NE)	11/30 (36.7)	NE (0.79, NE)	1.15 (0.37, 3.63)	0.8268	
Europe	10/68 (14.7)	NE (NE, NE)	17/177 (9.6)	NE (NE, NE)	0.51 (0.23, 1.14)	0.0938	
Rest of the world	12/28 (42.9)	2.33 (0.56, NE)	10/60 (16.7)	NE (NE, NE)	0.28 (0.12, 0.67)	0.0021	
Prior salvage therapy							0.0548
Yes	14/63 (22.2)	NE (2.33, NE)	30/161 (18.6)	NE (NE, NE)	0.65 (0.34, 1.24)	0.1905	
No	12/46 (26.1)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	0.26 (0.11, 0.64)	0.0015	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.2945
0	12/55 (21.8)	NE (2.33, NE)	10/112 (8.9)	NE (NE, NE)	0.32 (0.13, 0.77)	0.0071	
1	11/34 (32.4)	NE (0.66, NE)	16/91 (17.6)	NE (NE, NE)	0.38 (0.18, 0.84)	0.0125	
≥2	3/20 (15.0)	NE (NE, NE)	12/64 (18.8)	NE (NE, NE)	1.09 (0.30, 3.90)	0.8968	
Prior alloHSCT							0.7994
Yes	6/35 (17.1)	NE (NE, NE)	11/93 (11.8)	NE (NE, NE)	0.56 (0.20, 1.54)	0.2566	
No	20/74 (27.0)	NE (2.33, NE)	27/174 (15.5)	NE (NE, NE)	0.46 (0.26, 0.83)	0.0083	
Race							0.2472
Caucasian	22/90 (24.4)	NE (NE, NE)	36/226 (15.9)	NE (NE, NE)	0.53 (0.31, 0.91)	0.0190	
Others	4/19 (21.1)	2.33 (2.33, NE)	2/41 (4.9)	NE (NE, NE)	0.17 (0.03, 0.99)	0.0264	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0421
<50%	8/27 (29.6)	NE (1.74, NE)	5/73 (6.8)	NE (NE, NE)	0.18 (0.06, 0.56)	0.0009	
≥50%	16/77 (20.8)	NE (NE, NE)	28/168 (16.7)	NE (NE, NE)	0.66 (0.35, 1.23)	0.1838	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypokalaemia							
Overall	11/109 (10.1)	NE (NE, NE)	9/267 (3.4)	NE (NE, NE)	0.28 (0.11, 0.68)	0.0026	
Age group 1							0.7796
<35 years	3/50 (6.0)	NE (NE, NE)	3/123 (2.4)	NE (NE, NE)	0.34 (0.07, 1.70)	0.1685	
≥35 years	8/59 (13.6)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.25 (0.09, 0.74)	0.0069	
Age group 2							0.9248
<35 years	3/50 (6.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	5/25 (20.0)	-	4/77 (5.2)	-	-	-	
55 - 64 years	1/22 (4.5)	-	0/33 (0.0)	-	-	-	
≥65 years	2/12 (16.7)	-	2/33 (6.1)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6775
Male	5/64 (7.8)	NE (NE, NE)	5/159 (3.1)	NE (NE, NE)	0.37 (0.11, 1.29)	0.1064	
Female	6/45 (13.3)	NE (NE, NE)	4/108 (3.7)	NE (NE, NE)	0.19 (0.05, 0.70)	0.0057	
Region							0.5159
USA	1/13 (7.7)	-	2/30 (6.7)	-	-	-	
Europe	6/68 (8.8)	-	3/177 (1.7)	-	-	-	
Rest of the world	4/28 (14.3)	-	4/60 (6.7)	-	-	-	
Prior salvage therapy							0.3875
Yes	6/63 (9.5)	NE (NE, NE)	7/161 (4.3)	NE (NE, NE)	0.36 (0.12, 1.09)	0.0593	
No	5/46 (10.9)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	0.16 (0.03, 0.81)	0.0113	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 18.1. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 04JAN2016

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7870
0	5/55 (9.1)	-	2/112 (1.8)	-	-	-	
1	4/34 (11.8)	-	5/91 (5.5)	-	-	-	
≥2	2/20 (10.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.2977
Yes	3/35 (8.6)	NE (NE, NE)	1/93 (1.1)	NE (NE, NE)	0.12 (0.01, 1.11)	0.0242	
No	8/74 (10.8)	NE (NE, NE)	8/174 (4.6)	NE (NE, NE)	0.36 (0.13, 0.96)	0.0334	
Race							0.9913
Caucasian	9/90 (10.0)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.34 (0.13, 0.86)	0.0166	
Others	2/19 (10.5)	NE (NE, NE)	0/41 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0229	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9880
<50%	4/27 (14.8)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0003	
≥50%	7/77 (9.1)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.45 (0.16, 1.26)	0.1211	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hyperglycaemia							
Overall	7/109 (6.4)	NE (NE, NE)	8/267 (3.0)	NE (NE, NE)	0.43 (0.15, 1.18)	0.0901	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Musculoskeletal and connective tissue disorders							
Overall	6/109 (5.5)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.73 (0.28, 1.90)	0.5129	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Nervous system disorders							
Overall	11/109 (10.1)	NE (NE, NE)	23/267 (8.6)	NE (NE, NE)	0.70 (0.34, 1.46)	0.3422	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Respiratory, thoracic and mediastinal disorders							
Overall	12/109 (11.0)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	0.53 (0.25, 1.10)	0.0853	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Vascular disorders							
Overall	6/109 (5.5)	NE (NE, NE)	9/267 (3.4)	NE (NE, NE)	0.37 (0.12, 1.12)	0.0679	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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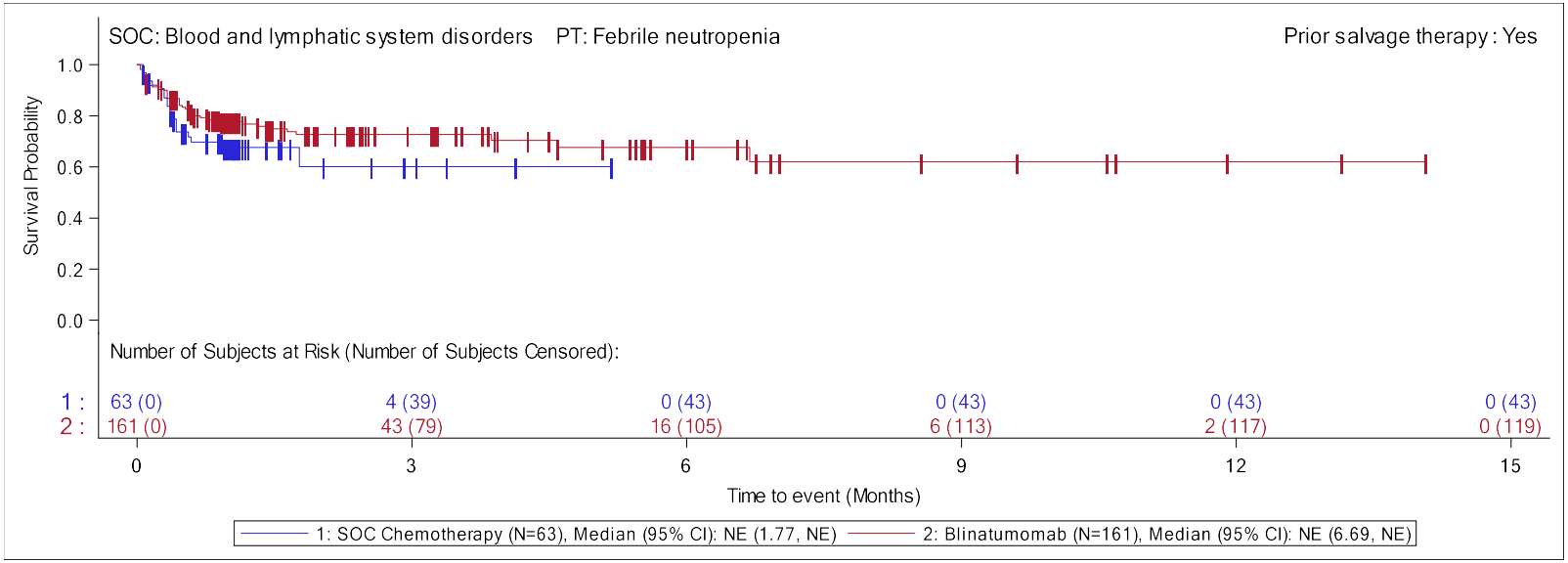
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade >= 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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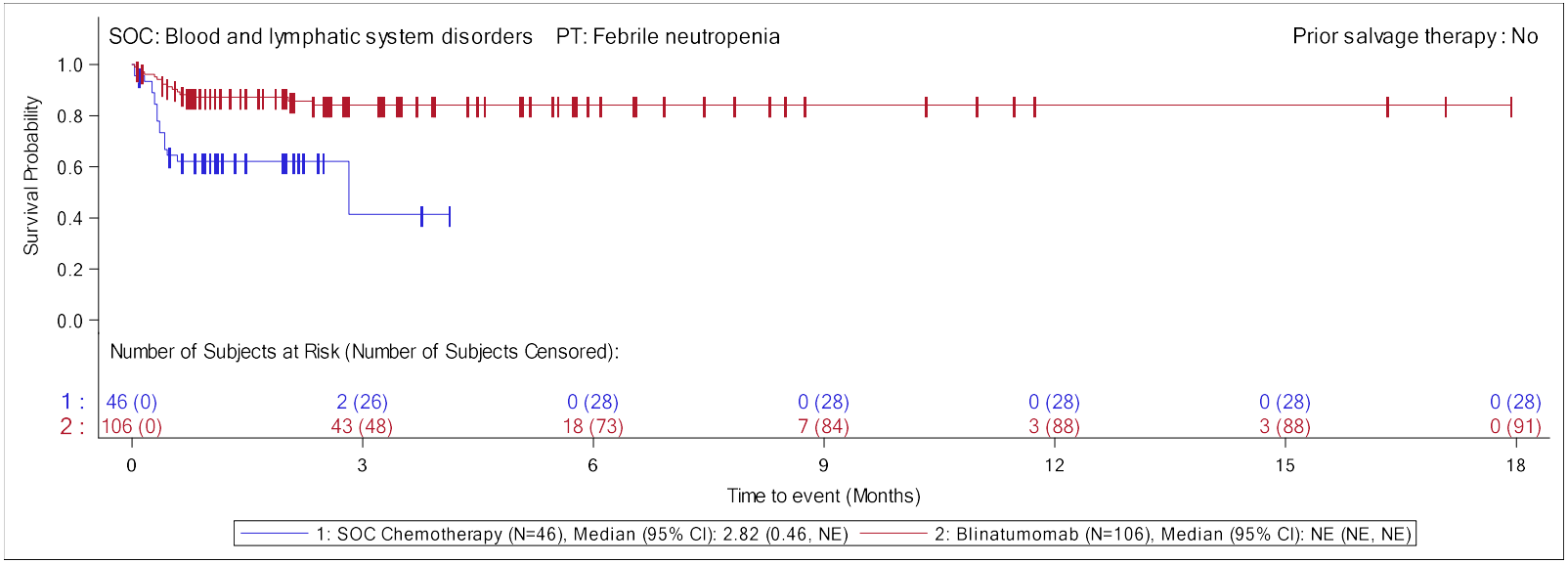

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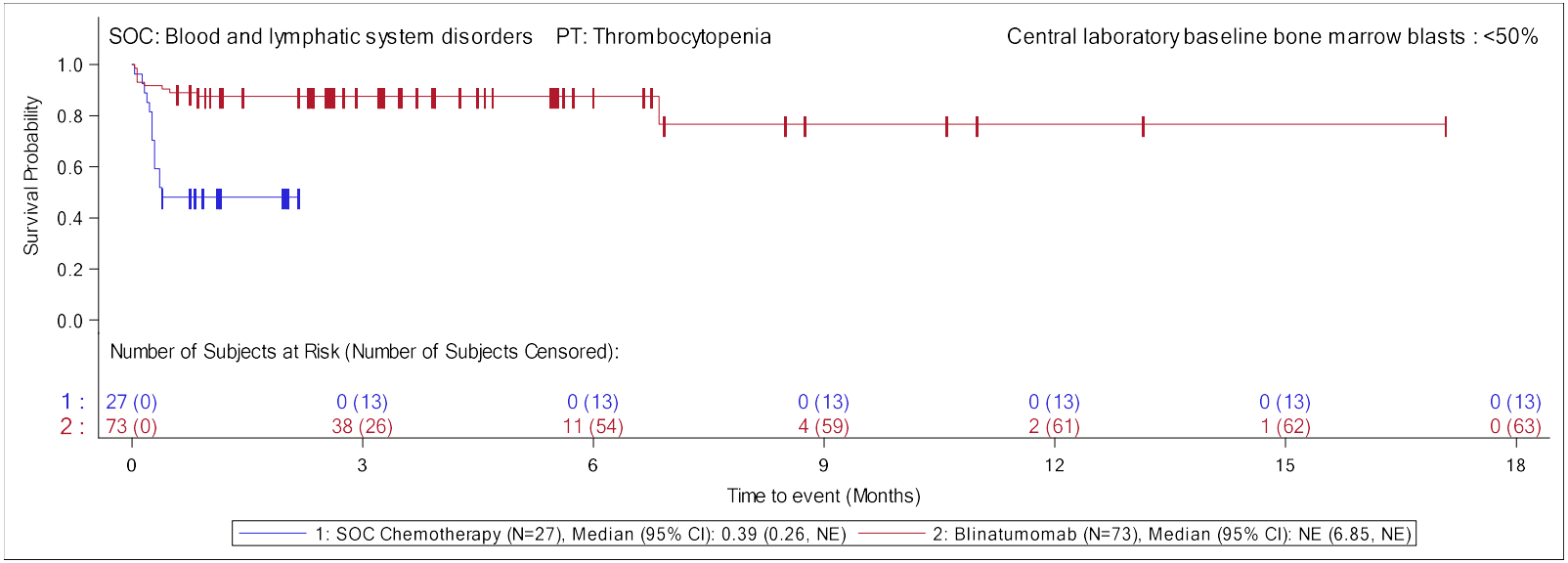

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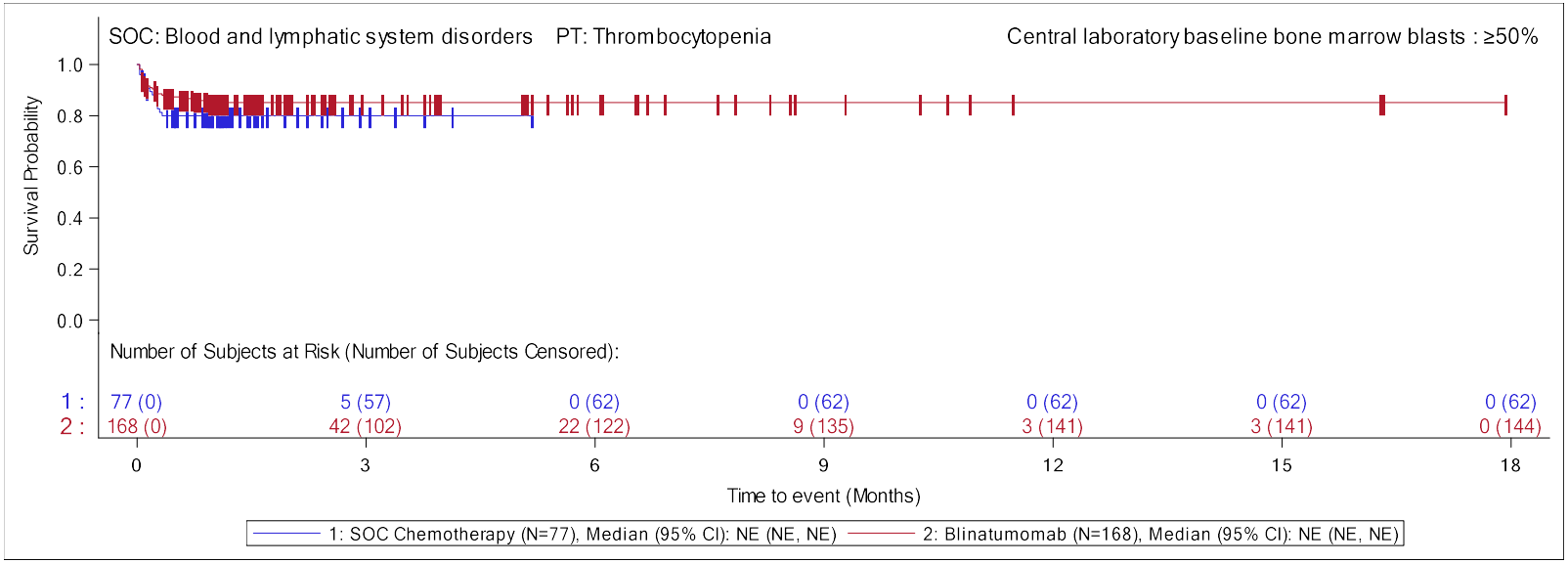

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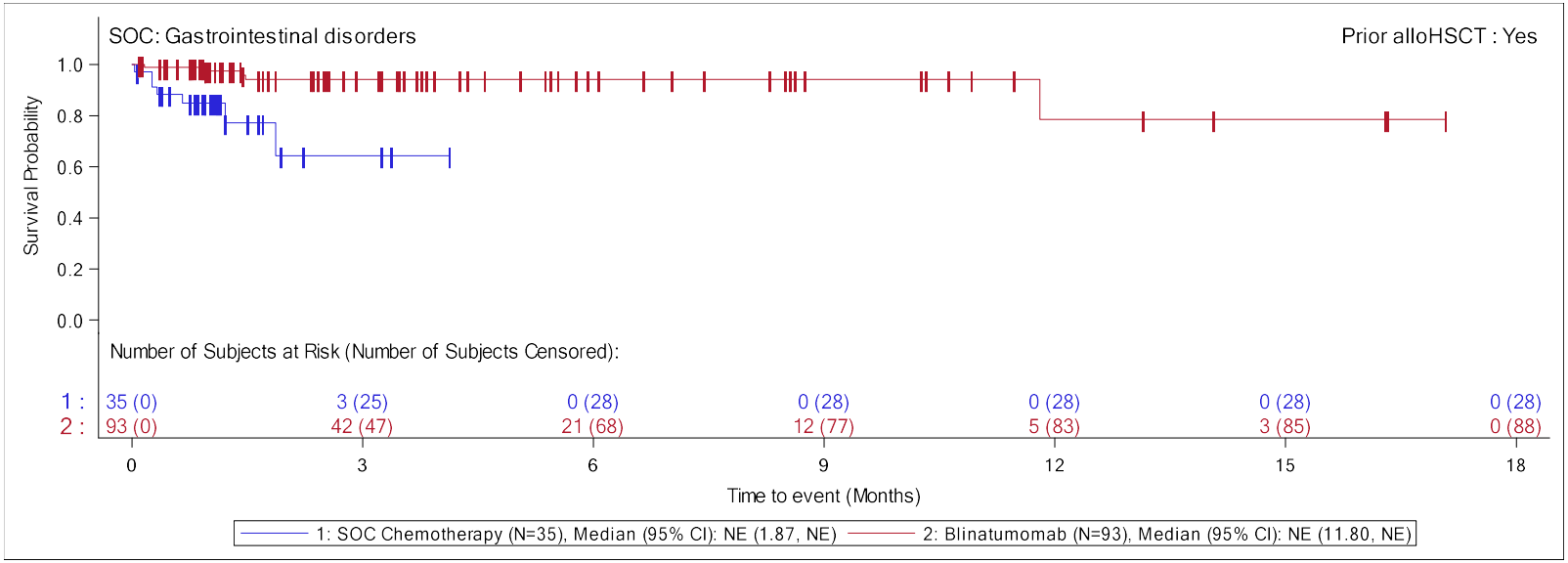

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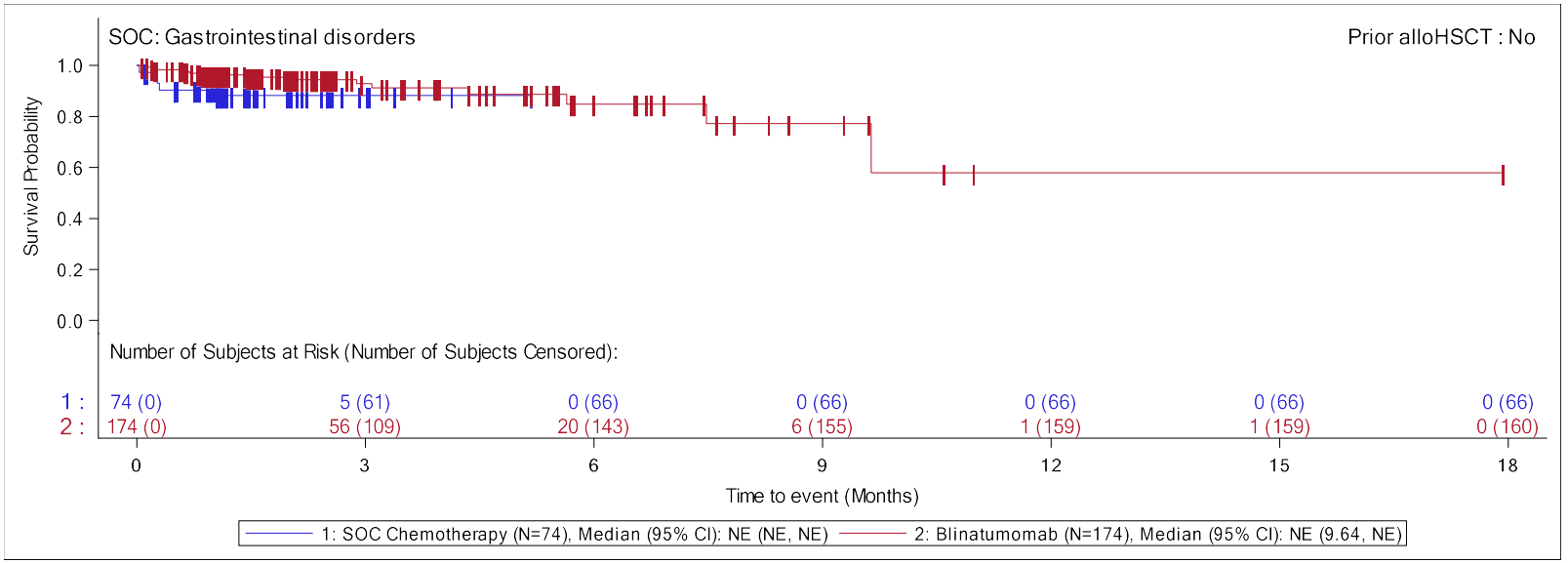

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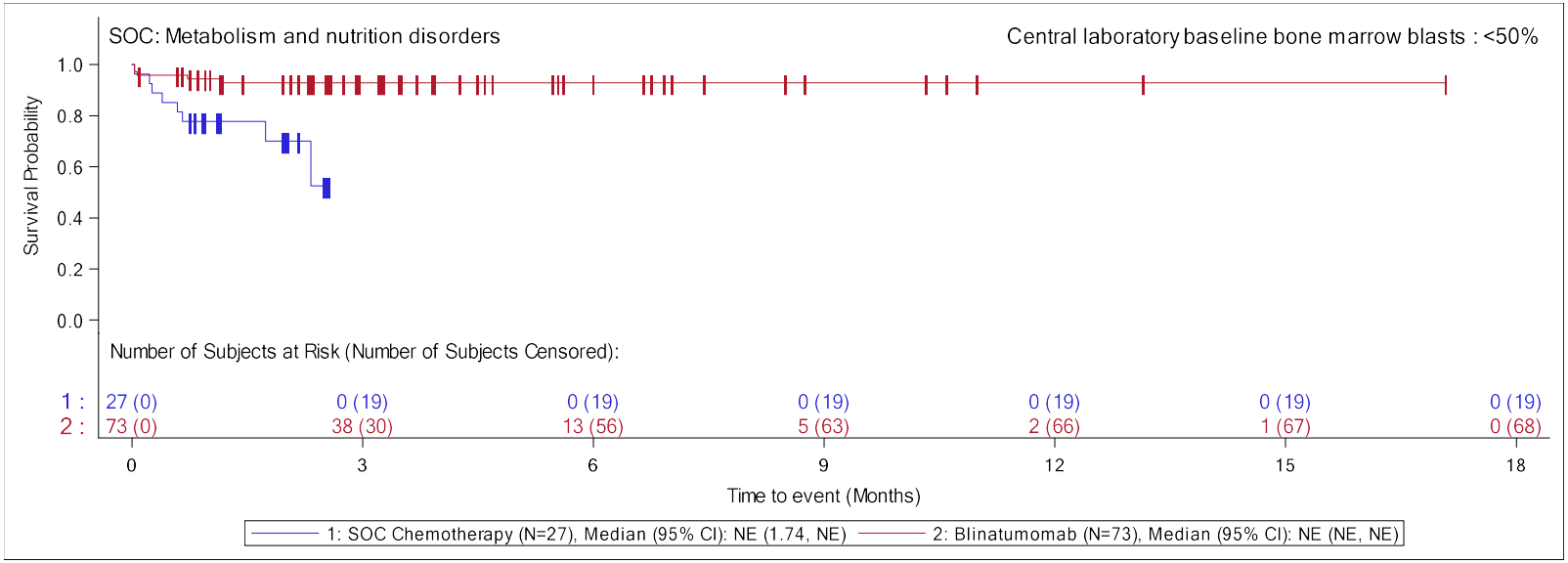

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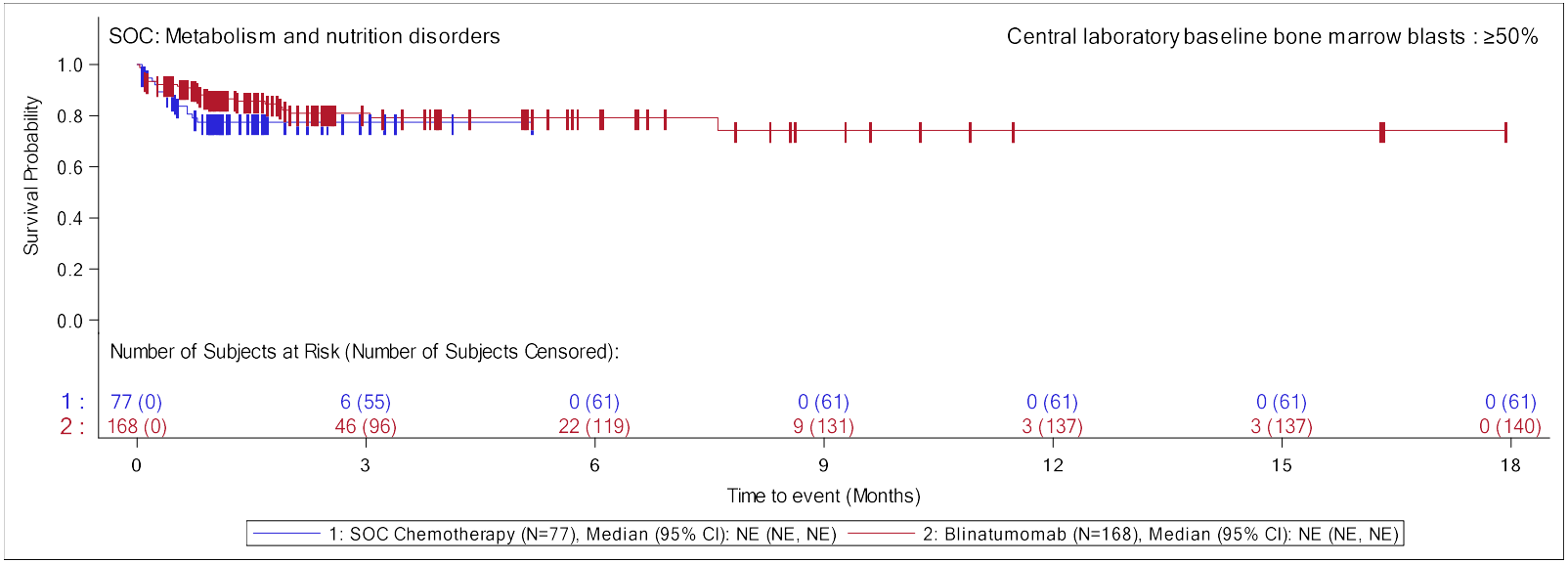

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Anhang 4-G4: Ergänzende Ergebnisdarstellung des Datenschnitts vom 14. März 2017

Anhang 4-G4.1: Ergänzende Darstellung der Studien und Patientencharakteristika (Datenschnitt vom 14. März 2017)

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t14-08-001-003-sum-dur-teae-saf.rtf....4
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t14-08-002-002-sum-cr-allss-fas.rtf....6

Table 14-8.1.1. Summary of Duration of Observation for OS and EFS Endpoints (Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Overall (N=405)
Overall survival (months)[a]			
n	134	271	405
Mean	5.66	7.75	7.06
SD	5.76	6.43	6.29
Median	3.46	6.26	5.31
Min, Max	0.0, 22.5	0.1, 25.8	0.0, 25.8
Event-free survival (months)[b]			
n	134	271	405
Mean	1.59	3.66	2.98
SD	3.78	5.42	5.03
Median	0.03	0.03	0.03
Min, Max	0.0, 20.2	0.0, 23.7	0.0, 23.7

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
[a] Months are calculated as days from randomization to death or last observation on study in absence of death, divided by 30.5.
[b] Months are calculated as days from randomization to relapse/death or last disease assessment date in absence of relapse/death, divided by 30.5. Subjects who fail to achieve a CR following treatment with investigational product or who died before the disease assessment at the end of treatment will be considered treatment failures and assigned an EFS duration of 1, divided by 30.5.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-sum-dur-os-efs-fas.sas
Output: t14-08-001-001-sum-dur-os-efs-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adtteeff

Table 14-8.1.2. Summary of Duration of Observation for CR and MRD response (Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Overall (N=405)
CR/CRh*/CRi response (months)[a]			
n	33	119	152
Mean	5.33	6.90	6.56
SD	5.31	5.45	5.44
Median	3.28	5.61	5.34
Min, Max	0.0, 19.0	0.0, 22.7	0.0, 22.7
MRD response (months)[b]			
n	109	267	376
Mean	0.71	3.59	2.76
SD	0.85	4.23	3.83
Median	0.26	2.33	1.18
Min, Max	0.1, 5.5	0.1, 18.9	0.1, 18.9

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
MRD = Minimal residual disease.
[a] Months are calculated as days from CR/CRh*/CRi is first achieved within first 2 cycles to relapse/death or last disease assessment date in absence of relapse/death, divided by 30.5.
[b] Months are calculated as days from randomization to treatment end date, divided by 30.5.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-sum-dur-resp-fas.sas
Output: t14-08-001-002-sum-dur-resp-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adtteeff

Table 14-8.1.3. Summary of Duration of Observation for Treatment-emergent Adverse Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Overall (N=376)
Treatment-emergent adverse events (months)[a]			
n	108	263	371
Mean	1.53	4.32	3.51
SD	0.91	4.35	3.91
Median	1.15	3.28	1.93
Min, Max	0.1, 6.2	0.1, 19.8	0.1, 19.8

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
[a] Months are calculated as days from start of treatment to end of treatment + 30 days or last observation on study whichever occurs first, divided by 30.5.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-sum-dur-teae-saf.sas
Output: t14-08-001-003-sum-dur-teae-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-8.2.1. Summary of Completion Rate for EORTC QLQ C30 (Full Analysis Set)

	SOC Chemotherapy (N=134)		Blinatumomab (N=271)	
EORTC QLQ C30	n/N1	Completion Rate	n/N1	Completion Rate
Baseline	90/112	80.4	226/267	84.6
Cycle 1 Day 8	73/106	68.9	209/258	81.0
Cycle 1 Day 15	69/102	67.6	208/243	85.6
Cycle 1 Day 29	53/90	58.9	152/218	69.7
Cycle 2 Day 1	24/31	77.4	135/152	88.8
Cycle 2 Day 15	20/27	74.1	113/142	79.6
Cycle 2 Day 29	15/23	65.2	107/138	77.5
Cycle 3 Day 1	7/7	100.0	79/88	89.8
Cycle 3 Day 15	3/3	100.0	75/85	88.2
Cycle 3 Day 29	3/5	60.0	66/81	81.5
Cycle 4 Day 1	2/2	100.0	60/65	92.3
Cycle 4 Day 15	3/3	100.0	55/63	87.3
Cycle 4 Day 29	1/1	100.0	53/61	86.9
Cycle 5 Day 1	0/0	-	42/48	87.5
Cycle 5 Day 15	0/0	-	40/48	83.3
Cycle 5 Day 29	0/0	-	38/45	84.4
Safety Follow Up	40/72	55.6	95/170	55.9

Page 1 of 1

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects who completed the forms.
N1 = Number of subjects expected to complete the forms. EORTC QLQ= European organization for research and treatment of cancer quality of life questionnaire.
The completion rate at each assessment time is defined as the number of received forms divided by the number of expected forms at each assessment time.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-sum-cr-eortc-qlq-fas.sas
Output: t14-08-002-001-sum-cr-eortc-qlq-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adqs

Table 14-8.2.2. Summary of Completion Rate for ALLSS sum score (Full Analysis Set)

	SOC Chemotherapy (N=134)		Blinatumomab (N=271)	
ALLSS sum score	n/N1	Completion Rate	n/N1	Completion Rate
Baseline	98/112	87.5	231/267	86.5
Cycle 1 Day 8	77/106	72.6	228/258	88.4
Cycle 1 Day 15	72/102	70.6	221/243	90.9
Cycle 1 Day 29	54/90	60.0	160/218	73.4
Cycle 2 Day 1	26/31	83.9	141/152	92.8
Cycle 2 Day 15	21/27	77.8	119/142	83.8
Cycle 2 Day 29	15/23	65.2	114/138	82.6
Cycle 3 Day 1	7/7	100.0	78/88	88.6
Cycle 3 Day 15	3/3	100.0	79/85	92.9
Cycle 3 Day 29	3/5	60.0	69/81	85.2
Cycle 4 Day 1	2/2	100.0	61/65	93.8
Cycle 4 Day 15	3/3	100.0	59/63	93.7
Cycle 4 Day 29	1/1	100.0	55/61	90.2
Cycle 5 Day 1	0/0	-	44/48	91.7
Cycle 5 Day 15	0/0	-	42/48	87.5
Cycle 5 Day 29	0/0	-	41/45	91.1
Safety Follow Up	43/72	59.7	99/170	58.2

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects who completed the forms.
N1 = Number of subjects expected to complete the forms. ALLSS= Acute lymphoblastic leukemia symptom scale.
The completion rate at each assessment time is defined as the number of received forms divided by the number of expected forms at each assessment time.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-sum-cr-allss-fas.sas
Output: t14-08-002-002-sum-cr-allss-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adqs

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
Number of subjects reporting first subsequent anti-cancer therapy during long-term follow-up	34 (25.4)	52 (19.2)
CYCLOPHOSPHAMIDE	1 (0.7)	5 (1.8)
FLAG-IDA	0 (0.0)	5 (1.8)
CLOFARBINE BASED COMBINATION REGIMEN	1 (0.7)	4 (1.5)
FLUDARABINE	2 (1.5)	3 (1.1)
ETOPOSIDE	1 (0.7)	3 (1.1)
DEXAMETHASONE	2 (1.5)	2 (0.7)
METHOTREXATE	1 (0.7)	2 (0.7)
CLOFARABINE	0 (0.0)	2 (0.7)
CYTARABINE	0 (0.0)	2 (0.7)
FLAG	0 (0.0)	2 (0.7)
PURINETHOL	0 (0.0)	2 (0.7)
VINCRISTINE SULPHATE LIPOSOME INJECTION (MARQUIBO)	0 (0.0)	2 (0.7)
BLINATUMOMAB	3 (2.2)	1 (0.4)
BUSULFAN	1 (0.7)	1 (0.4)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:21:02) Source data: adam_fa.adsl, adam_fa.adcm\line

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
DONOR LYMPHOCYTE INFUSION	1 (0.7)	1 (0.4)
FTBI	1 (0.7)	1 (0.4)
HYPERCVAD	1 (0.7)	1 (0.4)
TOTAL BODY IRRADIATION	1 (0.7)	1 (0.4)
VINCRISTINE	1 (0.7)	1 (0.4)
ADRIAMYCIN, CYTARABINE, ONCOVIN, PREDNISONE	0 (0.0)	1 (0.4)
ASPARAGINASE CYTARABINE METHOTREXATE	0 (0.0)	1 (0.4)
CVAD	0 (0.0)	1 (0.4)
CYCLOPHOSPHAMIDE AND TBI ALLOGENIC CONDITIONING PROTOCOL	0 (0.0)	1 (0.4)
DAY +8 POST CD22 CAR T CELLS TRANSPLANT	0 (0.0)	1 (0.4)
DOXORUBICIN	0 (0.0)	1 (0.4)
ERWINAZE	0 (0.0)	1 (0.4)
FLUDARABINE AND CYTARABINE	0 (0.0)	1 (0.4)
HIDROXIUREA	0 (0.0)	1 (0.4)
HOVAD B	0 (0.0)	1 (0.4)
HYDROXYUREA	0 (0.0)	1 (0.4)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:21:02) Source data: adam_fa.adsl, adam_fa.adcm\line

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
IDARUBICIN	0 (0.0)	1 (0.4)
IFOSPHAMIDE	0 (0.0)	1 (0.4)
INOTUZUMAB	0 (0.0)	1 (0.4)
METHOTREXAT, PEG-ASPARAGINASE	0 (0.0)	1 (0.4)
OTHER CLINICAL TRIAL	0 (0.0)	1 (0.4)
PALLIATIVE TREATMENT	0 (0.0)	1 (0.4)
POMP	0 (0.0)	1 (0.4)
PREDNISONE 20 MG	0 (0.0)	1 (0.4)
PURINETHOL 50 MG	0 (0.0)	1 (0.4)
RADIATION THERAPY	0 (0.0)	1 (0.4)
RITUXIMAB/VINCRISTINE	0 (0.0)	1 (0.4)
THYMOGLOBULIN	0 (0.0)	1 (0.4)
VINBLASTINE	0 (0.0)	1 (0.4)
MERCAPTOPURINE	3 (2.2)	0 (0.0)
INOTUZUMAB OZOGAMICIN (CMC-544)	2 (1.5)	0 (0.0)
PREDNISONE	2 (1.5)	0 (0.0)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:21:02) Source data: adam_fa.adsl, adam_fa.adcm\line

Table 14-8.3.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Medication	SOC Chemotherapy (N = 134) n (%)	Blinatumomab (N = 271) n (%)
6-MERCAPTOPURINE	1 (0.7)	0 (0.0)
ARA-C	1 (0.7)	0 (0.0)
CY-TBI	1 (0.7)	0 (0.0)
DAUNORUBICINE	1 (0.7)	0 (0.0)
DECITABINE	1 (0.7)	0 (0.0)
FLUDARABINE+TREOSULFAN	1 (0.7)	0 (0.0)
HYPERCHIDAM	1 (0.7)	0 (0.0)
MELPHALAN	1 (0.7)	0 (0.0)
METOTREXATE	1 (0.7)	0 (0.0)
RADIOACTIVE MONOCLONAL ANTIBODY	1 (0.7)	0 (0.0)
RITUXIMAB	1 (0.7)	0 (0.0)
SCT ALLO MUD FOR ALL -TREOSULFAN/FLUDARABINE/THYMOGLOBULIN	1 (0.7)	0 (0.0)
SGN-CD19A IV (INVESTIGATIONAL SUPPLY) 400 MG INTRAVENOUS	1 (0.7)	0 (0.0)
UKALL60	1 (0.7)	0 (0.0)
VINCRISTINE +DEXAMETHASONE+DASATINIB+PURINETHOL	1 (0.7)	0 (0.0)
VINCRISTINE, PEG-ASPARGINASE, DEXAMETHASONE, DOXORUBICIN, ARA-C, METHOTREXATE, M	1 (0.7)	0 (0.0)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Full analysis includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-cm-anticancer-ltfu-fas.sas
Output: t14-08-003-001-cm-anticancer-ltfu-fas.rtf (Date generated: 04NOV2025:21:02) Source data: adam_fa.adsl, adam_fa.adcm\line

Anhang 4-G4.2: Analysen zum Datenschnitt 14. März 2017

Table 14-4.5.1. Overall Survival
(Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Subject status			
Events - n (%)	90 (67.2)	184 (67.9)	
Deaths from any cause	90 (67.2)	184 (67.9)	
Censored - n (%)	44 (32.8)	87 (32.1)	
Alive at last follow-up	0 (0.0)	0 (0.0)	
Consent withdrawn	13 (9.7)	9 (3.3)	
Lost to follow-up	0 (0.0)	1 (0.4)	
Decision by sponsor	31 (23.1)	77 (28.4)	
Stratified log-rank test[a]			
Normal score[b]			-14.21
p-value			0.052
Unstratified log-rank test			
Normal score[b]			-13.84
p-value			0.061
Time to event (KM) (months)[c]			
Median	4.0	7.7	
95% CI (median)	(2.9, 5.5)	(5.6, 9.6)	
Q1, Q3	1.9, 20.2	2.1, 17.1	
Min, Max	0.1, 20.2	0.1, 23.4	

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KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final/tables/program/t-os.sas
Output: t14-04-005-001-os-fas.rtf (Date generated: 10MAY2017:03:47) Source data: adam.adsl, adam.adtteeff

Table 14-4.5.1. Overall Survival
(Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Time to censoring (months)[c,d]			
Median	13.6	15.7	
Q1, Q3	10.6, 16.8	11.3, 19.2	
Min, Max	0.0, 22.5	0.7, 25.8	
KM estimate - %			
At time 3 months[c]	58.4	67.0	
(95% CI)	(49.1, 66.5)	(61.0, 72.3)	
At time 6 months[c]	39.4	54.0	
(95% CI)	(30.8, 48.0)	(47.8, 59.8)	
At time 12 months[c]	28.1	34.0	
(95% CI)	(20.4, 36.4)	(28.0, 40.0)	
At time 18 months[c]	25.7	24.0	
(95% CI)	(18.0, 34.0)	(18.2, 30.3)	
At time 24 months[c]	NE	18.0	
(95% CI)	(NE, NE)	(8.5, 30.3)	
Stratified hazard ratio[e]			0.78
(95% CI)			(0.60, 1.00)

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KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final/tables/program/t-os.sas
Output: t14-04-005-001-os-fas.rtf (Date generated: 10MAY2017:03:47) Source data: adam.adsl, adam.adtteeff

Table 14-4.7.1. Event Free Survival
(Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Subject status			
Events - n (%)	120 (89.6)	220 (81.2)	
No CR/CRh*/CRi	101 (75.4)	152 (56.1)	
Relapse	8 (6.0)	33 (12.2)	
Progressive disease	1 (0.7)	7 (2.6)	
Extramedullary relapse	1 (0.7)	2 (0.7)	
Death from any cause	9 (6.7)	26 (9.6)	
Censored - n (%)	14 (10.4)	51 (18.8)	
Alive w/o relapse	14 (10.4)	51 (18.8)	
Stratified log-rank test[a]			
Normal score[b]			-22.29
p-value			<0.001
Time to event (KM) (months)[c]			
Median	0.0	0.0	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.0, 0.0	0.0, 8.4	
Min, Max	0.0, 20.2	0.0, 22.6	

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Observed/censored EFS times for both arms are assigned the scheduled time the assessment was supposed to occur in the blinatumomab arm to mitigate the potential bias associated with different treatment cycle lengths between arms; death events will still be reported as the actual death date.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final/tables/program/t-efs.sas
Output: t14-04-007-001-efs-fas.rtf (Date generated: 10MAY2017:03:45) Source data: adam.adsl, adam.adtteeff

Table 14-4.7.1. Event Free Survival (Full Analysis Set)

	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Time to censoring (months)[c,d]			
Median	11.6	16.1	
Q1, Q3	6.1, 15.7	7.8, 17.1	
Min, Max	1.0, 21.2	1.0, 19.8	
KM estimate - %			
At time 3 months[c]	16.8	41.6	
(95% CI)	(10.9, 23.9)	(35.7, 47.4)	
At time 6 months[c]	13.3	31.4	
(95% CI)	(8.0, 19.9)	(25.8, 37.1)	
At time 12 months[c]	7.9	14.4	
(95% CI)	(3.7, 14.0)	(9.8, 19.7)	
At time 18 months[c]	7.9	10.6	
(95% CI)	(3.7, 14.0)	(6.5, 15.8)	
At time 24 months[c]	NE	0.0	
(95% CI)	(NE, NE)	(NE, NE)	
Stratified hazard ratio[e]			0.57
(95% CI)			(0.44, 0.73)

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Observed/censored EFS times for both arms are assigned the scheduled time the assessment was supposed to occur in the blinatumomab arm to mitigate the potential bias associated with different treatment cycle lengths between arms; death events will still be reported as the actual death date.
KM = Kaplan-Meier. CI=Confidence Interval. NE=not estimable
[a]Stratification factors are: age (<35 vs. ≥35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b]A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time
[c]Months are calculated as days from randomization date to event/censor date, divided by 30.5
[d]Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e]The hazard and hazard ratio estimates are obtained from the Cox Proportional Hazard Model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final/tables/program/t-efs.sas
Output: t14-04-007-001-efs-fas.rtf (Date generated: 10MAY2017:03:45) Source data: adam.adsl, adam.adtteeff

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Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete Remission (CR)			
Number of subjects assessed[c]	72	206	
Events - n (%)	21 (29.2)	91 (44.2)	15.0
Unstratified odds ratio[b]			1.92
(95% CI)			(1.08, 3.42)
p-value			0.0267
Stratified odds ratio[a, b]			2.16
(95% CI)			(1.20, 3.90)
p-value			0.0106
Unstratified risk ratio[b]			1.51
(95% CI)			(1.02, 2.24)
p-value			0.0376
Stratified risk ratio[a, b]			1.53
(95% CI)			(1.04, 2.24)
p-value			0.0299
Absolute risk reduction			0.15
(95% CI)			(0.03, 0.28)
p-value			0.0186

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
[d] Stratified risk ratio obtained from generalized poisson model with log link.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete remission with partial hematological recovery (CRh*)			
Number of subjects assessed[c]	72	206	
Events - n (%)	6 (8.3)	24 (11.7)	3.3
Unstratified odds ratio[b]			1.45
(95% CI)			(0.57, 3.70)
p-value			0.4374
Stratified odds ratio[a, b]			1.36
(95% CI)			(0.53, 3.48)
p-value			0.5193
Unstratified risk ratio[b]			1.40
(95% CI)			(0.60, 3.28)
p-value			0.4416
Stratified risk ratio[a, b]			1.32
(95% CI)			(0.57, 3.08)
p-value			0.5141
Absolute risk reduction			0.03
(95% CI)			(-0.04, 0.11)
p-value			0.4011

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
[d] Stratified risk ratio obtained from generalized poisson model with log link.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete remission with incomplete hematological recovery (CRi)			
Number of subjects assessed[c]	72	206	
Events - n (%)	6 (8.3)	4 (1.9)	-6.4
Unstratified odds ratio[b]			0.22
(95% CI)			(0.06, 0.80)
p-value			0.0211
Stratified odds ratio[a, b]			0.23
(95% CI)			(0.06, 0.84)
p-value			0.0263
Unstratified risk ratio[b]			0.23
(95% CI)			(0.07, 0.80)
p-value			0.0209
Stratified risk ratio[a, d]			1.03
(95% CI)			(1.00, 1.07)
p-value			0.0663
Absolute risk reduction			-0.06
(95% CI)			(-0.13, 0.00)
p-value			0.0598

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
[d] Stratified risk ratio obtained from generalized poisson model with log link.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Minimal Residual Disease (MRD)			
Number of subjects assessed[c]	69	166	
Events - n (%)	19 (27.5)	81 (48.8)	21.3
Unstratified odds ratio[b]			2.51
(95% CI)			(1.36, 4.61)
p-value			0.0031
Stratified odds ratio[a, b]			2.54
(95% CI)			(1.38, 4.68)
p-value			0.0028
Unstratified risk ratio[b]			1.77
(95% CI)			(1.17, 2.68)
p-value			0.0067
Stratified risk ratio[a, b]			1.78
(95% CI)			(1.18, 2.69)
p-value			0.0060
Absolute risk reduction			0.21
(95% CI)			(0.08, 0.34)
p-value			0.0013

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
[d] Stratified risk ratio obtained from generalized poisson model with log link.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adrs

Table 14-4.1.1. Summary of Treatment Response and MRD Response (Full Analysis Set)

Parameter	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference
Complete MRD remission			
Number of subjects assessed[c]	69	166	
Events - n (%)	12 (17.4)	64 (38.6)	21.2
Unstratified odds ratio[b]			2.98
(95% CI)			(1.49, 5.98)
p-value			0.0021
Stratified odds ratio[a, b]			3.13
(95% CI)			(1.54, 6.34)
p-value			0.0015
Unstratified risk ratio[b]			2.22
(95% CI)			(1.28, 3.84)
p-value			0.0045
Stratified risk ratio[a, b]			2.21
(95% CI)			(1.29, 3.81)
p-value			0.0041
Absolute risk reduction			0.21
(95% CI)			(0.10, 0.33)
p-value			0.0004

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data. CI = Confidence interval.
[a] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no)
[b] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
[d] Stratified risk ratio obtained from generalized poisson model with log link.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-resp-fas.sas
Output: t14-04-001-001-binary-resp-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adrs

Table 14-4.3.1. Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	51 (59.3)	94 (42.3)	
Censored - n (%)	35 (40.7)	128 (57.7)	
Unstratified log-rank test			
Normal score[a]			-19.62
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-18.46
p-value			<0.0001

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ts-allas.sas
Output: t14-04-003-001-tte-de-allss-ts-allas.rtf (Date generated: 22JUN2025:23:43) Source data: adam_fa.adsl, adam_fa.adqs, adam.adtteqs

Table 14-4.3.1. Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.15	2.79	
95% CI (median)	(0.89, 1.48)	(1.64, 7.34)	
Q1, Q3	0.49, 2.39	0.95, NE	
Min, Max	0.2, 2.5	0.3, 13.8	
Time to censoring (months)[c,d]			
Median	1.54	2.69	
Q1, Q3	0.95, 2.72	0.85, 5.54	
Min, Max	0.2, 3.5	0.3, 20.0	

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ts-allas.sas
Output: t14-04-003-001-tte-de-allss-ts-allas.rtf (Date generated: 22JUN2025:23:43) Source data: adam_fa.adsl, adam_fa.adqs, adam.adtteqs

Table 14-4.3.1. Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	17.83 (7.26, 32.19)	48.11 (39.77, 55.96)	
At time 6 months[c]	NE (NE, NE)	43.14 (34.38, 51.58)	
At time 12 months[c]	NE (NE, NE)	36.20 (24.99, 47.50)	
At time 18 months[c]	NE (NE, NE)	28.96 (14.71, 44.88)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.51
(95% CI)			(0.35, 0.72)
p-value			0.0002

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ts-allas.sas
Output: t14-04-003-001-tte-de-allss-ts-allas.rtf (Date generated: 22JUN2025:23:43) Source data: adam_fa.adsl, adam_fa.adqs, adam.adtteqs

Table 14-4.3.2. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Tiredness (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	53 (61.6)	103 (46.4)	
Censored - n (%)	33 (38.4)	119 (53.6)	
Unstratified log-rank test			
Normal score[a]			-17.50
p-value			0.0003
Stratified log-rank test[b]			
Normal score[a]			-17.32
p-value			0.0003

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda1t-allas.sas
Output: t14-04-003-002-tte-de-allss-ttda1t-allas.rtf (Date generated: 24JUN2025:22:51) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.2. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Tiredness (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.52	3.25	
95% CI (median)	(0.46, 1.11)	(1.41, 11.51)	
Q1, Q3	0.26, NE	0.49, NE	
Min, Max	0.2, 1.8	0.3, 11.5	
Time to censoring (months)[c,d]			
Median	1.54	2.75	
Q1, Q3	1.02, 2.33	0.95, 6.26	
Min, Max	0.2, 3.4	0.3, 18.9	

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda1t-allas.sas
Output: t14-04-003-002-tte-de-allss-ttda1t-allas.rtf (Date generated: 24JUN2025:22:51) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.2. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Tiredness (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	31.34 (20.34, 42.93)	50.30 (42.64, 57.47)	
At time 6 months[c]	NE (NE, NE)	48.08 (40.16, 55.55)	
At time 12 months[c]	NE (NE, NE)	35.81 (23.68, 48.08)	
At time 18 months[c]	NE (NE, NE)	35.81 (23.68, 48.08)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.54
(95% CI)			(0.39, 0.77)
p-value			0.0005

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda1t-allas.sas
Output: t14-04-003-002-tte-de-allss-ttda1t-allas.rtf (Date generated: 24JUN2025:22:51) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.3. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Weakness (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	59 (68.6)	106 (47.7)	
Censored - n (%)	27 (31.4)	116 (52.3)	
Unstratified log-rank test			
Normal score[a]			-22.69
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-21.72
p-value			<0.0001

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda2pw-allas.sas
Output: t14-04-003-003-tte-de-allss-ttda2pw-allas.rtf (Date generated: 24JUN2025:23:08) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.3. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Weakness (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.49	2.46	
95% CI (median)	(0.46, 0.98)	(0.98, 8.13)	
Q1, Q3	0.26, 1.48	0.49, NE	
Min, Max	0.2, 1.8	0.3, 11.5	
Time to censoring (months)[c,d]			
Median	1.54	2.49	
Q1, Q3	1.02, 2.33	0.95, 5.77	
Min, Max	0.3, 3.4	0.3, 18.9	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda2pw-allas.sas
Output: t14-04-003-003-tte-de-allss-ttda2pw-allas.rtf (Date generated: 24JUN2025:23:08) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.3. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Weakness (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	21.08 (11.17, 33.08)	46.89 (39.02, 54.37)	
At time 6 months[c]	NE (NE, NE)	44.69 (36.63, 52.41)	
At time 12 months[c]	NE (NE, NE)	28.56 (15.62, 42.92)	
At time 18 months[c]	NE (NE, NE)	28.56 (15.62, 42.92)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.49
(95% CI)			(0.35, 0.68)
p-value			<0.0001

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda2pw-allas.sas
Output: t14-04-003-003-tte-de-allss-ttda2pw-allas.rtf (Date generated: 24JUN2025:23:08) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.4. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bruise (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	38 (44.2)	58 (26.1)	
Censored - n (%)	48 (55.8)	164 (73.9)	
Unstratified log-rank test			
Normal score[a]			-14.65
p-value			0.0003
Stratified log-rank test[b]			
Normal score[a]			-13.85
p-value			0.0006

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda3br-allas.sas
Output: t14-04-003-004-tte-de-allss-ttda3br-allas.rtf (Date generated: 24JUN2025:23:25) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.4. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bruise (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	2.33	NE	
95% CI (median)	(0.89, NE)	(8.13, NE)	
Q1, Q3	0.46, NE	1.18, NE	
Min, Max	0.2, 2.3	0.3, 8.1	
Time to censoring (months)[c,d]			
Median	1.61	2.49	
Q1, Q3	0.95, 2.43	0.95, 5.15	
Min, Max	0.2, 6.3	0.3, 18.9	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda3br-allas.sas
Output: t14-04-003-004-tte-de-allss-ttda3br-allas.rtf (Date generated: 24JUN2025:23:25) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.4. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bruise (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	48.77 (35.80, 60.54)	72.22 (65.07, 78.16)	
At time 6 months[c]	48.77 (35.80, 60.54)	67.53 (58.81, 74.80)	
At time 12 months[c]	NE (NE, NE)	62.33 (48.85, 73.21)	
At time 18 months[c]	NE (NE, NE)	62.33 (48.85, 73.21)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.50
(95% CI)			(0.33, 0.75)
p-value			0.0011

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda3br-allas.sas
Output: t14-04-003-004-tte-de-allss-ttda3br-allas.rtf (Date generated: 24JUN2025:23:25) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.5. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bleeding (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	27 (31.4)	61 (27.5)	
Censored - n (%)	59 (68.6)	161 (72.5)	
Unstratified log-rank test			
Normal score[a]			-4.74
p-value			0.2254
Stratified log-rank test[b]			
Normal score[a]			-4.38
p-value			0.2582

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda4bl-allas.sas
Output: t14-04-003-005-tte-de-allss-ttda4bl-allas.rtf (Date generated: 24JUN2025:23:25) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.5. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bleeding (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	NE	NE	
95% CI (median)	(2.43, NE)	(8.13, NE)	
Q1, Q3	0.75, NE	1.41, NE	
Min, Max	0.2, 2.5	0.3, 8.1	
Time to censoring (months)[c,d]			
Median	1.54	2.46	
Q1, Q3	0.95, 2.39	0.95, 4.85	
Min, Max	0.2, 6.3	0.3, 18.9	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda4bl-allas.sas
Output: t14-04-003-005-tte-de-allss-ttda4bl-allas.rtf (Date generated: 24JUN2025:23:25) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.5. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bleeding (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	57.47 (40.26, 71.36)	71.16 (63.90, 77.22)	
At time 6 months[c]	57.47 (40.26, 71.36)	68.55 (60.58, 75.24)	
At time 12 months[c]	NE (NE, NE)	58.20 (44.19, 69.85)	
At time 18 months[c]	NE (NE, NE)	58.20 (44.19, 69.85)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.78
(95% CI)			(0.49, 1.24)
p-value			0.2916

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda4bl-allas.sas
Output: t14-04-003-005-tte-de-allss-ttda4bl-allas.rtf (Date generated: 24JUN2025:23:25) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.6. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fever (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	59 (68.6)	150 (67.6)	
Censored - n (%)	27 (31.4)	72 (32.4)	
Unstratified log-rank test			
Normal score[a]			-0.17
p-value			0.9759
Stratified log-rank test[b]			
Normal score[a]			0.24
p-value			0.9653

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda5f-allas.sas
Output: t14-04-003-006-tte-de-allss-ttda5f-allas.rtf (Date generated: 24JUN2025:23:26) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.6. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fever (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.49	0.49	
95% CI (median)	(0.49, 0.92)	(0.26, 0.49)	
Q1, Q3	0.26, 2.10	0.26, 5.11	
Min, Max	0.2, 2.3	0.2, 5.1	
Time to censoring (months)[c,d]			
Median	1.48	2.49	
Q1, Q3	0.95, 2.43	0.98, 5.44	
Min, Max	0.3, 2.9	0.3, 18.9	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda5f-allas.sas
Output: t14-04-003-006-tte-de-allss-ttda5f-allas.rtf (Date generated: 24JUN2025:23:26) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.6. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fever (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	NE (NE, NE)	30.58 (24.11, 37.28)	
At time 6 months[c]	NE (NE, NE)	24.69 (17.61, 32.42)	
At time 12 months[c]	NE (NE, NE)	24.69 (17.61, 32.42)	
At time 18 months[c]	NE (NE, NE)	24.69 (17.61, 32.42)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			1.09
(95% CI)			(0.80, 1.49)
p-value			0.5866

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda5f-allas.sas
Output: t14-04-003-006-tte-de-allss-ttda5f-allas.rtf (Date generated: 24JUN2025:23:26) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.7. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Joint or bone pain (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	40 (46.5)	109 (49.1)	
Censored - n (%)	46 (53.5)	113 (50.9)	
Unstratified log-rank test			
Normal score[a]			-3.46
p-value			0.4839
Stratified log-rank test[b]			
Normal score[a]			-4.00
p-value			0.4080

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda6p-allas.sas
Output: t14-04-003-007-tte-de-allss-ttda6p-allas.rtf (Date generated: 24JUN2025:23:26) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.7. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Joint or bone pain (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.44	2.36	
95% CI (median)	(0.95, NE)	(1.41, 3.93)	
Q1, Q3	0.49, NE	0.49, NE	
Min, Max	0.2, 1.8	0.3, 11.5	
Time to censoring (months)[c,d]			
Median	1.54	2.56	
Q1, Q3	0.98, 2.39	0.95, 6.66	
Min, Max	0.3, 6.3	0.3, 20.0	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda6p-allas.sas
Output: t14-04-003-007-tte-de-allss-ttda6p-allas.rtf (Date generated: 24JUN2025:23:26) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.7. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Joint or bone pain (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	44.28 (31.45, 56.35)	44.63 (36.65, 52.28)	
At time 6 months[c]	44.28 (31.45, 56.35)	37.20 (28.73, 45.65)	
At time 12 months[c]	NE (NE, NE)	26.69 (12.16, 43.68)	
At time 18 months[c]	NE (NE, NE)	26.69 (12.16, 43.68)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.87
(95% CI)			(0.60, 1.27)
p-value			0.4676

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda6p-allas.sas
Output: t14-04-003-007-tte-de-allss-ttda6p-allas.rtf (Date generated: 24JUN2025:23:26) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.8. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Itch (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	38 (44.2)	90 (40.5)	
Censored - n (%)	48 (55.8)	132 (59.5)	
Unstratified log-rank test			
Normal score[a]			-9.48
p-value			0.0338
Stratified log-rank test[b]			
Normal score[a]			-10.12
p-value			0.0216

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda7i-allas.sas
Output: t14-04-003-008-tte-de-allss-ttda7i-allas.rtf (Date generated: 25JUN2025:00:05) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.8. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Itch (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	2.26	4.85	
95% CI (median)	(0.92, NE)	(2.52, 6.00)	
Q1, Q3	0.39, NE	0.95, NE	
Min, Max	0.2, 2.3	0.2, 11.4	
Time to censoring (months)[c,d]			
Median	1.48	2.49	
Q1, Q3	0.98, 2.33	0.95, 5.41	
Min, Max	0.2, 6.3	0.3, 20.0	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda7i-allas.sas
Output: t14-04-003-008-tte-de-allss-ttda7i-allas.rtf (Date generated: 25JUN2025:00:05) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.8. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Itch (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	48.26 (34.36, 60.84)	55.54 (47.25, 63.05)	
At time 6 months[c]	48.26 (34.36, 60.84)	39.75 (29.48, 49.82)	
At time 12 months[c]	NE (NE, NE)	29.88 (17.58, 43.19)	
At time 18 months[c]	NE (NE, NE)	29.88 (17.58, 43.19)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.64
(95% CI)			(0.43, 0.94)
p-value			0.0231

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda7i-allas.sas
Output: t14-04-003-008-tte-de-allss-ttda7i-allas.rtf (Date generated: 25JUN2025:00:05) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.9. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Swollen lymph nodes (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	17 (19.8)	39 (17.6)	
Censored - n (%)	69 (80.2)	183 (82.4)	
Unstratified log-rank test			
Normal score[a]			-3.73
p-value			0.2266
Stratified log-rank test[b]			
Normal score[a]			-3.51
p-value			0.2538

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda8sl-allas.sas
Output: t14-04-003-009-tte-de-allss-ttda8sl-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.9. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Swollen lymph nodes (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	4.52, NE	
Min, Max	0.2, 1.2	0.3, 7.3	
Time to censoring (months)[c,d]			
Median	1.54	2.46	
Q1, Q3	0.95, 2.33	0.79, 5.41	
Min, Max	0.2, 6.3	0.3, 20.0	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda8sl-allas.sas
Output: t14-04-003-009-tte-de-allss-ttda8sl-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.9. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Swollen lymph nodes (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	77.97 (66.74, 85.80)	79.87 (72.58, 85.42)	
At time 6 months[c]	77.97 (66.74, 85.80)	74.38 (65.45, 81.33)	
At time 12 months[c]	NE (NE, NE)	71.15 (60.07, 79.66)	
At time 18 months[c]	NE (NE, NE)	71.15 (60.07, 79.66)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.71
(95% CI)			(0.39, 1.29)
p-value			0.2623

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda8sl-allas.sas
Output: t14-04-003-009-tte-de-allss-ttda8sl-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.10. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fighting infection (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	58 (67.4)	120 (54.1)	
Censored - n (%)	28 (32.6)	102 (45.9)	
Unstratified log-rank test			
Normal score[a]			-17.34
p-value			0.0008
Stratified log-rank test[b]			
Normal score[a]			-14.68
p-value			0.0049

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda9fi-allas.sas
Output: t14-04-003-010-tte-de-allss-ttda9fi-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.10. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fighting infection (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.59	1.54	
95% CI (median)	(0.49, 1.15)	(0.95, 3.02)	
Q1, Q3	0.46, 2.33	0.49, NE	
Min, Max	0.2, 3.0	0.3, 6.9	
Time to censoring (months)[c,d]			
Median	1.54	2.69	
Q1, Q3	0.95, 2.66	0.95, 5.41	
Min, Max	0.3, 3.4	0.3, 18.9	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda9fi-allas.sas
Output: t14-04-003-010-tte-de-allss-ttda9fi-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.10. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fighting infection (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	9.74 (1.19, 29.42)	42.65 (35.08, 50.01)	
At time 6 months[c]	NE (NE, NE)	30.10 (21.54, 39.10)	
At time 12 months[c]	NE (NE, NE)	26.75 (17.34, 37.07)	
At time 18 months[c]	NE (NE, NE)	26.75 (17.34, 37.07)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.64
(95% CI)			(0.46, 0.89)
p-value			0.0076

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda9fi-allas.sas
Output: t14-04-003-010-tte-de-allss-ttda9fi-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.11. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Short of breath (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	41 (47.7)	74 (33.3)	
Censored - n (%)	45 (52.3)	148 (66.7)	
Unstratified log-rank test			
Normal score[a]			-14.18
p-value			0.0010
Stratified log-rank test[b]			
Normal score[a]			-12.51
p-value			0.0043

Page 1 of 3

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda10b-allas.sas
Output: t14-04-003-011-tte-de-allss-ttda10b-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.11. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Short of breath (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.87	NE	
95% CI (median)	(0.95, 2.56)	(4.98, NE)	
Q1, Q3	0.49, 2.82	0.95, NE	
Min, Max	0.2, 2.8	0.3, 5.3	
Time to censoring (months)[c,d]			
Median	1.48	2.56	
Q1, Q3	1.15, 2.03	0.95, 5.11	
Min, Max	0.2, 3.5	0.3, 20.0	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda10b-allas.sas
Output: t14-04-003-011-tte-de-allss-ttda10b-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.11. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Short of breath (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	19.25 (4.32, 42.15)	63.17 (55.45, 69.92)	
At time 6 months[c]	NE (NE, NE)	54.77 (44.92, 63.57)	
At time 12 months[c]	NE (NE, NE)	54.77 (44.92, 63.57)	
At time 18 months[c]	NE (NE, NE)	54.77 (44.92, 63.57)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.57
(95% CI)			(0.38, 0.85)
p-value			0.0057

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda10b-allas.sas
Output: t14-04-003-011-tte-de-allss-ttda10b-allas.rtf (Date generated: 25JUN2025:00:06) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.12. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Unable to eat (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	53 (61.6)	124 (55.9)	
Censored - n (%)	33 (38.4)	98 (44.1)	
Unstratified log-rank test			
Normal score[a]			-13.47
p-value			0.0094
Stratified log-rank test[b]			
Normal score[a]			-12.27
p-value			0.0181

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda11e-allas.sas
Output: t14-04-003-012-tte-de-allss-ttda11e-allas.rtf (Date generated: 25JUN2025:00:07) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.12. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Unable to eat (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.52	1.41	
95% CI (median)	(0.39, 1.38)	(0.98, 2.00)	
Q1, Q3	0.26, NE	0.49, 6.26	
Min, Max	0.2, 2.5	0.3, 6.3	
Time to censoring (months)[c,d]			
Median	1.74	2.56	
Q1, Q3	1.15, 2.72	0.95, 4.62	
Min, Max	0.2, 4.1	0.3, 13.0	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda11e-allas.sas
Output: t14-04-003-012-tte-de-allss-ttda11e-allas.rtf (Date generated: 25JUN2025:00:07) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.12. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Unable to eat (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	29.88 (18.43, 42.19)	37.64 (29.98, 45.26)	
At time 6 months[c]	NE (NE, NE)	25.48 (17.12, 34.66)	
At time 12 months[c]	NE (NE, NE)	20.38 (11.85, 30.54)	
At time 18 months[c]	NE (NE, NE)	NE (NE, NE)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.68
(95% CI)			(0.49, 0.95)
p-value			0.0226

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda11e-allas.sas
Output: t14-04-003-012-tte-de-allss-ttda11e-allas.rtf (Date generated: 25JUN2025:00:07) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.13. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Night sweats (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Subject status			
Number of subjects	86	222	
Events - n (%)	43 (50.0)	110 (49.5)	
Censored - n (%)	43 (50.0)	112 (50.5)	
Unstratified log-rank test			
Normal score[a]			-2.72
p-value			0.5920
Stratified log-rank test[b]			
Normal score[a]			-1.55
p-value			0.7590

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda12s-allas.sas
Output: t14-04-003-013-tte-de-allss-ttda12s-allas.rtf (Date generated: 25JUN2025:00:07) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.13. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Night sweats (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.38	1.87	
95% CI (median)	(0.92, NE)	(1.05, 6.46)	
Q1, Q3	0.49, NE	0.43, NE	
Min, Max	0.2, 2.5	0.3, 7.5	
Time to censoring (months)[c,d]			
Median	1.48	2.46	
Q1, Q3	1.08, 2.39	0.95, 5.64	
Min, Max	0.3, 4.1	0.3, 18.9	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda12s-allas.sas
Output: t14-04-003-013-tte-de-allss-ttda12s-allas.rtf (Date generated: 25JUN2025:00:07) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.13. Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Night sweats (ALLSS Analysis Set)

	SOC Chemotherapy (N=86)	Blinatumomab (N=223)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	37.63 (23.26, 51.94)	45.52 (37.86, 52.84)	
At time 6 months[c]	NE (NE, NE)	42.73 (34.64, 50.55)	
At time 12 months[c]	NE (NE, NE)	37.08 (26.83, 47.32)	
At time 18 months[c]	NE (NE, NE)	37.08 (26.83, 47.32)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.97
(95% CI)			(0.68, 1.39)
p-value			0.8772

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. ALLSS = Acute lymphoblastic leukemia symptom scale.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-allss-ttda12s-allas.sas
Output: t14-04-003-013-tte-de-allss-ttda12s-allas.rtf (Date generated: 25JUN2025:00:07) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.14. Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	95	240	
Events - n (%)	50 (52.6)	100 (41.7)	
Censored - n (%)	45 (47.4)	140 (58.3)	
Unstratified log-rank test			
Normal score[a]			-15.49
p-value			0.0012
Stratified log-rank test[b]			
Normal score[a]			-14.51
p-value			0.0026

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. QoL = Quality of Life.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-ghs-eqcas.sas
Output: t14-04-003-014-tte-de-eortc-ghs-eqcas.rtf (Date generated: 24JUN2025:23:13) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.14. Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.05	6.43	
95% CI (median)	(0.49, 1.77)	(2.82, NE)	
Q1, Q3	0.26, NE	0.49, NE	
Min, Max	0.2, 2.5	0.3, 8.1	
Time to censoring (months)[c,d]			
Median	1.54	2.56	
Q1, Q3	0.49, 2.43	0.95, 6.33	
Min, Max	0.2, 3.4	0.3, 18.6	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. QoL = Quality of Life.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-ghs-eqcas.sas
Output: t14-04-003-014-tte-de-eortc-ghs-eqcas.rtf (Date generated: 24JUN2025:23:13) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.14. Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	32.90 (19.91, 46.50)	55.78 (48.44, 62.50)	
At time 6 months[c]	NE (NE, NE)	51.16 (43.11, 58.63)	
At time 12 months[c]	NE (NE, NE)	45.28 (34.26, 55.65)	
At time 18 months[c]	NE (NE, NE)	45.28 (34.26, 55.65)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.60
(95% CI)			(0.42, 0.85)
p-value			0.0043

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. QoL = Quality of Life.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-ghs-eqcas.sas
Output: t14-04-003-014-tte-de-eortc-ghs-eqcas.rtf (Date generated: 24JUN2025:23:13) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.15. Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	241	
Events - n (%)	59 (62.8)	127 (52.7)	
Censored - n (%)	35 (37.2)	114 (47.3)	
Unstratified log-rank test			
Normal score[a]			-15.20
p-value			0.0046
Stratified log-rank test[b]			
Normal score[a]			-13.19
p-value			0.0142

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-pf-eqcas.sas
Output: t14-04-003-015-tte-de-eortc-pf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.15. Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.89	1.51	
95% CI (median)	(0.49, 1.05)	(0.95, 3.15)	
Q1, Q3	0.33, 2.46	0.49, NE	
Min, Max	0.2, 2.5	0.3, 11.5	
Time to censoring (months)[c,d]			
Median	1.54	3.15	
Q1, Q3	0.95, 2.43	1.05, 6.52	
Min, Max	0.2, 3.5	0.3, 18.6	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-pf-eqcas.sas
Output: t14-04-003-015-tte-de-eortc-pf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.15. Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	24.27 (13.07, 37.33)	45.31 (38.27, 52.07)	
At time 6 months[c]	NE (NE, NE)	39.96 (32.62, 47.19)	
At time 12 months[c]	NE (NE, NE)	31.08 (19.44, 43.44)	
At time 18 months[c]	NE (NE, NE)	31.08 (19.44, 43.44)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.69
(95% CI)			(0.50, 0.95)
p-value			0.0228

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-pf-eqcas.sas
Output: t14-04-003-015-tte-de-eortc-pf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.16. Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	91	241	
Events - n (%)	66 (72.5)	141 (58.5)	
Censored - n (%)	25 (27.5)	100 (41.5)	
Unstratified log-rank test			
Normal score[a]			-19.65
p-value			0.0002
Stratified log-rank test[b]			
Normal score[a]			-18.38
p-value			0.0006

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-rf-eqcas.sas
Output: t14-04-003-016-tte-de-eortc-rf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.16. Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.49	0.98	
95% CI (median)	(0.26, 0.95)	(0.56, 1.80)	
Q1, Q3	0.26, 1.70	0.26, 11.51	
Min, Max	0.2, 2.0	0.3, 11.5	
Time to censoring (months)[c,d]			
Median	1.61	2.56	
Q1, Q3	1.08, 2.26	0.95, 6.52	
Min, Max	0.2, 4.1	0.3, 18.9	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-rf-eqcas.sas
Output: t14-04-003-016-tte-de-eortc-rf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.16. Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	14.70 (6.56, 25.95)	37.75 (30.74, 44.73)	
At time 6 months[c]	NE (NE, NE)	31.12 (23.75, 38.76)	
At time 12 months[c]	NE (NE, NE)	23.52 (14.33, 34.01)	
At time 18 months[c]	NE (NE, NE)	23.52 (14.33, 34.01)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.60
(95% CI)			(0.44, 0.81)
p-value			0.0008

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-rf-eqcas.sas
Output: t14-04-003-016-tte-de-eortc-rf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.17. Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	95	242	
Events - n (%)	58 (61.1)	126 (52.1)	
Censored - n (%)	37 (38.9)	116 (47.9)	
Unstratified log-rank test			
Normal score[a]			-16.82
p-value			0.0012
Stratified log-rank test[b]			
Normal score[a]			-14.52
p-value			0.0050

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-cf-eqcas.sas
Output: t14-04-003-017-tte-de-eortc-cf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.17. Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.92	2.00	
95% CI (median)	(0.49, 1.38)	(1.41, 3.25)	
Q1, Q3	0.26, 2.13	0.46, NE	
Min, Max	0.2, 2.5	0.3, 7.4	
Time to censoring (months)[c,d]			
Median	1.61	2.75	
Q1, Q3	0.95, 2.43	0.95, 6.46	
Min, Max	0.2, 3.5	0.3, 20.0	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-cf-eqcas.sas
Output: t14-04-003-017-tte-de-eortc-cf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.17. Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	19.92 (9.13, 33.70)	44.57 (37.15, 51.70)	
At time 6 months[c]	NE (NE, NE)	33.41 (25.37, 41.63)	
At time 12 months[c]	NE (NE, NE)	30.84 (22.16, 39.93)	
At time 18 months[c]	NE (NE, NE)	30.84 (22.16, 39.93)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.66
(95% CI)			(0.48, 0.91)
p-value			0.0119

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-cf-eqcas.sas
Output: t14-04-003-017-tte-de-eortc-cf-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.18. Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	241	
Events - n (%)	35 (37.2)	75 (31.1)	
Censored - n (%)	59 (62.8)	166 (68.9)	
Unstratified log-rank test			
Normal score[a]			-11.10
p-value			0.0074
Stratified log-rank test[b]			
Normal score[a]			-9.75
p-value			0.0199

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-ef-eqcas.sas
Output: t14-04-003-018-tte-de-eortc-ef-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.18. Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	2.79	11.51	
95% CI (median)	(1.54, NE)	(6.66, NE)	
Q1, Q3	0.49, NE	1.54, NE	
Min, Max	0.2, 2.8	0.3, 11.5	
Time to censoring (months)[c,d]			
Median	1.48	2.56	
Q1, Q3	0.75, 2.33	0.95, 6.26	
Min, Max	0.2, 6.3	0.3, 20.0	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-ef-eqcas.sas
Output: t14-04-003-018-tte-de-eortc-ef-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.18. Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	43.78 (24.42, 61.63)	66.57 (59.05, 73.02)	
At time 6 months[c]	43.78 (24.42, 61.63)	60.94 (52.47, 68.36)	
At time 12 months[c]	NE (NE, NE)	45.58 (31.54, 58.58)	
At time 18 months[c]	NE (NE, NE)	45.58 (31.54, 58.58)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.61
(95% CI)			(0.40, 0.93)
p-value			0.0226

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-ef-eqcas.sas
Output: t14-04-003-018-tte-de-eortc-ef-eqcas.rtf (Date generated: 24JUN2025:23:14) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.19. Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	53 (56.4)	136 (56.2)	
Censored - n (%)	41 (43.6)	106 (43.8)	
Unstratified log-rank test			
Normal score[a]			-8.44
p-value			0.1164
Stratified log-rank test[b]			
Normal score[a]			-6.86
p-value			0.2039

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-sf-eqcas.sas
Output: t14-04-003-019-tte-de-eortc-sf-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.19. Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.98	1.15	
95% CI (median)	(0.49, 1.77)	(0.95, 2.00)	
Q1, Q3	0.26, NE	0.46, NE	
Min, Max	0.2, 2.5	0.2, 11.5	
Time to censoring (months)[c,d]			
Median	1.61	2.92	
Q1, Q3	0.75, 2.43	0.95, 6.46	
Min, Max	0.2, 4.1	0.3, 18.9	

Page 2 of 3

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-sf-eqcas.sas
Output: t14-04-003-019-tte-de-eortc-sf-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.19. Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	25.85 (13.42, 40.20)	39.30 (32.18, 46.34)	
At time 6 months[c]	NE (NE, NE)	30.32 (22.69, 38.30)	
At time 12 months[c]	NE (NE, NE)	26.96 (18.10, 36.58)	
At time 18 months[c]	NE (NE, NE)	26.96 (18.10, 36.58)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.82
(95% CI)			(0.59, 1.14)
p-value			0.2443

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-sf-eqcas.sas
Output: t14-04-003-019-tte-de-eortc-sf-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.20. Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	69 (73.4)	140 (57.9)	
Censored - n (%)	25 (26.6)	102 (42.1)	
Unstratified log-rank test			
Normal score[a]			-24.37
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-23.76
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-fs-eqcas.sas
Output: t14-04-003-020-tte-de-eortc-fs-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.20. Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.33	0.98	
95% CI (median)	(0.26, 0.49)	(0.52, 1.54)	
Q1, Q3	0.26, 1.25	0.26, NE	
Min, Max	0.2, 1.6	0.3, 6.9	
Time to censoring (months)[c,d]			
Median	1.48	2.56	
Q1, Q3	1.02, 2.03	0.95, 5.41	
Min, Max	0.3, 3.4	0.3, 17.7	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-fs-eqcas.sas
Output: t14-04-003-020-tte-de-eortc-fs-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.20. Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	18.64 (10.10, 29.22)	37.81 (30.88, 44.70)	
At time 6 months[c]	NE (NE, NE)	32.94 (25.54, 40.52)	
At time 12 months[c]	NE (NE, NE)	28.08 (19.47, 37.30)	
At time 18 months[c]	NE (NE, NE)	NE (NE, NE)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.53
(95% CI)			(0.39, 0.71)
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-fs-eqcas.sas
Output: t14-04-003-020-tte-de-eortc-fs-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.21. Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	245	
Events - n (%)	67 (71.3)	135 (55.1)	
Censored - n (%)	27 (28.7)	110 (44.9)	
Unstratified log-rank test			
Normal score[a]			-23.46
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-23.03
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-pas-eqcas.sas
Output: t14-04-003-021-tte-de-eortc-pas-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.21. Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.49	1.48	
95% CI (median)	(0.46, 0.92)	(1.11, 2.00)	
Q1, Q3	0.26, 1.70	0.49, NE	
Min, Max	0.2, 2.0	0.3, 6.5	
Time to censoring (months)[c,d]			
Median	1.87	2.56	
Q1, Q3	1.18, 2.79	1.05, 6.66	
Min, Max	0.3, 3.5	0.3, 20.0	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-pas-eqcas.sas
Output: t14-04-003-021-tte-de-eortc-pas-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.21. Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	20.16 (11.42, 30.67)	39.38 (32.17, 46.50)	
At time 6 months[c]	NE (NE, NE)	29.89 (22.18, 37.97)	
At time 12 months[c]	NE (NE, NE)	28.53 (20.81, 36.72)	
At time 18 months[c]	NE (NE, NE)	28.53 (20.81, 36.72)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.54
(95% CI)			(0.40, 0.73)
p-value			<0.0001

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-pas-eqcas.sas
Output: t14-04-003-021-tte-de-eortc-pas-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.22. Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	54 (57.4)	92 (38.0)	
Censored - n (%)	40 (42.6)	150 (62.0)	
Unstratified log-rank test			
Normal score[a]			-25.56
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-25.30
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-nvs-eqcas.sas
Output: t14-04-003-022-tte-de-eortc-nvs-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.22. Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.52	4.16	
95% CI (median)	(0.30, 1.87)	(3.15, 6.49)	
Q1, Q3	0.26, NE	0.95, NE	
Min, Max	0.2, 2.8	0.3, 6.5	
Time to censoring (months)[c,d]			
Median	1.48	2.43	
Q1, Q3	0.95, 2.33	0.95, 5.61	
Min, Max	0.2, 3.4	0.3, 18.9	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-nvs-eqcas.sas
Output: t14-04-003-022-tte-de-eortc-nvs-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.22. Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	27.38 (11.74, 45.70)	59.75 (51.86, 66.77)	
At time 6 months[c]	NE (NE, NE)	45.03 (35.51, 54.07)	
At time 12 months[c]	NE (NE, NE)	39.23 (29.07, 49.23)	
At time 18 months[c]	NE (NE, NE)	39.23 (29.07, 49.23)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.35
(95% CI)			(0.25, 0.51)
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-nvs-eqcas.sas
Output: t14-04-003-022-tte-de-eortc-nvs-eqcas.rtf (Date generated: 24JUN2025:23:15) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.23. Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	93	241	
Events - n (%)	39 (41.9)	75 (31.1)	
Censored - n (%)	54 (58.1)	166 (68.9)	
Unstratified log-rank test			
Normal score[a]			-11.62
p-value			0.0081
Stratified log-rank test[b]			
Normal score[a]			-11.92
p-value			0.0059

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-dys-eqcas.sas
Output: t14-04-003-023-tte-de-eortc-dys-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.23. Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	2.33	NE	
95% CI (median)	(1.21, NE)	(NE, NE)	
Q1, Q3	0.52, NE	0.98, NE	
Min, Max	0.2, 2.6	0.3, 5.3	
Time to censoring (months)[c,d]			
Median	1.48	2.49	
Q1, Q3	1.05, 2.03	0.95, 5.54	
Min, Max	0.3, 4.1	0.3, 20.0	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-dys-eqcas.sas
Output: t14-04-003-023-tte-de-eortc-dys-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.23. Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	34.95 (16.38, 54.29)	62.62 (54.98, 69.34)	
At time 6 months[c]	NE (NE, NE)	59.62 (51.18, 67.07)	
At time 12 months[c]	NE (NE, NE)	59.62 (51.18, 67.07)	
At time 18 months[c]	NE (NE, NE)	59.62 (51.18, 67.07)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.59
(95% CI)			(0.39, 0.87)
p-value			0.0085

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-dys-eqcas.sas
Output: t14-04-003-023-tte-de-eortc-dys-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.24. Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	93	241	
Events - n (%)	59 (63.4)	112 (46.5)	
Censored - n (%)	34 (36.6)	129 (53.5)	
Unstratified log-rank test			
Normal score[a]			-26.14
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-25.64
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-aps-eqcas.sas
Output: t14-04-003-024-tte-de-eortc-aps-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.24. Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.49	3.15	
95% CI (median)	(0.39, 1.05)	(2.33, 4.36)	
Q1, Q3	0.26, 2.56	0.49, NE	
Min, Max	0.2, 2.6	0.3, 8.1	
Time to censoring (months)[c,d]			
Median	1.54	2.56	
Q1, Q3	0.95, 2.33	0.95, 5.70	
Min, Max	0.2, 3.4	0.3, 18.9	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-aps-eqcas.sas
Output: t14-04-003-024-tte-de-eortc-aps-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.24. Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	22.92 (11.26, 37.01)	52.62 (44.98, 59.70)	
At time 6 months[c]	NE (NE, NE)	38.35 (29.61, 47.01)	
At time 12 months[c]	NE (NE, NE)	26.02 (14.59, 39.00)	
At time 18 months[c]	NE (NE, NE)	26.02 (14.59, 39.00)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.40
(95% CI)			(0.28, 0.56)
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-aps-eqcas.sas
Output: t14-04-003-024-tte-de-eortc-aps-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.25. Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	242	
Events - n (%)	48 (51.1)	120 (49.6)	
Censored - n (%)	46 (48.9)	122 (50.4)	
Unstratified log-rank test			
Normal score[a]			-8.74
p-value			0.0856
Stratified log-rank test[b]			
Normal score[a]			-7.33
p-value			0.1472

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-sls-eqcas.sas
Output: t14-04-003-025-tte-de-eortc-sls-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.25. Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.95	2.00	
95% CI (median)	(0.49, 2.46)	(1.15, 6.23)	
Q1, Q3	0.33, NE	0.49, NE	
Min, Max	0.2, 2.5	0.3, 10.0	
Time to censoring (months)[c,d]			
Median	1.41	2.49	
Q1, Q3	0.95, 2.33	0.95, 5.77	
Min, Max	0.2, 3.4	0.3, 18.6	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-sls-eqcas.sas
Output: t14-04-003-025-tte-de-eortc-sls-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.25. Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	31.80 (16.96, 47.73)	48.56 (41.31, 55.42)	
At time 6 months[c]	NE (NE, NE)	42.23 (34.02, 50.19)	
At time 12 months[c]	NE (NE, NE)	27.94 (16.28, 40.82)	
At time 18 months[c]	NE (NE, NE)	27.94 (16.28, 40.82)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.79
(95% CI)			(0.55, 1.11)
p-value			0.1746

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-sls-eqcas.sas
Output: t14-04-003-025-tte-de-eortc-sls-eqcas.rtf (Date generated: 24JUN2025:23:16) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.26. Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	240	
Events - n (%)	43 (45.7)	73 (30.4)	
Censored - n (%)	51 (54.3)	167 (69.6)	
Unstratified log-rank test			
Normal score[a]			-15.82
p-value			0.0002
Stratified log-rank test[b]			
Normal score[a]			-16.07
p-value			0.0002

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-cos-eqcas.sas
Output: t14-04-003-026-tte-de-eortc-cos-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.26. Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	1.70	NE	
95% CI (median)	(0.98, NE)	(5.05, NE)	
Q1, Q3	0.46, NE	1.18, NE	
Min, Max	0.2, 2.0	0.3, 5.0	
Time to censoring (months)[c,d]			
Median	1.38	2.33	
Q1, Q3	0.95, 2.33	0.95, 5.41	
Min, Max	0.2, 4.1	0.3, 20.0	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-cos-eqcas.sas
Output: t14-04-003-026-tte-de-eortc-cos-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.26. Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	42.15 (29.06, 54.67)	67.69 (60.34, 73.98)	
At time 6 months[c]	NE (NE, NE)	58.27 (48.94, 66.48)	
At time 12 months[c]	NE (NE, NE)	58.27 (48.94, 66.48)	
At time 18 months[c]	NE (NE, NE)	58.27 (48.94, 66.48)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.48
(95% CI)			(0.33, 0.71)
p-value			0.0003

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-cos-eqcas.sas
Output: t14-04-003-026-tte-de-eortc-cos-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.27. Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	240	
Events - n (%)	52 (55.3)	78 (32.5)	
Censored - n (%)	42 (44.7)	162 (67.5)	
Unstratified log-rank test			
Normal score[a]			-25.56
p-value			<0.0001
Stratified log-rank test[b]			
Normal score[a]			-25.56
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-dis-eqcas.sas
Output: t14-04-003-027-tte-de-eortc-dis-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.27. Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	0.75	5.97	
95% CI (median)	(0.49, 2.49)	(3.41, NE)	
Q1, Q3	0.30, 4.13	1.44, NE	
Min, Max	0.2, 4.1	0.3, 6.0	
Time to censoring (months)[c,d]			
Median	1.41	2.36	
Q1, Q3	0.95, 2.33	0.95, 5.64	
Min, Max	0.2, 3.5	0.3, 18.9	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-dis-eqcas.sas
Output: t14-04-003-027-tte-de-eortc-dis-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.27. Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	35.38 (21.68, 49.35)	63.99 (55.99, 70.92)	
At time 6 months[c]	0.00 (NE, NE)	49.40 (39.39, 58.63)	
At time 12 months[c]	0.00 (NE, NE)	49.40 (39.39, 58.63)	
At time 18 months[c]	0.00 (NE, NE)	49.40 (39.39, 58.63)	
At time 24 months[c]	0.00 (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.34
(95% CI)			(0.23, 0.49)
p-value			<0.0001

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-dis-eqcas.sas
Output: t14-04-003-027-tte-de-eortc-dis-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.28. Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Subject status			
Number of subjects	94	238	
Events - n (%)	31 (33.0)	79 (33.2)	
Censored - n (%)	63 (67.0)	159 (66.8)	
Unstratified log-rank test			
Normal score[a]			-4.69
p-value			0.2730
Stratified log-rank test[b]			
Normal score[a]			-4.96
p-value			0.2425

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-fis-eqcas.sas
Output: t14-04-003-028-tte-de-eortc-fis-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.28. Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
Time to event (KM) (months)[c]			
Median	2.46	17.74	
95% CI (median)	(1.80, NE)	(4.39, NE)	
Q1, Q3	0.89, NE	0.95, 18.62	
Min, Max	0.2, 2.5	0.3, 18.6	
Time to censoring (months)[c,d]			
Median	1.38	2.46	
Q1, Q3	0.82, 2.26	0.95, 5.41	
Min, Max	0.2, 4.1	0.3, 18.9	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-fis-eqcas.sas
Output: t14-04-003-028-tte-de-eortc-fis-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.3.28. Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N=95)	Blinatumomab (N=247)	Treatment Difference
KM estimate - % (95% CI)			
At time 3 months[c]	46.70 (28.12, 63.32)	61.36 (53.48, 68.31)	
At time 6 months[c]	NE (NE, NE)	57.82 (49.34, 65.38)	
At time 12 months[c]	NE (NE, NE)	57.82 (49.34, 65.38)	
At time 18 months[c]	NE (NE, NE)	38.54 (10.70, 66.58)	
At time 24 months[c]	NE (NE, NE)	NE (NE, NE)	
Stratified hazard ratio[b,e]			0.79
(95% CI)			(0.51, 1.21)
p-value			0.2732

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire.
[a] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[b] Stratification factors are: age (<35 vs.≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[c] Months are calculated as days from treatment start date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard and hazard ratio estimates are obtained from the stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-de-eortc-fis-eqcas.sas
Output: t14-04-003-028-tte-de-eortc-fis-eqcas.rtf (Date generated: 24JUN2025:23:17) Source data: adam_fa.adsl, adam_fa.adqs, adam_fa.adtteqs

Table 14-6.1.1. Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	108 (99.1)	263 (98.5)	
Unstratified log-rank test			
Normal score[b]			-1.67
p-value			0.8062
Stratified log-rank test[c]			
Normal score[b]			-0.61
p-value			0.9274
Time to event (KM) (months)[d]			
Median	0.07	0.07	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.03, 0.10	0.03, 0.10	
Min, Max	0.0, 1.5	0.0, 3.6	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-saf.sas
Output: t14-06-001-001-tte-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.1. Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.00
(95% CI)			(0.80, 1.25)
p-value			0.9923
Stratified hazard ratio[c,e]			1.01
(95% CI)			(0.80, 1.27)
p-value			0.9391

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-saf.sas
Output: t14-06-001-001-tte-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.2. Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	49 (45.0)	168 (62.9)	
Unstratified log-rank test			
Normal score[b]			1.45
p-value			0.8095
Stratified log-rank test[c]			
Normal score[b]			0.87
p-value			0.8835
Time to event (KM) (months)[d]			
Median	1.87	1.54	
95% CI (median)	(1.11, NE)	(1.28, 2.36)	
Q1, Q3	0.43, NE	0.52, 5.87	
Min, Max	0.0, 2.8	0.0, 14.8	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-saf.sas
Output: t14-06-001-002-tte-ser-teae-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.2. Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.04
(95% CI)			(0.75, 1.44)
p-value			0.8138
Stratified hazard ratio[c,e]			1.03
(95% CI)			(0.74, 1.43)
p-value			0.8789

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-saf.sas
Output: t14-06-001-002-tte-ser-teae-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.3. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event
(Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	100 (91.7)	231 (86.5)	
Unstratified log-rank test			
Normal score[b]			-23.37
p-value			0.0010
Stratified log-rank test[c]			
Normal score[b]			-21.82
p-value			0.0020
Time to event (KM) (months)[d]			
Median	0.23	0.26	
95% CI (median)	(0.16, 0.26)	(0.16, 0.36)	
Q1, Q3	0.10, 0.33	0.07, 1.08	
Min, Max	0.0, 2.0	0.0, 8.3	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-saf.sas
Output: t14-06-001-003-tte-sev-teae-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.3. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event
(Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			0.68
(95% CI)			(0.53, 0.86)
p-value			0.0016
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.54, 0.88)
p-value			0.0028

Page 2 of 2

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-saf.sas
Output: t14-06-001-003-tte-sev-teae-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.4. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	42 (15.7)	
Unstratified log-rank test			
Normal score[b]			1.88
p-value			0.5241
Stratified log-rank test[c]			
Normal score[b]			1.37
p-value			0.6360
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(16.33, NE)	
Q1, Q3	NE, NE	16.33, NE	
Min, Max	0.1, 2.0	0.0, 16.3	

Page 1 of 2

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-trt-disc-saf.sas
Output: t14-06-001-004-tte-teae-trt-disc-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.4. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.26
(95% CI)			(0.62, 2.54)
p-value			0.5248
Stratified hazard ratio[c,e]			1.18
(95% CI)			(0.58, 2.40)
p-value			0.6379

Page 2 of 2

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-trt-disc-saf.sas
Output: t14-06-001-004-tte-teae-trt-disc-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.5. Time to First Onset of Treatment-emergent Adverse Event Leading to Death
(Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	20 (18.3)	52 (19.5)	
Unstratified log-rank test			
Normal score[b]			-3.73
p-value			0.2841
Stratified log-rank test[c]			
Normal score[b]			-4.20
p-value			0.2208
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(16.49, NE)	
Q1, Q3	2.10, NE	14.07, NE	
Min, Max	0.0, 2.1	0.1, 16.5	

Page 1 of 2

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to death.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-fatal-saf.sas
Output: t14-06-001-005-tte-teae-fatal-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.5. Time to First Onset of Treatment-emergent Adverse Event Leading to Death
(Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			0.75
(95% CI)			(0.44, 1.27)
p-value			0.2870
Stratified hazard ratio[c,e]			0.72
(95% CI)			(0.42, 1.22)
p-value			0.2251

Page 2 of 2

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to death.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-fatal-saf.sas
Output: t14-06-001-005-tte-teae-fatal-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Capillary leak syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	54 (49.5)	164 (61.4)	
Unstratified log-rank test			
Normal score[b]			7.62
p-value			0.2400
Stratified log-rank test[c]			
Normal score[b]			7.60
p-value			0.2364

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.11	0.92	
95% CI (median)	(0.56, NE)	(0.52, 1.44)	
Q1, Q3	0.23, NE	0.16, NE	
Min, Max	0.0, 1.4	0.0, 6.2	
Unstratified hazard ratio[e]			1.20
(95% CI)			(0.88, 1.64)
p-value			0.2385
Stratified hazard ratio[c,e]			1.21
(95% CI)			(0.88, 1.65)
p-value			0.2376

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Cytokine release syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	43 (16.1)	
Unstratified log-rank test			
Normal score[b]			12.34
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			12.09
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 8.3	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Decreased immunoglobulins (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	29 (10.9)	
Unstratified log-rank test			
Normal score[b]			1.87
p-value			0.2811
Stratified log-rank test[c]			
Normal score[b]			1.71
p-value			0.3101

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	16.03	
95% CI (median)	(NE, NE)	(14.79, NE)	
Q1, Q3	NE, NE	7.18, NE	
Min, Max	0.2, 0.5	0.6, 16.0	
Unstratified hazard ratio[e]			2.21
(95% CI)			(0.51, 9.65)
p-value			0.2922
Stratified hazard ratio[c,e]			2.12
(95% CI)			(0.48, 9.40)
p-value			0.3210

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Haematopoietic cytopenias (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	79 (72.5)	160 (59.9)	
Unstratified log-rank test			
Normal score[b]			-25.86
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-24.58
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	1.15	
95% CI (median)	(0.23, 0.30)	(0.62, 2.10)	
Q1, Q3	0.10, 2.49	0.13, 6.62	
Min, Max	0.0, 2.5	0.0, 8.3	
Unstratified hazard ratio[e]			0.56
(95% CI)			(0.42, 0.73)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.57
(95% CI)			(0.43, 0.76)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infections and infestations (SOC)			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	79 (72.5)	172 (64.4)	
Unstratified log-rank test			
Normal score[b]			-29.73
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-29.98
p-value			<0.0001

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[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.49	1.31	
95% CI (median)	(0.39, 0.62)	(1.05, 1.90)	
Q1, Q3	0.30, 1.51	0.39, 4.69	
Min, Max	0.0, 2.1	0.0, 15.5	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.38, 0.66)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.37, 0.65)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infusion reaction (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	129 (48.3)	
Unstratified log-rank test			
Normal score[b]			30.76
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			30.37
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	2.85	
95% CI (median)	(NE, NE)	(1.41, NE)	
Q1, Q3	NE, NE	0.07, NE	
Min, Max	0.0, 0.1	0.0, 6.2	
Unstratified hazard ratio[e]			5.25
(95% CI)			(2.90, 9.49)
p-value			<0.0001
Stratified hazard ratio[c,e]			5.23
(95% CI)			(2.89, 9.46)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Liver related investigations, signs and symptoms (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	27 (24.8)	58 (21.7)	
Unstratified log-rank test			
Normal score[b]			-3.84
p-value			0.3407
Stratified log-rank test[c]			
Normal score[b]			-3.59
p-value			0.3725

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(3.02, NE)	(NE, NE)	
Q1, Q3	3.02, NE	5.67, NE	
Min, Max	0.1, 3.0	0.0, 5.7	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.51, 1.27)
p-value			0.3478
Stratified hazard ratio[c,e]			0.82
(95% CI)			(0.51, 1.30)
p-value			0.3950

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Lymphopenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	6 (2.2)	
Unstratified log-rank test			
Normal score[b]			-1.89
p-value			0.1236
Stratified log-rank test[c]			
Normal score[b]			-1.77
p-value			0.1598

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.8	0.0, 13.6	
Unstratified hazard ratio[e]			0.34
(95% CI)			(0.08, 1.42)
p-value			0.1407
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.09, 1.54)
p-value			0.1756

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Medication errors and product use issues (SMQ) - Broad			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			3.19
p-value			0.0355
Stratified log-rank test[c]			
Normal score[b]			3.26
p-value			0.0330

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 2.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Neutropenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	70 (64.2)	111 (41.6)	
Unstratified log-rank test			
Normal score[b]			-32.44
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-32.14
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.36	4.79	
95% CI (median)	(0.26, 0.43)	(2.59, 6.69)	
Q1, Q3	0.20, NE	0.52, NE	
Min, Max	0.0, 2.5	0.0, 8.3	
Unstratified hazard ratio[e]			0.39
(95% CI)			(0.28, 0.53)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.28, 0.53)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
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Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Tumour lysis syndrome (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			1.75
p-value			0.2148
Stratified log-rank test[c]			
Normal score[b]			1.71
p-value			0.2200

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.6. Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 13.9	
Unstratified hazard ratio[e]			3.42
(95% CI)			(0.43, 27.02)
p-value			0.2439
Stratified hazard ratio[c,e]			3.39
(95% CI)			(0.43, 26.90)
p-value			0.2484

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-aesi-saf.sas
Output: t14-06-001-006-tte-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Capillary leak syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			2.45
p-value			0.1777
Stratified log-rank test[c]			
Normal score[b]			2.27
p-value			0.2020

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 0.5	0.0, 13.1	
Unstratified hazard ratio[e]			2.65
(95% CI)			(0.61, 11.59)
p-value			0.1951
Stratified hazard ratio[c,e]			2.54
(95% CI)			(0.58, 11.15)
p-value			0.2179

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Cytokine release syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			2.69
p-value			0.0541
Stratified log-rank test[c]			
Normal score[b]			2.57
p-value			0.0590

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 1.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Decreased immunoglobulins (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Haematopoietic cytopenias (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	17 (15.6)	36 (13.5)	
Unstratified log-rank test			
Normal score[b]			-6.68
p-value			0.0166
Stratified log-rank test[c]			
Normal score[b]			-6.89
p-value			0.0124

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	1.97, NE	11.05, NE	
Min, Max	0.1, 2.8	0.1, 14.1	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.26, 0.89)
p-value			0.0189
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.25, 0.86)
p-value			0.0147

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infections and infestations (SOC)			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	33 (30.3)	79 (29.6)	
Unstratified log-rank test			
Normal score[b]			-12.05
p-value			0.0023
Stratified log-rank test[c]			
Normal score[b]			-11.93
p-value			0.0025

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	8.07	
95% CI (median)	(2.03, NE)	(5.87, 16.13)	
Q1, Q3	0.92, NE	2.56, NE	
Min, Max	0.0, 2.1	0.0, 16.3	
Unstratified hazard ratio[e]			0.51
(95% CI)			(0.33, 0.80)
p-value			0.0028
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.33, 0.80)
p-value			0.0029

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infusion reaction (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	3 (1.1)	
Unstratified log-rank test			
Normal score[b]			0.87
p-value			0.2674
Stratified log-rank test[c]			
Normal score[b]			0.91
p-value			0.2513

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 0.1	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Liver related investigations, signs and symptoms (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	3 (1.1)	
Unstratified log-rank test			
Normal score[b]			0.85
p-value			0.2766
Stratified log-rank test[c]			
Normal score[b]			0.85
p-value			0.2755

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.1, 0.9	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Lymphopenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Medication errors and product use issues (SMQ) - Broad			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			3.19
p-value			0.0355
Stratified log-rank test[c]			
Normal score[b]			3.26
p-value			0.0330

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 2.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Neutropenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	29 (10.9)	
Unstratified log-rank test			
Normal score[b]			-6.31
p-value			0.0136
Stratified log-rank test[c]			
Normal score[b]			-6.27
p-value			0.0139

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	2.82, NE	14.07, NE	
Min, Max	0.1, 2.8	0.1, 14.1	
Unstratified hazard ratio[e]			0.44
(95% CI)			(0.23, 0.86)
p-value			0.0160
Stratified hazard ratio[c,e]			0.44
(95% CI)			(0.23, 0.86)
p-value			0.0166

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Tumour lysis syndrome (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	3 (1.1)	
Unstratified log-rank test			
Normal score[b]			0.74
p-value			0.3189
Stratified log-rank test[c]			
Normal score[b]			0.76
p-value			0.3063

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.7. Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.6, 1.4	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-aesi-saf.sas
Output: t14-06-001-007-tte-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Capillary leak syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
Normal score[b]			0.00
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	NE, NE	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	27 (10.1)	
Unstratified log-rank test			
Normal score[b]			-0.55
p-value			0.8263
Stratified log-rank test[c]			
Normal score[b]			-0.67
p-value			0.7866

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.0, 13.1	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.42, 1.99)
p-value			0.8265
Stratified hazard ratio[c,e]			0.90
(95% CI)			(0.42, 1.95)
p-value			0.7906

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Cytokine release syndrome (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			3.28
p-value			0.0327
Stratified log-rank test[c]			
Normal score[b]			3.17
p-value			0.0353

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 8.3	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Decreased immunoglobulins (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	7 (2.6)	
Unstratified log-rank test			
Normal score[b]			0.55
p-value			0.4197
Stratified log-rank test[c]			
Normal score[b]			0.50
p-value			0.4449

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	1.4, 7.2	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Haematopoietic cytopenias (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	74 (67.9)	142 (53.2)	
Unstratified log-rank test			
Normal score[b]			-26.56
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-25.67
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	2.07	
95% CI (median)	(0.26, 0.36)	(1.08, 3.11)	
Q1, Q3	0.13, NE	0.26, 11.05	
Min, Max	0.0, 1.0	0.0, 11.0	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.39, 0.69)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.39, 0.70)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infections and infestations (SOC)			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	57 (52.3)	93 (34.8)	
Unstratified log-rank test			
Normal score[b]			-29.02
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-29.18
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.11	7.25	
95% CI (median)	(0.62, 2.03)	(5.54, 16.13)	
Q1, Q3	0.39, NE	1.57, NE	
Min, Max	0.0, 2.1	0.0, 16.1	
Unstratified hazard ratio[e]			0.33
(95% CI)			(0.23, 0.48)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.22, 0.46)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 14MAR2017

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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Infusion reaction (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			3.77
p-value			0.0384
Stratified log-rank test[c]			
Normal score[b]			3.94
p-value			0.0329

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 8.1	
Unstratified hazard ratio[e]			6.38
(95% CI)			(0.84, 48.21)
p-value			0.0725
Stratified hazard ratio[c,e]			6.70
(95% CI)			(0.89, 50.66)
p-value			0.0652

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Liver related investigations, signs and symptoms (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	34 (12.7)	
Unstratified log-rank test			
Normal score[b]			-2.26
p-value			0.4694
Stratified log-rank test[c]			
Normal score[b]			-1.91
p-value			0.5451

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(3.02, NE)	(NE, NE)	
Q1, Q3	3.02, NE	NE, NE	
Min, Max	0.1, 3.0	0.0, 3.0	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.44, 1.46)
p-value			0.4727
Stratified hazard ratio[c,e]			0.84
(95% CI)			(0.46, 1.52)
p-value			0.5551

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Lymphopenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	5 (1.9)	
Unstratified log-rank test			
Normal score[b]			-1.98
p-value			0.0980
Stratified log-rank test[c]			
Normal score[b]			-1.90
p-value			0.1161

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.8	0.0, 13.6	
Unstratified hazard ratio[e]			0.30
(95% CI)			(0.07, 1.36)
p-value			0.1189
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.07, 1.43)
p-value			0.1362

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Medication errors and product use issues (SMQ) - Broad			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	4 (1.5)	
Unstratified log-rank test			
Normal score[b]			0.87
p-value			0.2826
Stratified log-rank test[c]			
Normal score[b]			0.94
p-value			0.2608

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 2.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Neutropenia (AMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	63 (57.8)	101 (37.8)	
Unstratified log-rank test			
Normal score[b]			-28.73
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-28.39
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.43	4.95	
95% CI (median)	(0.30, 0.95)	(3.87, NE)	
Q1, Q3	0.23, NE	0.62, NE	
Min, Max	0.0, 1.0	0.0, 8.3	
Unstratified hazard ratio[e]			0.40
(95% CI)			(0.29, 0.55)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.28, 0.55)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Tumour lysis syndrome (SMQ) - Narrow			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	8 (3.0)	
Unstratified log-rank test			
Normal score[b]			1.45
p-value			0.2763
Stratified log-rank test[c]			
Normal score[b]			1.46
p-value			0.2705

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.8. Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 1.4	
Unstratified hazard ratio[e]			3.00
(95% CI)			(0.37, 24.05)
p-value			0.3006
Stratified hazard ratio[c,e]			3.05
(95% CI)			(0.38, 24.56)
p-value			0.2949

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event of interest.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-aesi-saf.sas
Output: t14-06-001-008-tte-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.9. Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	108 (99.1)	263 (98.5)	
Unstratified log-rank test			
Normal score[b]			-1.67
p-value			0.8062
Stratified log-rank test[c]			
Normal score[b]			-0.61
p-value			0.9274
Time to event (KM) (months)[d]			
Median	0.07	0.07	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.03, 0.10	0.03, 0.10	
Min, Max	0.0, 1.5	0.0, 3.6	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-edp-saf.sas
Output: t14-06-001-009-tte-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.9. Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.00
(95% CI)			(0.80, 1.25)
p-value			0.9923
Stratified hazard ratio[c,e]			1.01
(95% CI)			(0.80, 1.27)
p-value			0.9391

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-edp-saf.sas
Output: t14-06-001-009-tte-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.10. Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	49 (45.0)	167 (62.5)	
Unstratified log-rank test			
Normal score[b]			1.17
p-value			0.8454
Stratified log-rank test[c]			
Normal score[b]			0.74
p-value			0.9000
Time to event (KM) (months)[d]			
Median	1.87	1.54	
95% CI (median)	(1.11, NE)	(1.28, 2.46)	
Q1, Q3	0.43, NE	0.52, 5.87	
Min, Max	0.0, 2.8	0.0, 14.8	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-edp-saf.sas
Output: t14-06-001-010-tte-ser-teae-edp-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.10. Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.03
(95% CI)			(0.75, 1.43)
p-value			0.8489
Stratified hazard ratio[c,e]			1.02
(95% CI)			(0.73, 1.42)
p-value			0.8962

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-edp-saf.sas
Output: t14-06-001-010-tte-ser-teae-edp-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.11. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	100 (91.7)	231 (86.5)	
Unstratified log-rank test			
Normal score[b]			-23.37
p-value			0.0010
Stratified log-rank test[c]			
Normal score[b]			-21.82
p-value			0.0020
Time to event (KM) (months)[d]			
Median	0.23	0.26	
95% CI (median)	(0.16, 0.26)	(0.16, 0.36)	
Q1, Q3	0.10, 0.33	0.07, 1.08	
Min, Max	0.0, 2.0	0.0, 8.3	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-edp-saf.sas
Output: t14-06-001-011-tte-sev-teae-edp-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.11. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			0.68
(95% CI)			(0.53, 0.86)
p-value			0.0016
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.54, 0.88)
p-value			0.0028

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-edp-saf.sas
Output: t14-06-001-011-tte-sev-teae-edp-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	83 (76.1)	182 (68.2)	
Unstratified log-rank test			
Normal score[b]			-22.88
p-value			0.0004
Stratified log-rank test[c]			
Normal score[b]			-21.93
p-value			0.0007

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	0.52	
95% CI (median)	(0.20, 0.30)	(0.39, 0.82)	
Q1, Q3	0.10, 0.59	0.10, 4.52	
Min, Max	0.0, 1.9	0.0, 8.3	
Unstratified hazard ratio[e]			0.62
(95% CI)			(0.48, 0.81)
p-value			0.0005
Stratified hazard ratio[c,e]			0.63
(95% CI)			(0.48, 0.83)
p-value			0.0009

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Anaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	46 (42.2)	68 (25.5)	
Unstratified log-rank test			
Normal score[b]			-15.89
p-value			0.0006
Stratified log-rank test[c]			
Normal score[b]			-15.74
p-value			0.0006

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.93	NE	
95% CI (median)	(0.79, NE)	(NE, NE)	
Q1, Q3	0.26, NE	0.98, NE	
Min, Max	0.0, 1.9	0.0, 11.9	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.36, 0.76)
p-value			0.0008
Stratified hazard ratio[c,e]			0.52
(95% CI)			(0.36, 0.76)
p-value			0.0007

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	43 (39.4)	65 (24.3)	
Unstratified log-rank test			
Normal score[b]			-16.46
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			-16.27
p-value			0.0002

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	2.82	NE	
95% CI (median)	(1.77, NE)	(NE, NE)	
Q1, Q3	0.39, NE	2.36, NE	
Min, Max	0.0, 2.8	0.0, 6.7	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.32, 0.71)
p-value			0.0002
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.32, 0.71)
p-value			0.0003

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	33 (30.3)	53 (19.9)	
Unstratified log-rank test			
Normal score[b]			-14.54
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-14.75
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.30, NE)	(8.26, NE)	
Q1, Q3	0.30, NE	3.84, NE	
Min, Max	0.1, 2.3	0.0, 8.3	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.26, 0.65)
p-value			0.0001
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.25, 0.62)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Thrombocytopenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	32 (29.4)	48 (18.0)	
Unstratified log-rank test			
Normal score[b]			-11.22
p-value			0.0035
Stratified log-rank test[c]			
Normal score[b]			-10.68
p-value			0.0059

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.30, NE	16.26, NE	
Min, Max	0.0, 2.0	0.0, 16.3	
Unstratified hazard ratio[e]			0.51
(95% CI)			(0.33, 0.81)
p-value			0.0041
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.34, 0.84)
p-value			0.0069

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Leukopenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-0.82
p-value			0.6352
Stratified log-rank test[c]			
Normal score[b]			-0.81
p-value			0.6396

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.8	0.0, 0.9	
Unstratified hazard ratio[e]			0.77
(95% CI)			(0.26, 2.26)
p-value			0.6358
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.26, 2.27)
p-value			0.6396

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Cardiac disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	26 (23.9)	49 (18.4)	
Unstratified log-rank test			
Normal score[b]			-6.88
p-value			0.0630
Stratified log-rank test[c]			
Normal score[b]			-6.60
p-value			0.0749

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.26, NE)	(NE, NE)	
Q1, Q3	1.64, NE	8.72, NE	
Min, Max	0.0, 2.3	0.0, 8.7	
Unstratified hazard ratio[e]			0.64
(95% CI)			(0.39, 1.03)
p-value			0.0666
Stratified hazard ratio[c,e]			0.65
(95% CI)			(0.40, 1.06)
p-value			0.0822

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Tachycardia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-2.83
p-value			0.2118
Stratified log-rank test[c]			
Normal score[b]			-2.74
p-value			0.2290

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 2.8	0.0, 3.9	
Unstratified hazard ratio[e]			0.61
(95% CI)			(0.28, 1.34)
p-value			0.2188
Stratified hazard ratio[c,e]			0.62
(95% CI)			(0.28, 1.37)
p-value			0.2409

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sinus tachycardia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-0.25
p-value			0.9006
Stratified log-rank test[c]			
Normal score[b]			-0.32
p-value			0.8745

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.2	0.0, 2.5	
Unstratified hazard ratio[e]			0.94
(95% CI)			(0.36, 2.44)
p-value			0.9014
Stratified hazard ratio[c,e]			0.93
(95% CI)			(0.36, 2.40)
p-value			0.8745

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Ear and labyrinth disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			0.37
p-value			0.8363
Stratified log-rank test[c]			
Normal score[b]			0.34
p-value			0.8464

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 0.6	0.1, 13.5	
Unstratified hazard ratio[e]			1.13
(95% CI)			(0.36, 3.51)
p-value			0.8363
Stratified hazard ratio[c,e]			1.12
(95% CI)			(0.36, 3.54)
p-value			0.8444

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Eye disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	27 (10.1)	
Unstratified log-rank test			
Normal score[b]			-5.28
p-value			0.0469
Stratified log-rank test[c]			
Normal score[b]			-5.26
p-value			0.0471

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 8.7	
Unstratified hazard ratio[e]			0.52
(95% CI)			(0.27, 1.00)
p-value			0.0505
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.26, 1.00)
p-value			0.0500

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	88 (80.7)	154 (57.7)	
Unstratified log-rank test			
Normal score[b]			-42.29
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-42.53
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.23	1.21	
95% CI (median)	(0.10, 0.26)	(0.95, 2.13)	
Q1, Q3	0.07, 0.69	0.23, 11.28	
Min, Max	0.0, 2.2	0.0, 11.3	
Unstratified hazard ratio[e]			0.37
(95% CI)			(0.28, 0.49)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.36
(95% CI)			(0.27, 0.47)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Diarrhoea			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	38 (34.9)	59 (22.1)	
Unstratified log-rank test			
Normal score[b]			-17.31
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-17.50
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.67, NE)	(13.41, NE)	
Q1, Q3	0.39, NE	2.95, NE	
Min, Max	0.0, 2.2	0.1, 13.4	
Unstratified hazard ratio[e]			0.40
(95% CI)			(0.26, 0.61)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.25, 0.59)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Nausea			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	46 (42.2)	51 (19.1)	
Unstratified log-rank test			
Normal score[b]			-25.13
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-24.71
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.61	NE	
95% CI (median)	(1.02, NE)	(NE, NE)	
Q1, Q3	0.23, NE	5.41, NE	
Min, Max	0.0, 1.8	0.0, 6.1	
Unstratified hazard ratio[e]			0.28
(95% CI)			(0.19, 0.43)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.18, 0.43)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Constipation			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	28 (25.7)	35 (13.1)	
Unstratified log-rank test			
Normal score[b]			-12.51
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			-12.67
p-value			0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.90, NE)	(NE, NE)	
Q1, Q3	1.28, NE	NE, NE	
Min, Max	0.0, 1.9	0.0, 4.0	
Unstratified hazard ratio[e]			0.39
(95% CI)			(0.24, 0.65)
p-value			0.0003
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.23, 0.64)
p-value			0.0002

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Vomiting			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	26 (23.9)	35 (13.1)	
Unstratified log-rank test			
Normal score[b]			-15.35
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-15.77
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.44, NE	6.13, NE	
Min, Max	0.0, 1.8	0.1, 8.3	
Unstratified hazard ratio[e]			0.23
(95% CI)			(0.13, 0.41)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.21
(95% CI)			(0.12, 0.38)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Abdominal pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	19 (17.4)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-11.04
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-10.68
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.7	0.1, 13.4	
Unstratified hazard ratio[e]			0.23
(95% CI)			(0.12, 0.46)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.25
(95% CI)			(0.12, 0.49)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Stomatitis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-7.15
p-value			0.0015
Stratified log-rank test[c]			
Normal score[b]			-6.95
p-value			0.0022

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.79, NE)	(NE, NE)	
Q1, Q3	2.79, NE	NE, NE	
Min, Max	0.2, 2.8	0.0, 11.8	
Unstratified hazard ratio[e]			0.31
(95% CI)			(0.15, 0.66)
p-value			0.0025
Stratified hazard ratio[c,e]			0.33
(95% CI)			(0.15, 0.69)
p-value			0.0034

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Abdominal pain upper			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-2.32
p-value			0.1012
Stratified log-rank test[c]			
Normal score[b]			-2.28
p-value			0.1087

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.3	0.4, 15.8	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.12, 1.26)
p-value			0.1134
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.12, 1.28)
p-value			0.1206

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Dyspepsia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-2.97
p-value			0.0854
Stratified log-rank test[c]			
Normal score[b]			-2.65
p-value			0.1365

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.8	0.1, 3.1	
Unstratified hazard ratio[e]			0.43
(95% CI)			(0.16, 1.16)
p-value			0.0942
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.18, 1.29)
p-value			0.1447

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	83 (76.1)	210 (78.7)	
Unstratified log-rank test			
Normal score[b]			3.57
p-value			0.6260
Stratified log-rank test[c]			
Normal score[b]			1.90
p-value			0.7911

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.33	0.20	
95% CI (median)	(0.23, 0.39)	(0.13, 0.33)	
Q1, Q3	0.13, 1.11	0.07, 1.54	
Min, Max	0.0, 2.3	0.0, 7.0	
Unstratified hazard ratio[e]			1.09
(95% CI)			(0.85, 1.41)
p-value			0.4996
Stratified hazard ratio[c,e]			1.07
(95% CI)			(0.82, 1.38)
p-value			0.6239

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	49 (45.0)	159 (59.6)	
Unstratified log-rank test			
Normal score[b]			15.88
p-value			0.0125
Stratified log-rank test[c]			
Normal score[b]			16.14
p-value			0.0107

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.70	0.69	
95% CI (median)	(1.08, 2.62)	(0.36, 1.34)	
Q1, Q3	0.39, NE	0.07, NE	
Min, Max	0.0, 2.6	0.0, 7.0	
Unstratified hazard ratio[e]			1.54
(95% CI)			(1.11, 2.12)
p-value			0.0088
Stratified hazard ratio[c,e]			1.56
(95% CI)			(1.13, 2.15)
p-value			0.0072

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Oedema peripheral			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	40 (15.0)	
Unstratified log-rank test			
Normal score[b]			-1.87
p-value			0.5607
Stratified log-rank test[c]			
Normal score[b]			-1.88
p-value			0.5549

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.1, 7.1	
Unstratified hazard ratio[e]			0.84
(95% CI)			(0.47, 1.51)
p-value			0.5612
Stratified hazard ratio[c,e]			0.84
(95% CI)			(0.46, 1.51)
p-value			0.5579

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Fatigue			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	36 (13.5)	
Unstratified log-rank test			
Normal score[b]			-2.64
p-value			0.3586
Stratified log-rank test[c]			
Normal score[b]			-2.77
p-value			0.3291

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	11.51, NE	
Min, Max	0.1, 1.4	0.0, 11.5	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.39, 1.41)
p-value			0.3601
Stratified hazard ratio[c,e]			0.73
(95% CI)			(0.38, 1.39)
p-value			0.3312

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Asthenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	22 (8.2)	
Unstratified log-rank test			
Normal score[b]			-3.26
p-value			0.1734
Stratified log-rank test[c]			
Normal score[b]			-3.04
p-value			0.2075

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.7	0.0, 6.9	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.29, 1.26)
p-value			0.1779
Stratified hazard ratio[c,e]			0.62
(95% CI)			(0.30, 1.31)
p-value			0.2110

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Chills			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			-4.82
p-value			0.0338
Stratified log-rank test[c]			
Normal score[b]			-4.63
p-value			0.0422

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 2.0	0.0, 14.3	
Unstratified hazard ratio[e]			0.45
(95% CI)			(0.21, 0.96)
p-value			0.0391
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.21, 0.99)
p-value			0.0483

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-1.03
p-value			0.5898
Stratified log-rank test[c]			
Normal score[b]			-1.02
p-value			0.5941

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 2.6	0.1, 3.7	
Unstratified hazard ratio[e]			0.77
(95% CI)			(0.29, 2.01)
p-value			0.5888
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.29, 2.03)
p-value			0.5950

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Mucosal inflammation			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	9 (3.4)	
Unstratified log-rank test			
Normal score[b]			-8.23
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-8.20
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.7	0.1, 3.5	
Unstratified hazard ratio[e]			0.20
(95% CI)			(0.08, 0.47)
p-value			0.0003
Stratified hazard ratio[c,e]			0.19
(95% CI)			(0.08, 0.47)
p-value			0.0003

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Hepatobiliary disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	14 (12.8)	30 (11.2)	
Unstratified log-rank test			
Normal score[b]			-2.82
p-value			0.3231
Stratified log-rank test[c]			
Normal score[b]			-2.76
p-value			0.3325

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.2	0.0, 3.0	
Unstratified hazard ratio[e]			0.72
(95% CI)			(0.38, 1.38)
p-value			0.3246
Stratified hazard ratio[c,e]			0.73
(95% CI)			(0.38, 1.39)
p-value			0.3346

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	66 (24.7)	
Unstratified log-rank test			
Normal score[b]			12.63
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			12.30
p-value			0.0003

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	14.79	
95% CI (median)	(NE, NE)	(7.74, NE)	
Q1, Q3	NE, NE	3.02, NE	
Min, Max	0.2, 1.1	0.0, 14.8	
Unstratified hazard ratio[e]			5.50
(95% CI)			(1.99, 15.20)
p-value			0.0010
Stratified hazard ratio[c,e]			5.38
(95% CI)			(1.95, 14.86)
p-value			0.0012

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Cytokine release syndrome			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	38 (14.2)	
Unstratified log-rank test			
Normal score[b]			11.17
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			10.98
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 1.5	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypogammaglobulinaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			1.10
p-value			0.3931
Stratified log-rank test[c]			
Normal score[b]			0.98
p-value			0.4290

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(14.79, NE)	
Q1, Q3	NE, NE	14.79, NE	
Min, Max	0.2, 0.2	0.6, 16.0	
Unstratified hazard ratio[e]			2.39
(95% CI)			(0.30, 18.91)
p-value			0.4075
Stratified hazard ratio[c,e]			2.27
(95% CI)			(0.28, 18.26)
p-value			0.4414

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	79 (72.5)	172 (64.4)	
Unstratified log-rank test			
Normal score[b]			-29.97
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-30.21
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.49	1.31	
95% CI (median)	(0.39, 0.62)	(1.05, 1.90)	
Q1, Q3	0.30, 1.51	0.39, 4.69	
Min, Max	0.0, 2.1	0.0, 15.5	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.38, 0.66)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.37, 0.65)
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Upper respiratory tract infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			1.72
p-value			0.2358
Stratified log-rank test[c]			
Normal score[b]			1.75
p-value			0.2242

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	15.61, NE	
Min, Max	0.4, 0.4	0.3, 15.6	
Unstratified hazard ratio[e]			3.24
(95% CI)			(0.42, 25.18)
p-value			0.2618
Stratified hazard ratio[c,e]			3.34
(95% CI)			(0.43, 26.23)
p-value			0.2510

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Device related infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-1.78
p-value			0.3121
Stratified log-rank test[c]			
Normal score[b]			-1.71
p-value			0.3326

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(16.66, NE)	
Q1, Q3	NE, NE	16.66, NE	
Min, Max	0.1, 0.7	0.2, 16.7	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.22, 1.64)
p-value			0.3169
Stratified hazard ratio[c,e]			0.61
(95% CI)			(0.22, 1.68)
p-value			0.3369

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pneumonia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-9.20
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-9.16
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.8	0.0, 8.3	
Unstratified hazard ratio[e]			0.22
(95% CI)			(0.10, 0.48)
p-value			0.0001
Stratified hazard ratio[c,e]			0.22
(95% CI)			(0.10, 0.49)
p-value			0.0002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Oral herpes			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-3.53
p-value			0.0772
Stratified log-rank test[c]			
Normal score[b]			-3.54
p-value			0.0755

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 0.6	0.1, 4.7	
Unstratified hazard ratio[e]			0.47
(95% CI)			(0.20, 1.11)
p-value			0.0837
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.19, 1.11)
p-value			0.0827

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Urinary tract infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			0.82
p-value			0.5694
Stratified log-rank test[c]			
Normal score[b]			0.88
p-value			0.5349

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.0	0.1, 15.5	
Unstratified hazard ratio[e]			1.56
(95% CI)			(0.34, 7.24)
p-value			0.5717
Stratified hazard ratio[c,e]			1.63
(95% CI)			(0.34, 7.75)
p-value			0.5374

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Viral upper respiratory tract infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			1.72
p-value			0.1373
Stratified log-rank test[c]			
Normal score[b]			1.91
p-value			0.1136

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.1, 9.2	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sepsis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-3.43
p-value			0.0647
Stratified log-rank test[c]			
Normal score[b]			-3.25
p-value			0.0829

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.1, 8.1	
Unstratified hazard ratio[e]			0.44
(95% CI)			(0.18, 1.08)
p-value			0.0719
Stratified hazard ratio[c,e]			0.45
(95% CI)			(0.18, 1.13)
p-value			0.0912

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Injury, poisoning and procedural complications			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	40 (15.0)	
Unstratified log-rank test			
Normal score[b]			-0.04
p-value			0.9876
Stratified log-rank test[c]			
Normal score[b]			0.63
p-value			0.8277

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	16.23, NE	
Min, Max	0.0, 2.7	0.0, 16.2	
Unstratified hazard ratio[e]			0.99
(95% CI)			(0.50, 1.98)
p-value			0.9880
Stratified hazard ratio[c,e]			1.08
(95% CI)			(0.54, 2.14)
p-value			0.8276

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Investigations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	40 (36.7)	112 (41.9)	
Unstratified log-rank test			
Normal score[b]			0.43
p-value			0.9348
Stratified log-rank test[c]			
Normal score[b]			1.26
p-value			0.8116

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	5.31	
95% CI (median)	(1.41, NE)	(2.85, NE)	
Q1, Q3	0.26, NE	0.26, NE	
Min, Max	0.0, 1.5	0.0, 6.2	
Unstratified hazard ratio[e]			1.02
(95% CI)			(0.71, 1.46)
p-value			0.9270
Stratified hazard ratio[c,e]			1.05
(95% CI)			(0.73, 1.52)
p-value			0.7893

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Alanine aminotransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	24 (9.0)	
Unstratified log-rank test			
Normal score[b]			-1.40
p-value			0.5936
Stratified log-rank test[c]			
Normal score[b]			-1.72
p-value			0.5036

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 3.0	0.0, 1.5	
Unstratified hazard ratio[e]			0.82
(95% CI)			(0.40, 1.69)
p-value			0.5961
Stratified hazard ratio[c,e]			0.79
(95% CI)			(0.38, 1.62)
p-value			0.5159

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Platelet count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-5.47
p-value			0.0190
Stratified log-rank test[c]			
Normal score[b]			-5.24
p-value			0.0254

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
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	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.2	0.0, 10.8	
Unstratified hazard ratio[e]			0.42
(95% CI)			(0.20, 0.89)
p-value			0.0228
Stratified hazard ratio[c,e]			0.44
(95% CI)			(0.21, 0.92)
p-value			0.0297

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Aspartate aminotransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-3.09
p-value			0.1631
Stratified log-rank test[c]			
Normal score[b]			-3.44
p-value			0.1134

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 3.0	0.1, 0.7	
Unstratified hazard ratio[e]			0.57
(95% CI)			(0.25, 1.27)
p-value			0.1707
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.24, 1.19)
p-value			0.1251

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: White blood cell count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-0.92
p-value			0.6282
Stratified log-rank test[c]			
Normal score[b]			-0.77
p-value			0.6871

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 13.6	
Unstratified hazard ratio[e]			0.79
(95% CI)			(0.30, 2.09)
p-value			0.6330
Stratified hazard ratio[c,e]			0.82
(95% CI)			(0.31, 2.18)
p-value			0.6924

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Gamma-glutamyltransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			0.50
p-value			0.7822
Stratified log-rank test[c]			
Normal score[b]			0.20
p-value			0.9094

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 1.5	
Unstratified hazard ratio[e]			1.17
(95% CI)			(0.38, 3.64)
p-value			0.7832
Stratified hazard ratio[c,e]			1.07
(95% CI)			(0.34, 3.33)
p-value			0.9106

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Blood bilirubin increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-3.79
p-value			0.0515
Stratified log-rank test[c]			
Normal score[b]			-3.67
p-value			0.0609

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.3	0.1, 3.0	
Unstratified hazard ratio[e]			0.42
(95% CI)			(0.17, 1.03)
p-value			0.0587
Stratified hazard ratio[c,e]			0.44
(95% CI)			(0.18, 1.06)
p-value			0.0682

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
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[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutrophil count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-5.85
p-value			0.0025
Stratified log-rank test[c]			
Normal score[b]			-5.71
p-value			0.0035

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 5.5	
Unstratified hazard ratio[e]			0.27
(95% CI)			(0.11, 0.67)
p-value			0.0046
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.12, 0.70)
p-value			0.0059

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Transaminases increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			2.62
p-value			0.0539
Stratified log-rank test[c]			
Normal score[b]			2.74
p-value			0.0458

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.1, 5.7	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	57 (52.3)	116 (43.4)	
Unstratified log-rank test			
Normal score[b]			-13.60
p-value			0.0134
Stratified log-rank test[c]			
Normal score[b]			-12.80
p-value			0.0201

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.82	8.00	
95% CI (median)	(0.49, 2.82)	(1.90, NE)	
Q1, Q3	0.23, NE	0.20, NE	
Min, Max	0.0, 2.8	0.0, 12.0	
Unstratified hazard ratio[e]			0.67
(95% CI)			(0.48, 0.92)
p-value			0.0142
Stratified hazard ratio[c,e]			0.68
(95% CI)			(0.49, 0.95)
p-value			0.0218

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypokalaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	30 (27.5)	46 (17.2)	
Unstratified log-rank test			
Normal score[b]			-11.40
p-value			0.0019
Stratified log-rank test[c]			
Normal score[b]			-11.41
p-value			0.0017

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.75, NE	12.26, NE	
Min, Max	0.1, 1.7	0.0, 12.3	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.30, 0.77)
p-value			0.0024
Stratified hazard ratio[c,e]			0.47
(95% CI)			(0.29, 0.76)
p-value			0.0021

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypomagnesaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	18 (16.5)	29 (10.9)	
Unstratified log-rank test			
Normal score[b]			-5.94
p-value			0.0440
Stratified log-rank test[c]			
Normal score[b]			-5.91
p-value			0.0446

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 2.0	0.0, 5.5	
Unstratified hazard ratio[e]			0.55
(95% CI)			(0.30, 0.99)
p-value			0.0476
Stratified hazard ratio[c,e]			0.55
(95% CI)			(0.30, 1.00)
p-value			0.0489

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hyperglycaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	22 (8.2)	
Unstratified log-rank test			
Normal score[b]			-0.93
p-value			0.6961
Stratified log-rank test[c]			
Normal score[b]			-1.04
p-value			0.6608

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 13.4	
Unstratified hazard ratio[e]			0.86
(95% CI)			(0.39, 1.88)
p-value			0.6981
Stratified hazard ratio[c,e]			0.84
(95% CI)			(0.38, 1.85)
p-value			0.6587

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Decreased appetite			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			-8.45
p-value			0.0001
Stratified log-rank test[c]			
Normal score[b]			-8.14
p-value			0.0003

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	2.82, NE	NE, NE	
Min, Max	0.1, 2.8	0.0, 15.8	
Unstratified hazard ratio[e]			0.26
(95% CI)			(0.13, 0.55)
p-value			0.0004
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.13, 0.58)
p-value			0.0007

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypoalbuminaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-4.54
p-value			0.0355
Stratified log-rank test[c]			
Normal score[b]			-4.77
p-value			0.0249

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.8	0.0, 13.6	
Unstratified hazard ratio[e]			0.43
(95% CI)			(0.19, 0.97)
p-value			0.0408
Stratified hazard ratio[c,e]			0.40
(95% CI)			(0.18, 0.92)
p-value			0.0298

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypophosphataemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-1.12
p-value			0.5478
Stratified log-rank test[c]			
Normal score[b]			-1.23
p-value			0.5096

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.6	0.0, 16.1	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.28, 1.99)
p-value			0.5500
Stratified hazard ratio[c,e]			0.72
(95% CI)			(0.27, 1.93)
p-value			0.5114

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypocalcaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			-4.53
p-value			0.0225
Stratified log-rank test[c]			
Normal score[b]			-4.44
p-value			0.0251

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.2	0.1, 16.1	
Unstratified hazard ratio[e]			0.37
(95% CI)			(0.16, 0.90)
p-value			0.0284
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.15, 0.91)
p-value			0.0310

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Tumour lysis syndrome			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			1.75
p-value			0.2148
Stratified log-rank test[c]			
Normal score[b]			1.71
p-value			0.2200

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.1	0.0, 13.9	
Unstratified hazard ratio[e]			3.42
(95% CI)			(0.43, 27.02)
p-value			0.2439
Stratified hazard ratio[c,e]			3.39
(95% CI)			(0.43, 26.90)
p-value			0.2484

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Musculoskeletal and connective tissue disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	37 (33.9)	110 (41.2)	
Unstratified log-rank test			
Normal score[b]			-2.27
p-value			0.6507
Stratified log-rank test[c]			
Normal score[b]			-1.54
p-value			0.7582

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	3.84	
95% CI (median)	(1.70, NE)	(2.92, 8.23)	
Q1, Q3	0.52, NE	0.75, NE	
Min, Max	0.0, 1.7	0.0, 8.2	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.63, 1.34)
p-value			0.6479
Stratified hazard ratio[c,e]			0.94
(95% CI)			(0.64, 1.38)
p-value			0.7403

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Back pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	36 (13.5)	
Unstratified log-rank test			
Normal score[b]			-0.71
p-value			0.7889
Stratified log-rank test[c]			
Normal score[b]			-0.48
p-value			0.8540

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	8.49, NE	
Min, Max	0.0, 1.5	0.1, 10.2	
Unstratified hazard ratio[e]			0.91
(95% CI)			(0.44, 1.87)
p-value			0.7888
Stratified hazard ratio[c,e]			0.93
(95% CI)			(0.45, 1.94)
p-value			0.8499

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Bone pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	31 (11.6)	
Unstratified log-rank test			
Normal score[b]			0.53
p-value			0.8332
Stratified log-rank test[c]			
Normal score[b]			0.62
p-value			0.8041

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	12.00, NE	
Min, Max	0.1, 0.9	0.0, 12.0	
Unstratified hazard ratio[e]			1.09
(95% CI)			(0.49, 2.43)
p-value			0.8317
Stratified hazard ratio[c,e]			1.11
(95% CI)			(0.50, 2.48)
p-value			0.8013

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pain in extremity			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	25 (9.4)	
Unstratified log-rank test			
Normal score[b]			-1.09
p-value			0.6303
Stratified log-rank test[c]			
Normal score[b]			-0.84
p-value			0.7141

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.6	0.0, 10.2	
Unstratified hazard ratio[e]			0.82
(95% CI)			(0.36, 1.87)
p-value			0.6321
Stratified hazard ratio[c,e]			0.86
(95% CI)			(0.37, 1.97)
p-value			0.7162

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Myalgia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			-0.20
p-value			0.9219
Stratified log-rank test[c]			
Normal score[b]			-0.34
p-value			0.8677

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.3	0.1, 5.9	
Unstratified hazard ratio[e]			0.95
(95% CI)			(0.37, 2.45)
p-value			0.9210
Stratified hazard ratio[c,e]			0.92
(95% CI)			(0.36, 2.39)
p-value			0.8667

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Arthralgia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			-0.97
p-value			0.5734
Stratified log-rank test[c]			
Normal score[b]			-1.06
p-value			0.5327

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.2, 8.0	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.25, 2.15)
p-value			0.5747
Stratified hazard ratio[c,e]			0.71
(95% CI)			(0.24, 2.10)
p-value			0.5345

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Muscle spasms			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-0.88
p-value			0.5597
Stratified log-rank test[c]			
Normal score[b]			-0.99
p-value			0.5059

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 2.7	0.1, 9.9	
Unstratified hazard ratio[e]			0.70
(95% CI)			(0.21, 2.35)
p-value			0.5615
Stratified hazard ratio[c,e]			0.66
(95% CI)			(0.20, 2.25)
p-value			0.5085

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Musculoskeletal pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	3 (2.8)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-0.17
p-value			0.9036
Stratified log-rank test[c]			
Normal score[b]			-0.65
p-value			0.6193

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 0.1	0.1, 13.2	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.24, 3.51)
p-value			0.9034
Stratified hazard ratio[c,e]			0.70
(95% CI)			(0.18, 2.83)
p-value			0.6209

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	46 (42.2)	141 (52.8)	
Unstratified log-rank test			
Normal score[b]			4.87
p-value			0.4135
Stratified log-rank test[c]			
Normal score[b]			4.36
p-value			0.4609

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	1.54	
95% CI (median)	(0.82, NE)	(1.08, 2.85)	
Q1, Q3	0.33, NE	0.30, NE	
Min, Max	0.0, 1.6	0.0, 6.2	
Unstratified hazard ratio[e]			1.15
(95% CI)			(0.82, 1.61)
p-value			0.4093
Stratified hazard ratio[c,e]			1.14
(95% CI)			(0.81, 1.59)
p-value			0.4526

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Headache			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	32 (29.4)	79 (29.6)	
Unstratified log-rank test			
Normal score[b]			-4.59
p-value			0.3000
Stratified log-rank test[c]			
Normal score[b]			-4.78
p-value			0.2761

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(6.23, NE)	
Q1, Q3	0.72, NE	1.44, NE	
Min, Max	0.0, 1.3	0.0, 7.9	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.53, 1.22)
p-value			0.3032
Stratified hazard ratio[c,e]			0.79
(95% CI)			(0.52, 1.21)
p-value			0.2764

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Tremor			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	26 (9.7)	
Unstratified log-rank test			
Normal score[b]			7.33
p-value			0.0013
Stratified log-rank test[c]			
Normal score[b]			7.33
p-value			0.0012

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 3.8	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Dizziness			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-1.62
p-value			0.4512
Stratified log-rank test[c]			
Normal score[b]			-1.31
p-value			0.5460

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 8.3	
Unstratified hazard ratio[e]			0.72
(95% CI)			(0.31, 1.70)
p-value			0.4532
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.32, 1.82)
p-value			0.5477

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Somnolence			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			3.00
p-value			0.0773
Stratified log-rank test[c]			
Normal score[b]			2.93
p-value			0.0820

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.5, 0.5	0.1, 10.4	
Unstratified hazard ratio[e]			5.17
(95% CI)			(0.68, 39.43)
p-value			0.1133
Stratified hazard ratio[c,e]			5.07
(95% CI)			(0.66, 38.78)
p-value			0.1178

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Paraesthesia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			2.39
p-value			0.1282
Stratified log-rank test[c]			
Normal score[b]			2.55
p-value			0.1087

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 0.3	0.0, 12.4	
Unstratified hazard ratio[e]			4.29
(95% CI)			(0.55, 33.15)
p-value			0.1629
Stratified hazard ratio[c,e]			4.59
(95% CI)			(0.59, 35.49)
p-value			0.1442

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Psychiatric disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	21 (19.3)	70 (26.2)	
Unstratified log-rank test			
Normal score[b]			1.73
p-value			0.6690
Stratified log-rank test[c]			
Normal score[b]			2.03
p-value			0.6117

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(10.59, NE)	
Q1, Q3	NE, NE	2.23, NE	
Min, Max	0.0, 1.4	0.0, 10.6	
Unstratified hazard ratio[e]			1.11
(95% CI)			(0.68, 1.83)
p-value			0.6686
Stratified hazard ratio[c,e]			1.14
(95% CI)			(0.69, 1.88)
p-value			0.6181

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Insomnia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	31 (11.6)	
Unstratified log-rank test			
Normal score[b]			-0.94
p-value			0.7128
Stratified log-rank test[c]			
Normal score[b]			-1.07
p-value			0.6698

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	15.97, NE	
Min, Max	0.0, 1.3	0.0, 16.0	
Unstratified hazard ratio[e]			0.87
(95% CI)			(0.42, 1.83)
p-value			0.7161
Stratified hazard ratio[c,e]			0.85
(95% CI)			(0.40, 1.80)
p-value			0.6705

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
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[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Anxiety			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-1.54
p-value			0.3945
Stratified log-rank test[c]			
Normal score[b]			-1.33
p-value			0.4652

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 16.5	
Unstratified hazard ratio[e]			0.65
(95% CI)			(0.24, 1.76)
p-value			0.3965
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.25, 1.88)
p-value			0.4675

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Renal and urinary disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	24 (22.0)	36 (13.5)	
Unstratified log-rank test			
Normal score[b]			-11.27
p-value			0.0003
Stratified log-rank test[c]			
Normal score[b]			-11.32
p-value			0.0002

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.59, NE)	(NE, NE)	
Q1, Q3	1.28, NE	NE, NE	
Min, Max	0.1, 2.9	0.0, 10.0	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.22, 0.65)
p-value			0.0004
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.22, 0.65)
p-value			0.0004

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
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[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Acute kidney injury			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-3.75
p-value			0.0360
Stratified log-rank test[c]			
Normal score[b]			-3.78
p-value			0.0334

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.2, 2.9	0.0, 3.2	
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.15, 0.97)
p-value			0.0430
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.15, 0.96)
p-value			0.0401

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Reproductive system and breast disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	3 (2.8)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			0.39
p-value			0.8046
Stratified log-rank test[c]			
Normal score[b]			0.71
p-value			0.6635

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.6	0.1, 4.7	
Unstratified hazard ratio[e]			1.18
(95% CI)			(0.32, 4.27)
p-value			0.8051
Stratified hazard ratio[c,e]			1.33
(95% CI)			(0.37, 4.82)
p-value			0.6646

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	37 (33.9)	102 (38.2)	
Unstratified log-rank test			
Normal score[b]			-7.03
p-value			0.1347
Stratified log-rank test[c]			
Normal score[b]			-6.88
p-value			0.1397

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	4.46	
95% CI (median)	(2.03, NE)	(3.61, 7.84)	
Q1, Q3	0.59, NE	1.21, NE	
Min, Max	0.0, 2.8	0.0, 9.3	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.50, 1.10)
p-value			0.1360
Stratified hazard ratio[c,e]			0.74
(95% CI)			(0.50, 1.10)
p-value			0.1402

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Cough			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	42 (15.7)	
Unstratified log-rank test			
Normal score[b]			3.28
p-value			0.2110
Stratified log-rank test[c]			
Normal score[b]			3.30
p-value			0.2068

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(16.36, NE)	
Q1, Q3	NE, NE	6.10, NE	
Min, Max	0.1, 2.0	0.0, 16.4	
Unstratified hazard ratio[e]			1.74
(95% CI)			(0.72, 4.18)
p-value			0.2171
Stratified hazard ratio[c,e]			1.75
(95% CI)			(0.73, 4.22)
p-value			0.2131

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Epistaxis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-2.50
p-value			0.2501
Stratified log-rank test[c]			
Normal score[b]			-2.32
p-value			0.2885

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 0.9	0.0, 9.2	
Unstratified hazard ratio[e]			0.62
(95% CI)			(0.27, 1.41)
p-value			0.2539
Stratified hazard ratio[c,e]			0.64
(95% CI)			(0.28, 1.47)
p-value			0.2919

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Dyspnoea			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	8 (7.3)	17 (6.4)	
Unstratified log-rank test			
Normal score[b]			-2.20
p-value			0.2876
Stratified log-rank test[c]			
Normal score[b]			-1.96
p-value			0.3478

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.1, 16.3	
Unstratified hazard ratio[e]			0.63
(95% CI)			(0.27, 1.49)
p-value			0.2913
Stratified hazard ratio[c,e]			0.66
(95% CI)			(0.28, 1.58)
p-value			0.3512

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Oropharyngeal pain			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-3.78
p-value			0.0160
Stratified log-rank test[c]			
Normal score[b]			-3.85
p-value			0.0112

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	18.72	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	18.72, 18.72	
Min, Max	0.1, 1.4	0.1, 18.7	
Unstratified hazard ratio[e]			0.31
(95% CI)			(0.11, 0.84)
p-value			0.0217
Stratified hazard ratio[c,e]			0.27
(95% CI)			(0.09, 0.80)
p-value			0.0178

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Productive cough			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			0.42
p-value			0.6891
Stratified log-rank test[c]			
Normal score[b]			0.15
p-value			0.8754

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	2.1, 2.1	0.0, 14.2	
Unstratified hazard ratio[e]			1.54
(95% CI)			(0.18, 12.92)
p-value			0.6912
Stratified hazard ratio[c,e]			1.19
(95% CI)			(0.14, 10.23)
p-value			0.8756

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Skin and subcutaneous tissue disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	41 (37.6)	93 (34.8)	
Unstratified log-rank test			
Normal score[b]			-10.71
p-value			0.0231
Stratified log-rank test[c]			
Normal score[b]			-10.62
p-value			0.0236

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	2.72	7.84	
95% CI (median)	(1.25, NE)	(3.84, NE)	
Q1, Q3	0.49, NE	0.95, NE	
Min, Max	0.0, 2.7	0.0, 8.7	
Unstratified hazard ratio[e]			0.65
(95% CI)			(0.44, 0.94)
p-value			0.0239
Stratified hazard ratio[c,e]			0.65
(95% CI)			(0.44, 0.95)
p-value			0.0256

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Rash			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			-5.16
p-value			0.0311
Stratified log-rank test[c]			
Normal score[b]			-5.11
p-value			0.0316

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.7	0.1, 6.6	
Unstratified hazard ratio[e]			0.46
(95% CI)			(0.22, 0.95)
p-value			0.0353
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.22, 0.95)
p-value			0.0363

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hyperhidrosis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			1.10
p-value			0.4617
Stratified log-rank test[c]			
Normal score[b]			1.33
p-value			0.3845

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas
Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:29) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.4, 1.0	0.0, 7.8	
Unstratified hazard ratio[e]			1.76
(95% CI)			(0.38, 8.16)
p-value			0.4677
Stratified hazard ratio[c,e]			1.95
(95% CI)			(0.42, 9.01)
p-value			0.3931

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Vascular disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	28 (25.7)	64 (24.0)	
Unstratified log-rank test			
Normal score[b]			-7.17
p-value			0.0648
Stratified log-rank test[c]			
Normal score[b]			-6.95
p-value			0.0726

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	14.20	
95% CI (median)	(NE, NE)	(10.10, NE)	
Q1, Q3	1.21, NE	3.21, NE	
Min, Max	0.1, 1.5	0.0, 14.2	
Unstratified hazard ratio[e]			0.65
(95% CI)			(0.41, 1.03)
p-value			0.0672
Stratified hazard ratio[c,e]			0.65
(95% CI)			(0.41, 1.04)
p-value			0.0737

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypotension			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	33 (12.4)	
Unstratified log-rank test			
Normal score[b]			-1.86
p-value			0.5117
Stratified log-rank test[c]			
Normal score[b]			-1.83
p-value			0.5168

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.0, 6.3	
Unstratified hazard ratio[e]			0.80
(95% CI)			(0.41, 1.55)
p-value			0.5127
Stratified hazard ratio[c,e]			0.80
(95% CI)			(0.41, 1.56)
p-value			0.5157

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypertension			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-3.01
p-value			0.1508
Stratified log-rank test[c]			
Normal score[b]			-2.95
p-value			0.1592

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.0, 14.2	
Unstratified hazard ratio[e]			0.54
(95% CI)			(0.24, 1.26)
p-value			0.1568
Stratified hazard ratio[c,e]			0.55
(95% CI)			(0.24, 1.28)
p-value			0.1647

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	17 (15.6)	38 (14.2)	
Unstratified log-rank test			
Normal score[b]			-5.69
p-value			0.0504
Stratified log-rank test[c]			
Normal score[b]			-5.99
p-value			0.0365

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	1.97, NE	11.05, NE	
Min, Max	0.1, 2.8	0.1, 11.0	
Unstratified hazard ratio[e]			0.55
(95% CI)			(0.30, 1.01)
p-value			0.0533
Stratified hazard ratio[c,e]			0.53
(95% CI)			(0.29, 0.97)
p-value			0.0399

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	12 (11.0)	24 (9.0)	
Unstratified log-rank test			
Normal score[b]			-4.56
p-value			0.0530
Stratified log-rank test[c]			
Normal score[b]			-4.51
p-value			0.0550

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(2.82, NE)	(NE, NE)	
Q1, Q3	2.82, NE	NE, NE	
Min, Max	0.2, 2.8	0.1, 6.7	
Unstratified hazard ratio[e]			0.49
(95% CI)			(0.24, 1.02)
p-value			0.0576
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.24, 1.03)
p-value			0.0602

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-0.33
p-value			0.7691
Stratified log-rank test[c]			
Normal score[b]			-0.38
p-value			0.7354

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.2	0.6, 16.0	
Unstratified hazard ratio[e]			0.78
(95% CI)			(0.15, 4.07)
p-value			0.7703
Stratified hazard ratio[c,e]			0.75
(95% CI)			(0.15, 3.91)
p-value			0.7361

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	27 (10.1)	
Unstratified log-rank test			
Normal score[b]			3.77
p-value			0.0694
Stratified log-rank test[c]			
Normal score[b]			3.66
p-value			0.0735

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.7, 1.0	0.1, 10.0	
Unstratified hazard ratio[e]			3.53
(95% CI)			(0.83, 15.07)
p-value			0.0887
Stratified hazard ratio[c,e]			3.49
(95% CI)			(0.81, 14.96)
p-value			0.0928

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			2.26
p-value			0.1490
Stratified log-rank test[c]			
Normal score[b]			2.27
p-value			0.1460

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	1.0, 1.0	0.1, 10.0	
Unstratified hazard ratio[e]			4.01
(95% CI)			(0.52, 30.89)
p-value			0.1820
Stratified hazard ratio[c,e]			4.06
(95% CI)			(0.53, 31.30)
p-value			0.1792

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			2.65
p-value			0.0566
Stratified log-rank test[c]			
Normal score[b]			2.57
p-value			0.0625

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 3.3	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	33 (30.3)	79 (29.6)	
Unstratified log-rank test			
Normal score[b]			-12.05
p-value			0.0023
Stratified log-rank test[c]			
Normal score[b]			-11.93
p-value			0.0025

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	8.07	
95% CI (median)	(2.03, NE)	(5.87, 16.13)	
Q1, Q3	0.92, NE	2.56, NE	
Min, Max	0.0, 2.1	0.0, 16.3	
Unstratified hazard ratio[e]			0.51
(95% CI)			(0.33, 0.80)
p-value			0.0028
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.33, 0.80)
p-value			0.0029

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sepsis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-2.99
p-value			0.0865
Stratified log-rank test[c]			
Normal score[b]			-2.85
p-value			0.1053

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.1, 8.1	
Unstratified hazard ratio[e]			0.44
(95% CI)			(0.17, 1.15)
p-value			0.0947
Stratified hazard ratio[c,e]			0.46
(95% CI)			(0.17, 1.21)
p-value			0.1145

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pneumonia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			0.33
p-value			0.8010
Stratified log-rank test[c]			
Normal score[b]			0.26
p-value			0.8398

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.6	0.0, 8.3	
Unstratified hazard ratio[e]			1.22
(95% CI)			(0.25, 5.96)
p-value			0.8018
Stratified hazard ratio[c,e]			1.18
(95% CI)			(0.24, 5.77)
p-value			0.8400

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Injury, poisoning and procedural complications			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	1 (0.9)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			3.36
p-value			0.0573
Stratified log-rank test[c]			
Normal score[b]			3.49
p-value			0.0506

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.5, 0.5	0.0, 2.5	
Unstratified hazard ratio[e]			5.70
(95% CI)			(0.75, 43.24)
p-value			0.0925
Stratified hazard ratio[c,e]			5.93
(95% CI)			(0.78, 45.01)
p-value			0.0854

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	2 (1.8)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			1.19
p-value			0.4337
Stratified log-rank test[c]			
Normal score[b]			1.18
p-value			0.4353

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
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Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.4, 0.7	0.0, 12.0	
Unstratified hazard ratio[e]			1.82
(95% CI)			(0.40, 8.36)
p-value			0.4408
Stratified hazard ratio[c,e]			1.82
(95% CI)			(0.40, 8.37)
p-value			0.4419

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	21 (7.9)	
Unstratified log-rank test			
Normal score[b]			1.18
p-value			0.5482
Stratified log-rank test[c]			
Normal score[b]			0.91
p-value			0.6331

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 8.9	
Unstratified hazard ratio[e]			1.40
(95% CI)			(0.47, 4.17)
p-value			0.5508
Stratified hazard ratio[c,e]			1.31
(95% CI)			(0.43, 3.93)
p-value			0.6342

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	16 (6.0)	
Unstratified log-rank test			
Normal score[b]			-0.30
p-value			0.8730
Stratified log-rank test[c]			
Normal score[b]			-0.60
p-value			0.7411

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.13. Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 2.0	0.1, 16.4	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.33, 2.57)
p-value			0.8728
Stratified hazard ratio[c,e]			0.84
(95% CI)			(0.30, 2.36)
p-value			0.7372

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-ser-teae-soc-pt-saf.sas
Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	75 (68.8)	154 (57.7)	
Unstratified log-rank test			
Normal score[b]			-23.26
p-value			0.0001
Stratified log-rank test[c]			
Normal score[b]			-22.16
p-value			0.0003

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.30	1.44	
95% CI (median)	(0.26, 0.39)	(0.75, 2.36)	
Q1, Q3	0.16, NE	0.20, 8.26	
Min, Max	0.0, 1.9	0.0, 11.0	
Unstratified hazard ratio[e]			0.58
(95% CI)			(0.44, 0.77)
p-value			0.0002
Stratified hazard ratio[c,e]			0.59
(95% CI)			(0.44, 0.79)
p-value			0.0003

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	38 (34.9)	58 (21.7)	
Unstratified log-rank test			
Normal score[b]			-14.53
p-value			0.0004
Stratified log-rank test[c]			
Normal score[b]			-14.32
p-value			0.0005

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.77, NE)	(NE, NE)	
Q1, Q3	0.43, NE	4.59, NE	
Min, Max	0.0, 2.8	0.0, 6.7	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.32, 0.73)
p-value			0.0006
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.32, 0.74)
p-value			0.0007

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Anaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	38 (34.9)	53 (19.9)	
Unstratified log-rank test			
Normal score[b]			-14.34
p-value			0.0005
Stratified log-rank test[c]			
Normal score[b]			-14.23
p-value			0.0005

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(1.93, NE)	(15.93, NE)	
Q1, Q3	0.39, NE	11.90, NE	
Min, Max	0.0, 1.9	0.0, 15.9	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.32, 0.73)
p-value			0.0007
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.31, 0.73)
p-value			0.0007

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	29 (26.6)	47 (17.6)	
Unstratified log-rank test			
Normal score[b]			-12.79
p-value			0.0002
Stratified log-rank test[c]			
Normal score[b]			-13.19
p-value			<0.0001

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.36, NE	4.62, NE	
Min, Max	0.1, 2.3	0.0, 8.3	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.25, 0.66)
p-value			0.0003
Stratified hazard ratio[c,e]			0.38
(95% CI)			(0.23, 0.63)
p-value			0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Thrombocytopenia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	30 (27.5)	40 (15.0)	
Unstratified log-rank test			
Normal score[b]			-11.60
p-value			0.0014
Stratified log-rank test[c]			
Normal score[b]			-11.03
p-value			0.0026

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Data cut-off date: 14MAR2017

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.36, NE	NE, NE	
Min, Max	0.0, 2.0	0.0, 16.3	
Unstratified hazard ratio[e]			0.46
(95% CI)			(0.29, 0.75)
p-value			0.0018
Stratified hazard ratio[c,e]			0.48
(95% CI)			(0.30, 0.78)
p-value			0.0032

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Cardiac disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	4 (3.7)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-0.31
p-value			0.8490
Stratified log-rank test[c]			
Normal score[b]			-0.57
p-value			0.7218

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.3	0.0, 16.4	
Unstratified hazard ratio[e]			0.89
(95% CI)			(0.28, 2.86)
p-value			0.8491
Stratified hazard ratio[c,e]			0.81
(95% CI)			(0.25, 2.62)
p-value			0.7223

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	15 (13.8)	21 (7.9)	
Unstratified log-rank test			
Normal score[b]			-8.08
p-value			0.0004
Stratified log-rank test[c]			
Normal score[b]			-8.02
p-value			0.0004

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	15.97, NE	
Min, Max	0.0, 1.9	0.1, 16.0	
Unstratified hazard ratio[e]			0.28
(95% CI)			(0.13, 0.59)
p-value			0.0008
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.13, 0.59)
p-value			0.0009

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	16 (14.7)	47 (17.6)	
Unstratified log-rank test			
Normal score[b]			-0.94
p-value			0.7762
Stratified log-rank test[c]			
Normal score[b]			-0.98
p-value			0.7656

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	10.23, NE	
Min, Max	0.0, 2.0	0.0, 10.4	
Unstratified hazard ratio[e]			0.92
(95% CI)			(0.52, 1.65)
p-value			0.7806
Stratified hazard ratio[c,e]			0.92
(95% CI)			(0.51, 1.64)
p-value			0.7684

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	20 (7.5)	
Unstratified log-rank test			
Normal score[b]			0.88
p-value			0.6701
Stratified log-rank test[c]			
Normal score[b]			0.82
p-value			0.6912

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.5	0.0, 10.2	
Unstratified hazard ratio[e]			1.25
(95% CI)			(0.46, 3.39)
p-value			0.6680
Stratified hazard ratio[c,e]			1.22
(95% CI)			(0.45, 3.33)
p-value			0.6921

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Hepatobiliary disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	14 (5.2)	
Unstratified log-rank test			
Normal score[b]			-1.18
p-value			0.5289
Stratified log-rank test[c]			
Normal score[b]			-1.06
p-value			0.5748

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.0, 3.0	
Unstratified hazard ratio[e]			0.73
(95% CI)			(0.28, 1.94)
p-value			0.5296
Stratified hazard ratio[c,e]			0.76
(95% CI)			(0.29, 2.01)
p-value			0.5766

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	0 (0.0)	19 (7.1)	
Unstratified log-rank test			
Normal score[b]			3.83
p-value			0.0231
Stratified log-rank test[c]			
Normal score[b]			3.74
p-value			0.0251

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	NE, NE	0.0, 7.0	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	57 (52.3)	93 (34.8)	
Unstratified log-rank test			
Normal score[b]			-29.02
p-value			<0.0001
Stratified log-rank test[c]			
Normal score[b]			-29.18
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.11	7.25	
95% CI (median)	(0.62, 2.03)	(5.54, 16.13)	
Q1, Q3	0.39, NE	1.57, NE	
Min, Max	0.0, 2.1	0.0, 16.1	
Unstratified hazard ratio[e]			0.33
(95% CI)			(0.23, 0.48)
p-value			<0.0001
Stratified hazard ratio[c,e]			0.32
(95% CI)			(0.22, 0.46)
p-value			<0.0001

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Sepsis			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-3.20
p-value			0.0616
Stratified log-rank test[c]			
Normal score[b]			-3.02
p-value			0.0812

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 2.0	0.1, 8.1	
Unstratified hazard ratio[e]			0.41
(95% CI)			(0.16, 1.07)
p-value			0.0696
Stratified hazard ratio[c,e]			0.43
(95% CI)			(0.16, 1.14)
p-value			0.0903

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Device related infection			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	5 (4.6)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			-1.87
p-value			0.2157
Stratified log-rank test[c]			
Normal score[b]			-1.75
p-value			0.2512

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 0.7	0.2, 16.7	
Unstratified hazard ratio[e]			0.49
(95% CI)			(0.15, 1.55)
p-value			0.2251
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.16, 1.63)
p-value			0.2591

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Pneumonia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	11 (4.1)	
Unstratified log-rank test			
Normal score[b]			-5.64
p-value			0.0042
Stratified log-rank test[c]			
Normal score[b]			-5.67
p-value			0.0039

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.6	0.0, 8.3	
Unstratified hazard ratio[e]			0.29
(95% CI)			(0.12, 0.72)
p-value			0.0069
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.12, 0.71)
p-value			0.0066

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Bacteraemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	2 (0.7)	
Unstratified log-rank test			
Normal score[b]			-3.97
p-value			0.0011
Stratified log-rank test[c]			
Normal score[b]			-3.98
p-value			0.0011

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 2.1	0.1, 1.3	
Unstratified hazard ratio[e]			0.11
(95% CI)			(0.02, 0.54)
p-value			0.0069
Stratified hazard ratio[c,e]			0.11
(95% CI)			(0.02, 0.54)
p-value			0.0067

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Investigations			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	28 (25.7)	61 (22.8)	
Unstratified log-rank test			
Normal score[b]			-5.33
p-value			0.1829
Stratified log-rank test[c]			
Normal score[b]			-4.75
p-value			0.2374

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(13.61, NE)	
Q1, Q3	0.98, NE	4.59, NE	
Min, Max	0.0, 1.5	0.0, 13.6	
Unstratified hazard ratio[e]			0.74
(95% CI)			(0.47, 1.16)
p-value			0.1889
Stratified hazard ratio[c,e]			0.77
(95% CI)			(0.48, 1.21)
p-value			0.2535

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Alanine aminotransferase increased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	9 (8.3)	15 (5.6)	
Unstratified log-rank test			
Normal score[b]			-2.62
p-value			0.2217
Stratified log-rank test[c]			
Normal score[b]			-2.60
p-value			0.2248

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 3.0	0.0, 3.0	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.26, 1.38)
p-value			0.2265
Stratified hazard ratio[c,e]			0.60
(95% CI)			(0.26, 1.39)
p-value			0.2320

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: White blood cell count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	13 (4.9)	
Unstratified log-rank test			
Normal score[b]			-1.25
p-value			0.4993
Stratified log-rank test[c]			
Normal score[b]			-1.23
p-value			0.5059

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.0	0.1, 13.6	
Unstratified hazard ratio[e]			0.72
(95% CI)			(0.27, 1.92)
p-value			0.5059
Stratified hazard ratio[c,e]			0.72
(95% CI)			(0.27, 1.94)
p-value			0.5141

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Platelet count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	12 (4.5)	
Unstratified log-rank test			
Normal score[b]			-6.76
p-value			0.0015
Stratified log-rank test[c]			
Normal score[b]			-6.55
p-value			0.0023

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KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.3	0.0, 16.0	
Unstratified hazard ratio[e]			0.29
(95% CI)			(0.13, 0.65)
p-value			0.0029
Stratified hazard ratio[c,e]			0.30
(95% CI)			(0.13, 0.68)
p-value			0.0040

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Neutrophil count decreased			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-5.90
p-value			0.0023
Stratified log-rank test[c]			
Normal score[b]			-5.78
p-value			0.0030

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.4	0.1, 5.5	
Unstratified hazard ratio[e]			0.27
(95% CI)			(0.11, 0.66)
p-value			0.0043
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.12, 0.69)
p-value			0.0053

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	26 (23.9)	40 (15.0)	
Unstratified log-rank test			
Normal score[b]			-9.90
p-value			0.0038
Stratified log-rank test[c]			
Normal score[b]			-9.58
p-value			0.0054

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.74, NE	12.00, NE	
Min, Max	0.0, 2.3	0.0, 12.0	
Unstratified hazard ratio[e]			0.48
(95% CI)			(0.29, 0.80)
p-value			0.0047
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.30, 0.82)
p-value			0.0065

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hypokalaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	11 (10.1)	10 (3.7)	
Unstratified log-rank test			
Normal score[b]			-5.85
p-value			0.0026
Stratified log-rank test[c]			
Normal score[b]			-5.67
p-value			0.0038

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.3, 1.7	0.1, 12.3	
Unstratified hazard ratio[e]			0.28
(95% CI)			(0.11, 0.68)
p-value			0.0048
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.12, 0.70)
p-value			0.0064

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
PT: Hyperglycaemia			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	7 (6.4)	9 (3.4)	
Unstratified log-rank test			
Normal score[b]			-2.91
p-value			0.0903
Stratified log-rank test[c]			
Normal score[b]			-2.96
p-value			0.0828

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 12.0	
Unstratified hazard ratio[e]			0.43
(95% CI)			(0.15, 1.18)
p-value			0.1004
Stratified hazard ratio[c,e]			0.42
(95% CI)			(0.15, 1.16)
p-value			0.0932

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Musculoskeletal and connective tissue disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	18 (6.7)	
Unstratified log-rank test			
Normal score[b]			-1.23
p-value			0.5138
Stratified log-rank test[c]			
Normal score[b]			-0.92
p-value			0.6324

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.7	0.1, 14.2	
Unstratified hazard ratio[e]			0.73
(95% CI)			(0.28, 1.91)
p-value			0.5156
Stratified hazard ratio[c,e]			0.79
(95% CI)			(0.30, 2.08)
p-value			0.6331

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	25 (9.4)	
Unstratified log-rank test			
Normal score[b]			-1.65
p-value			0.5056
Stratified log-rank test[c]			
Normal score[b]			-1.82
p-value			0.4570

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.0, 1.1	0.0, 8.9	
Unstratified hazard ratio[e]			0.78
(95% CI)			(0.37, 1.64)
p-value			0.5065
Stratified hazard ratio[c,e]			0.75
(95% CI)			(0.35, 1.60)
p-value			0.4582

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	13 (11.9)	21 (7.9)	
Unstratified log-rank test			
Normal score[b]			-4.80
p-value			0.0506
Stratified log-rank test[c]			
Normal score[b]			-5.09
p-value			0.0346

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 2.0	0.1, 16.4	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.25, 1.02)
p-value			0.0550
Stratified hazard ratio[c,e]			0.47
(95% CI)			(0.23, 0.96)
p-value			0.0389

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
SOC: Vascular disorders			
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	6 (5.5)	9 (3.4)	
Unstratified log-rank test			
Normal score[b]			-2.81
p-value			0.0682
Stratified log-rank test[c]			
Normal score[b]			-2.72
p-value			0.0799

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
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Table 14-6.1.14. Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	NE, NE	
Min, Max	0.1, 1.2	0.0, 5.7	
Unstratified hazard ratio[e]			0.37
(95% CI)			(0.12, 1.12)
p-value			0.0788
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.13, 1.16)
p-value			0.0903

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of severe treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sev-teae-soc-pt-saf.sas
Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adae

Table 14-6.1.15. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Subject status			
Number of subjects	109	267	
Events - n (%)[a]	10 (9.2)	41 (15.4)	
Unstratified log-rank test			
Normal score[b]			1.58
p-value			0.5880
Stratified log-rank test[c]			
Normal score[b]			1.09
p-value			0.7032
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(16.33, NE)	
Q1, Q3	NE, NE	16.33, NE	
Min, Max	0.1, 2.0	0.0, 16.3	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment excluding disease-related events.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-trt-disc-edp-saf.sas
Output: t14-06-001-015-tte-teae-trt-disc-edp-saf.rtf (Date generated: 04DEC2025:07:00) Source data: adam_fa.adsl, adam.adtteae

Table 14-6.1.15. Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N=109)	Blinatumomab (N=267)	Treatment Difference
Unstratified hazard ratio[e]			1.22
(95% CI)			(0.60, 2.46)
p-value			0.5883
Stratified hazard ratio[c,e]			1.15
(95% CI)			(0.56, 2.33)
p-value			0.7049

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. n = Number of subjects with observed data.
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event leading to discontinuation of study treatment excluding disease-related events.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to SOC Chemotherapy and therefore a longer survival time.
[c] Stratification factors are: age (<35 vs. ≥ 35), prior salvage therapy (yes vs. no), and prior alloHSCT (yes vs. no).
[d] Months are calculated as days from treatment start date to event date, divided by 30.5.
[e] The hazard and hazard ratio estimates are obtained from the unstratified and stratified Cox proportional hazard model. A hazard ratio < 1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to SOC Chemotherapy.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-teae-trt-disc-edp-saf.sas
Output: t14-06-001-015-tte-teae-trt-disc-edp-saf.rtf (Date generated: 04DEC2025:07:00) Source data: adam_fa.adsl, adam.adtteae

Anhang 4-G4.3: Analysen zum Datenschnitt 14. März 2017 (Grafiken)

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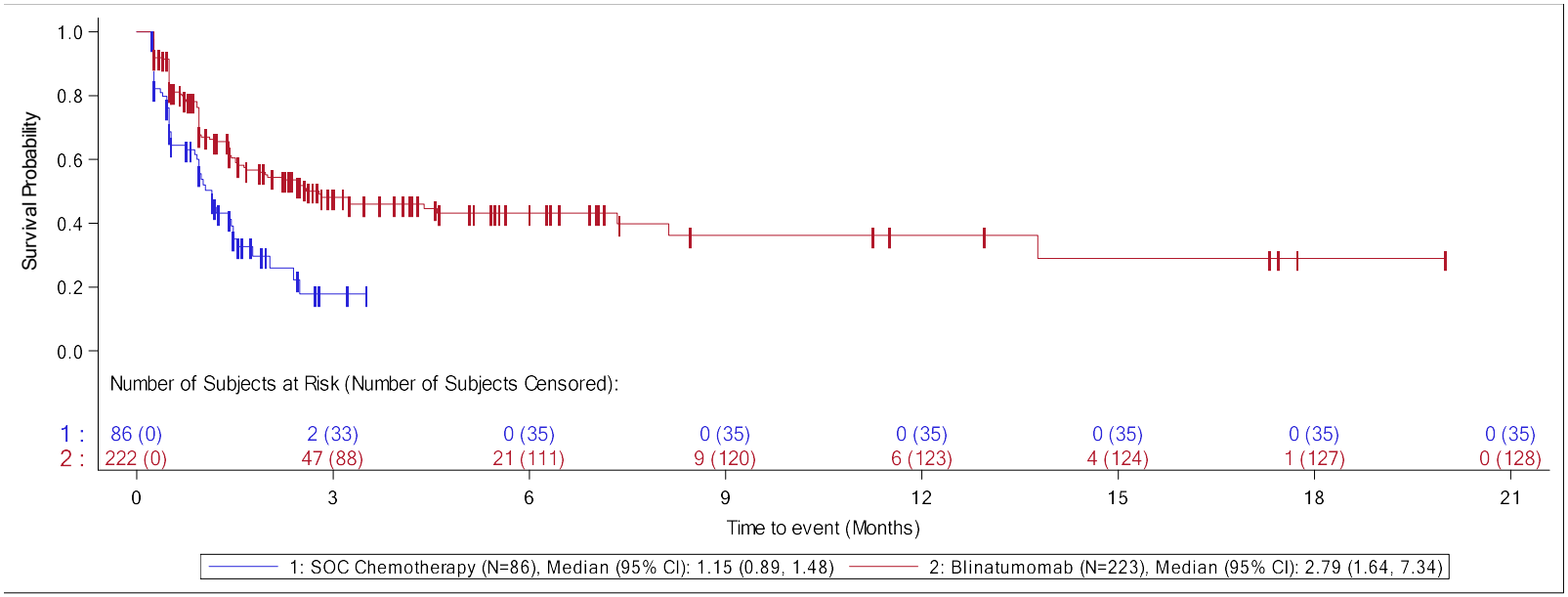
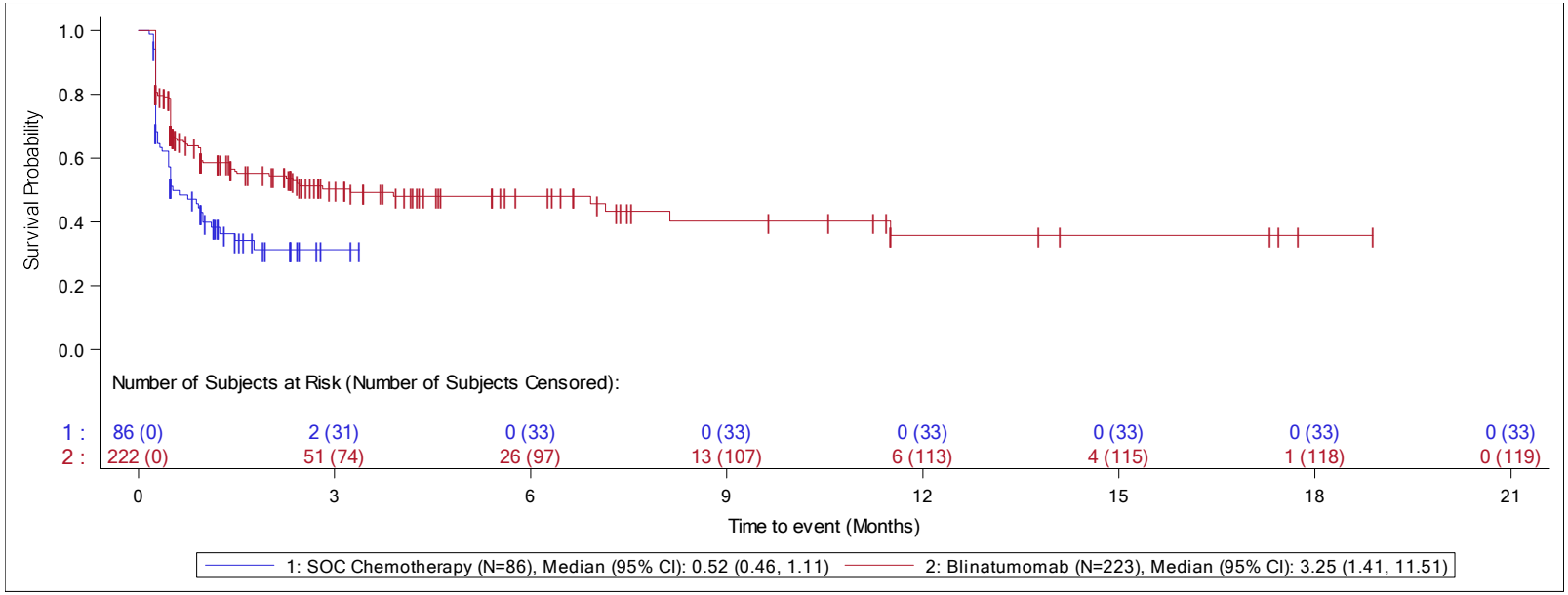
Figure 14-4.3.1. Kaplan-Meier plot for Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ts-allas.sas
Output: f14-04-003-001-km-de-allss-ts-allas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam.adtteqs

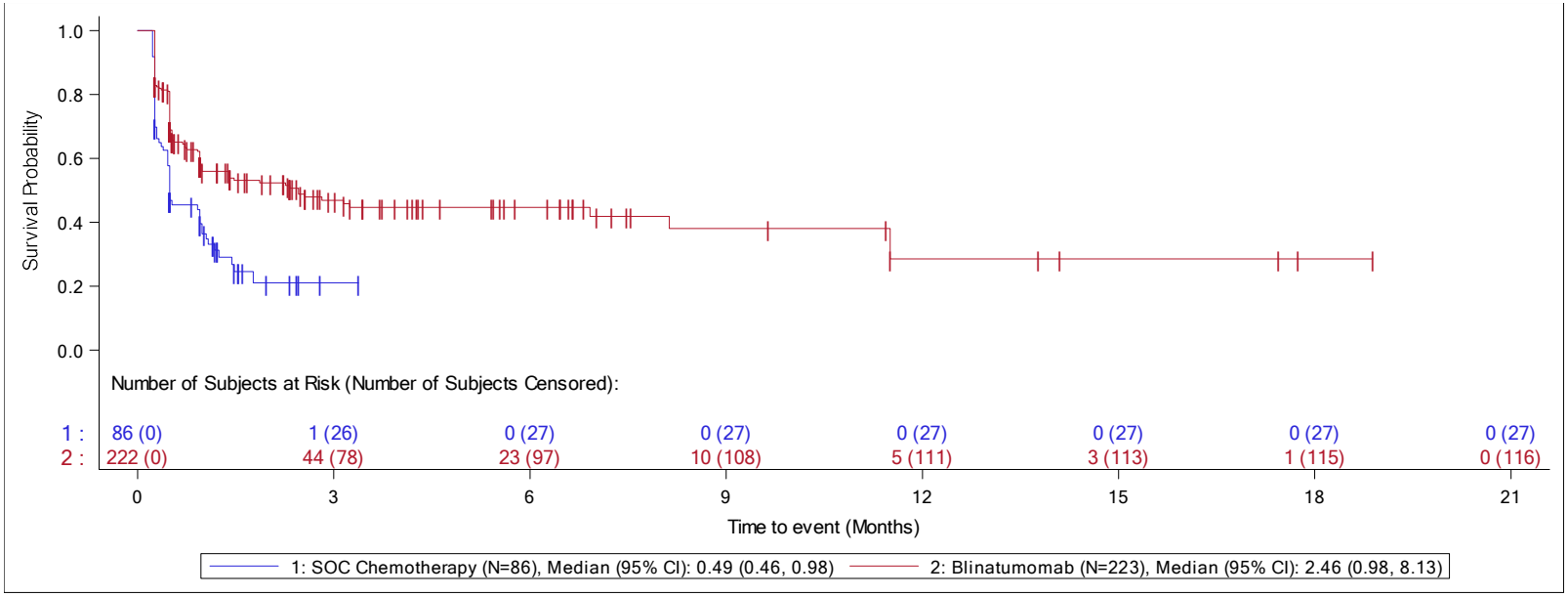
Figure 14-4.3.2. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Tiredness (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda1t-allas.sas
Output: f14-04-003-002-km-de-allss-ttda1t-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

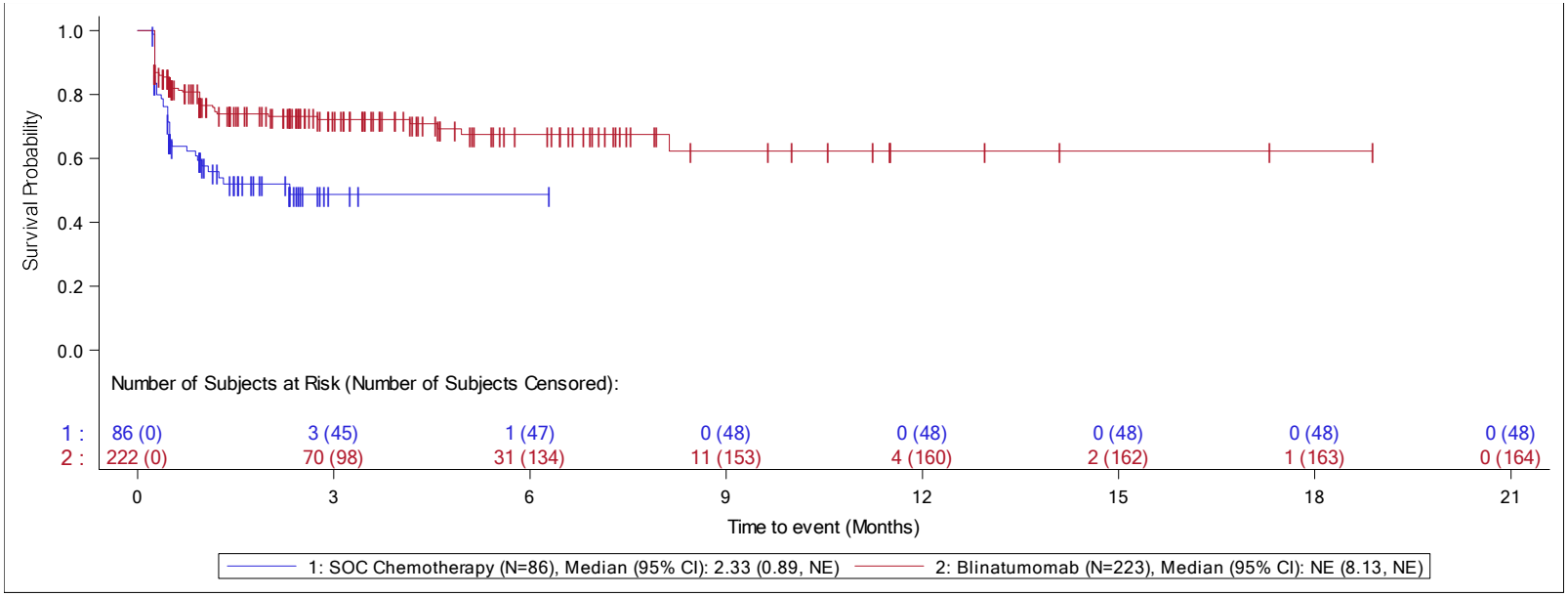
Figure 14-4.3.3. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Weakness (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda2pw-allas.sas
Output: f14-04-003-003-km-de-allss-ttda2pw-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

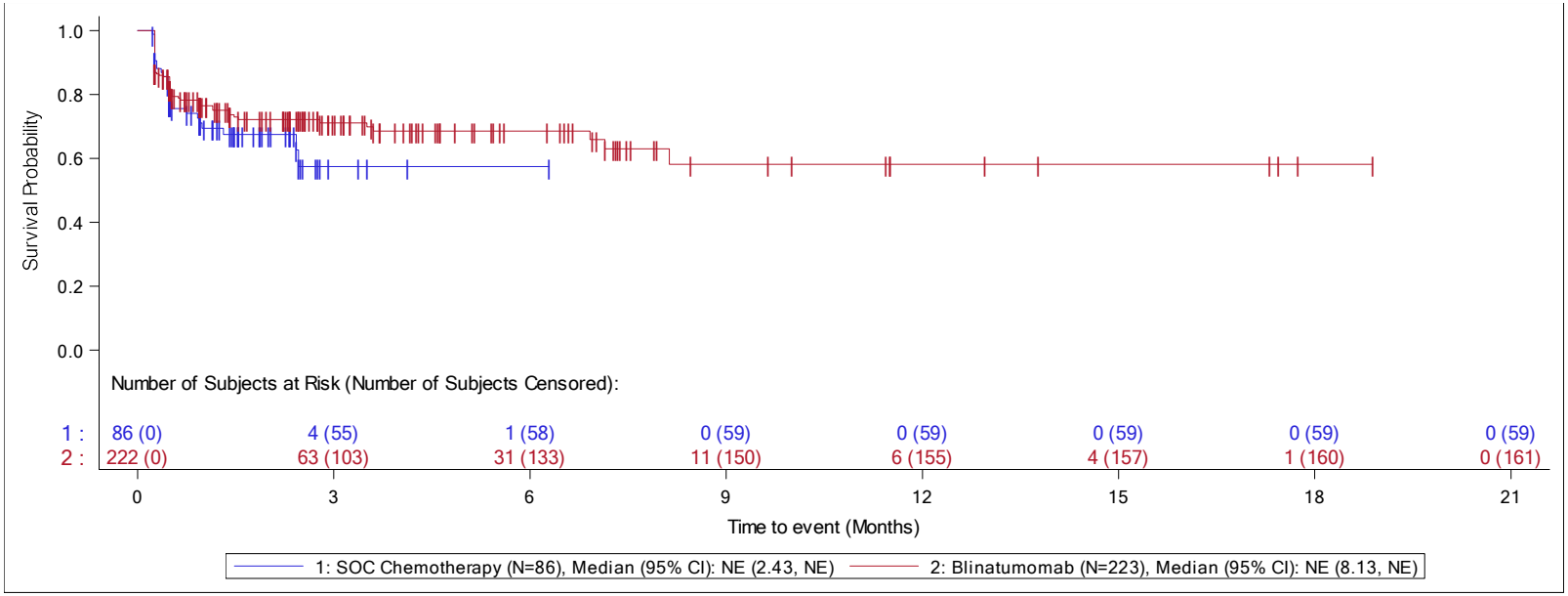
Figure 14-4.3.4. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bruise (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda3br-allas.sas
Output: f14-04-003-004-km-de-allss-ttda3br-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

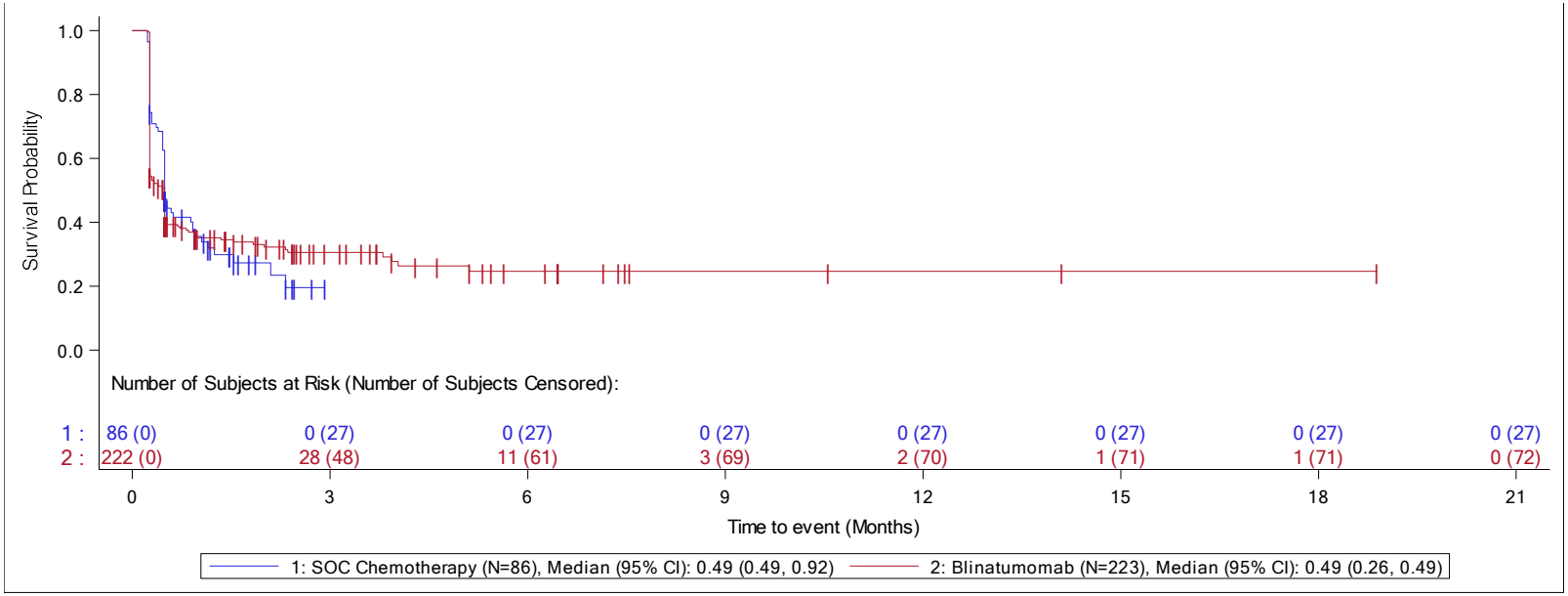
Figure 14-4.3.5. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Bleeding (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda4bl-allas.sas
Output: f14-04-003-005-km-de-allss-ttda4bl-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

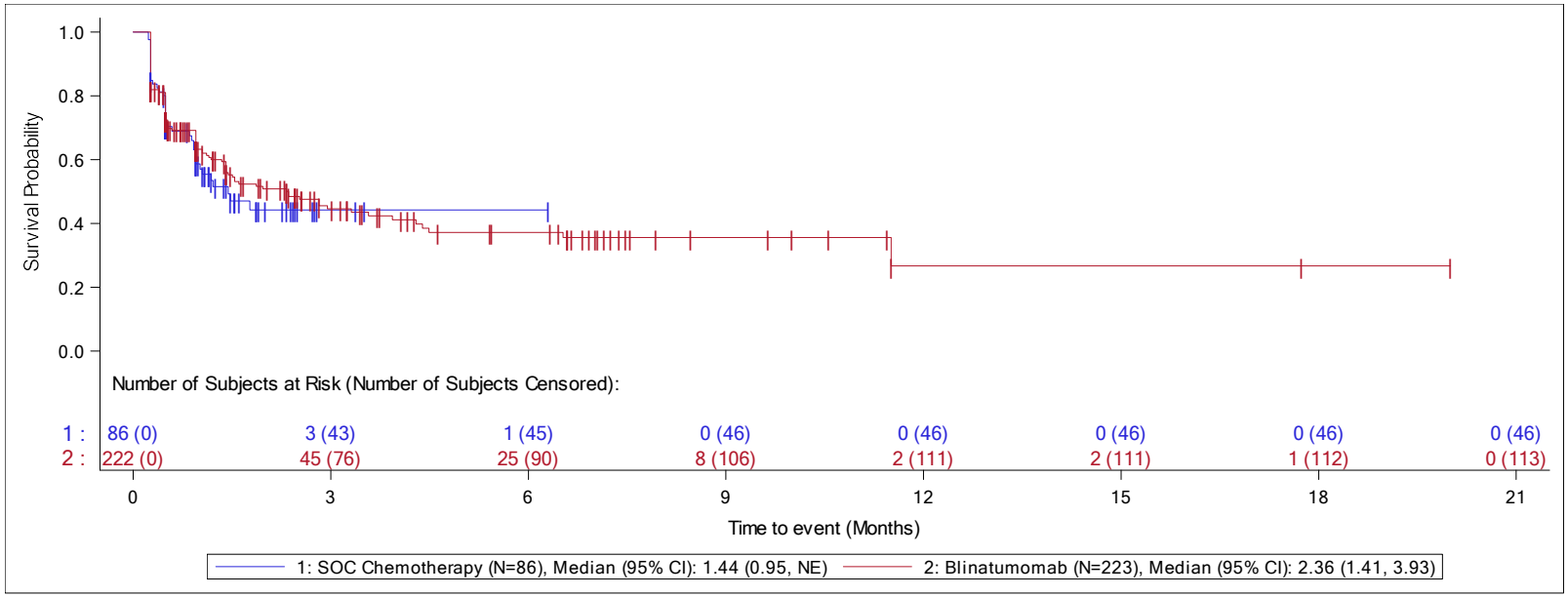
Figure 14-4.3.6. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fever (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda5f-allas.sas
Output: f14-04-003-006-km-de-allss-ttda5f-allas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

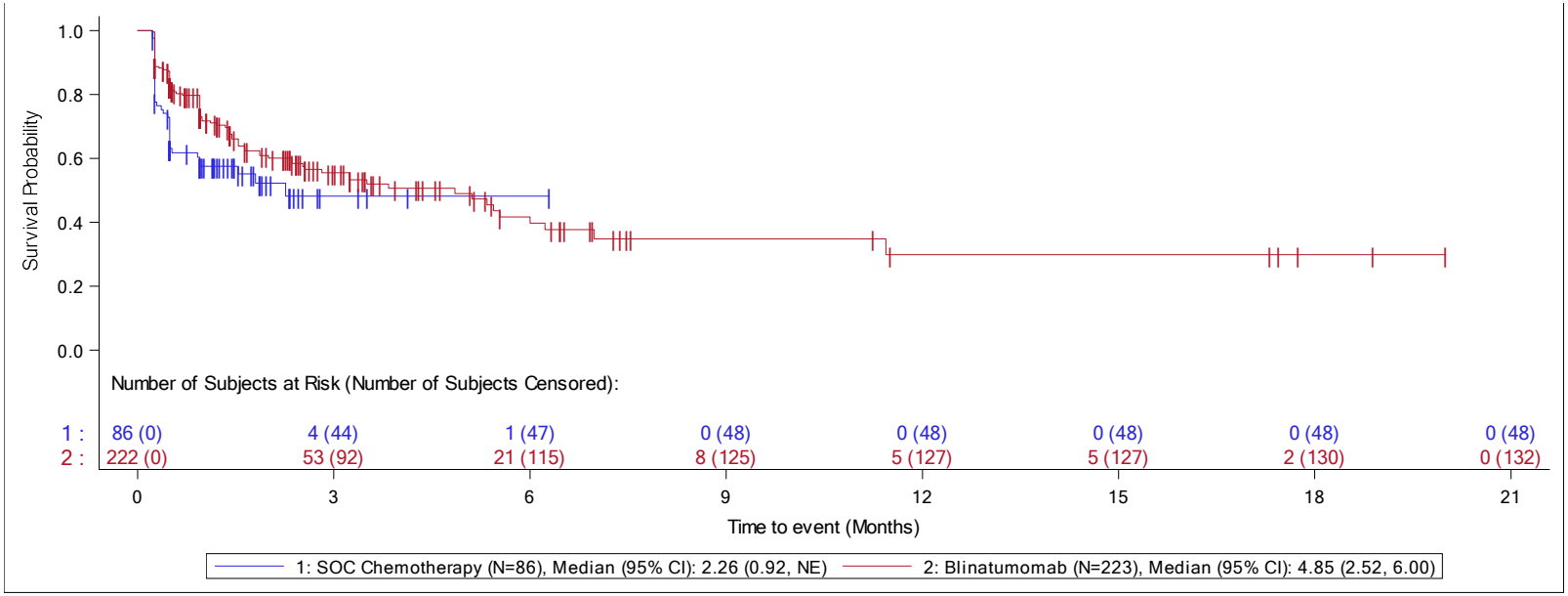
Figure 14-4.3.7. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Joint or bone pain
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda6p-allas.sas
Output: f14-04-003-007-km-de-allss-ttda6p-allas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

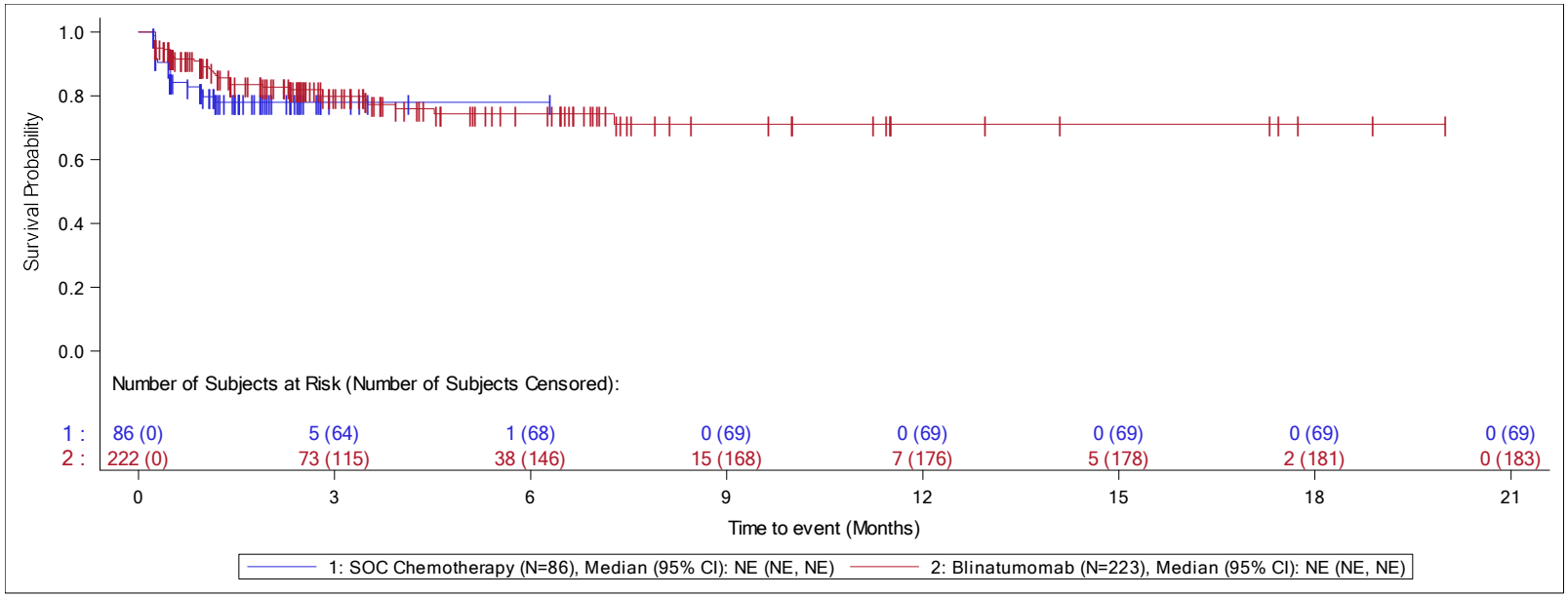
Figure 14-4.3.8. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Itch (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda7i-allas.sas
Output: f14-04-003-008-km-de-allss-ttda7i-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

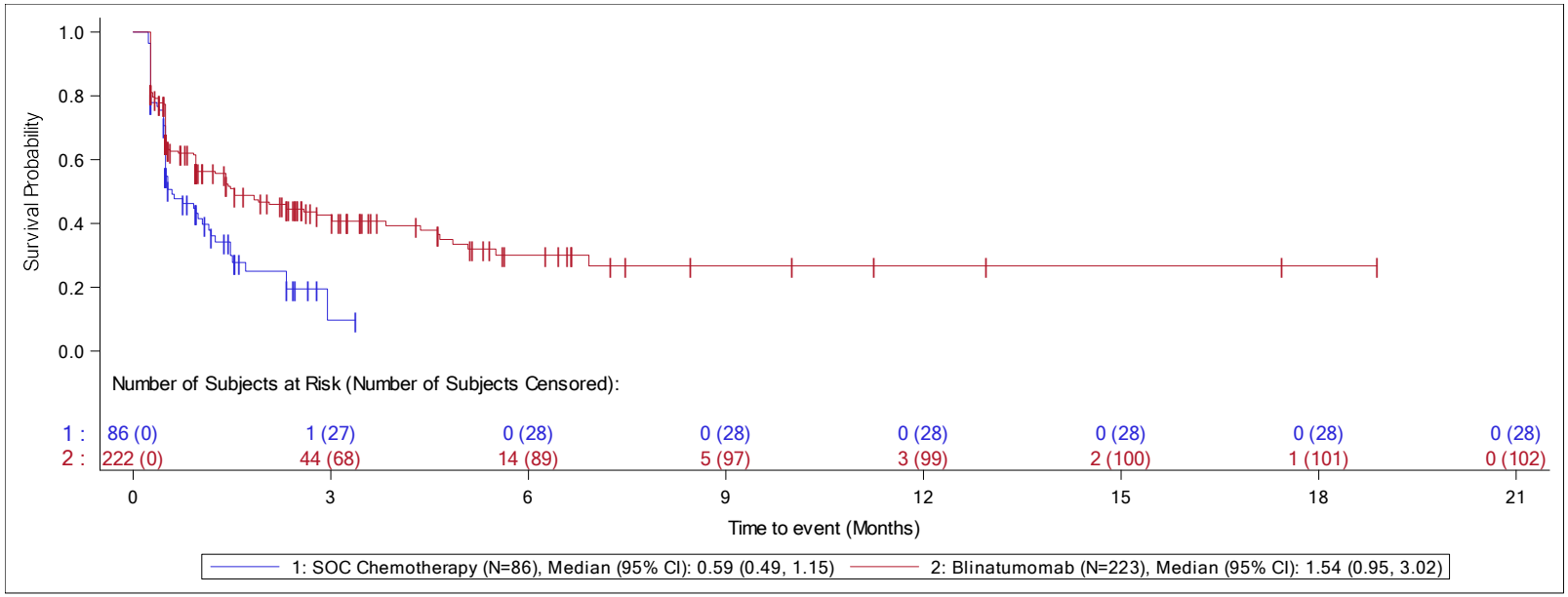
Figure 14-4.3.9. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Swollen lymph nodes (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda8sl-allas.sas
Output: f14-04-003-009-km-de-allss-ttda8sl-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

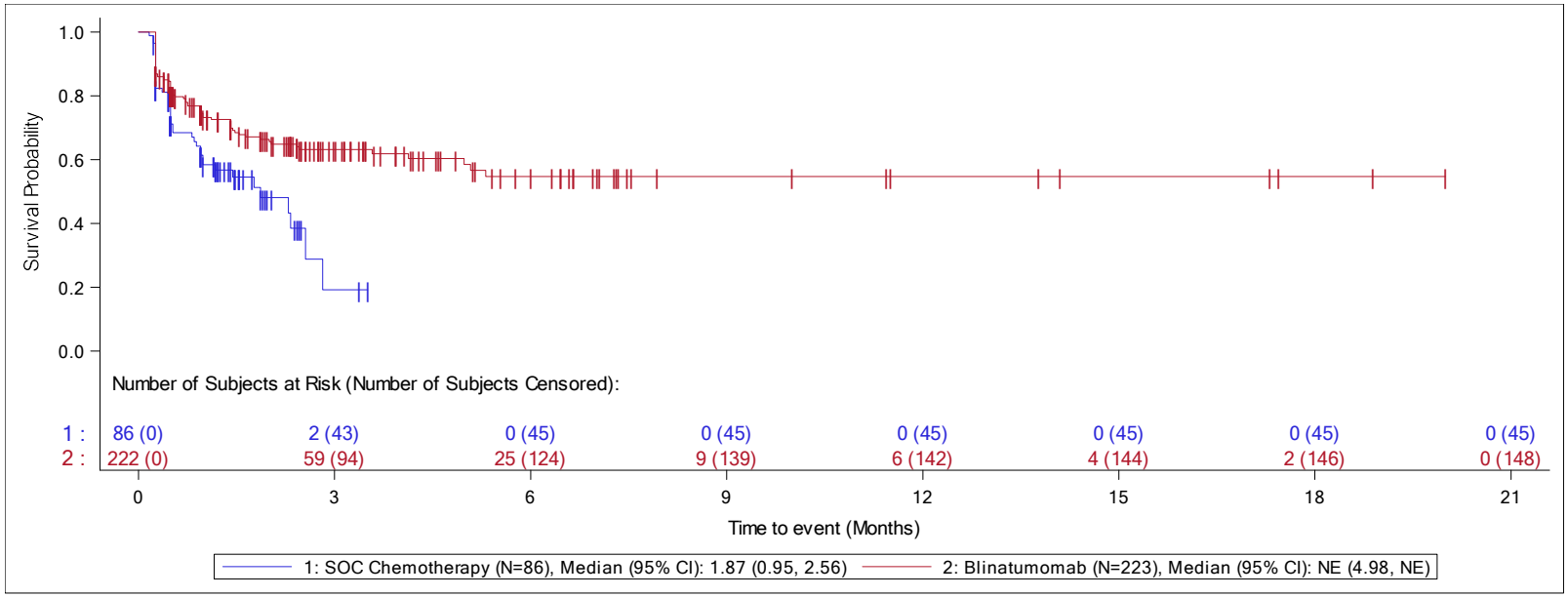
Figure 14-4.3.10. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Fighting infection
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda9fi-allas.sas
Output: f14-04-003-010-km-de-allss-ttda9fi-allas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

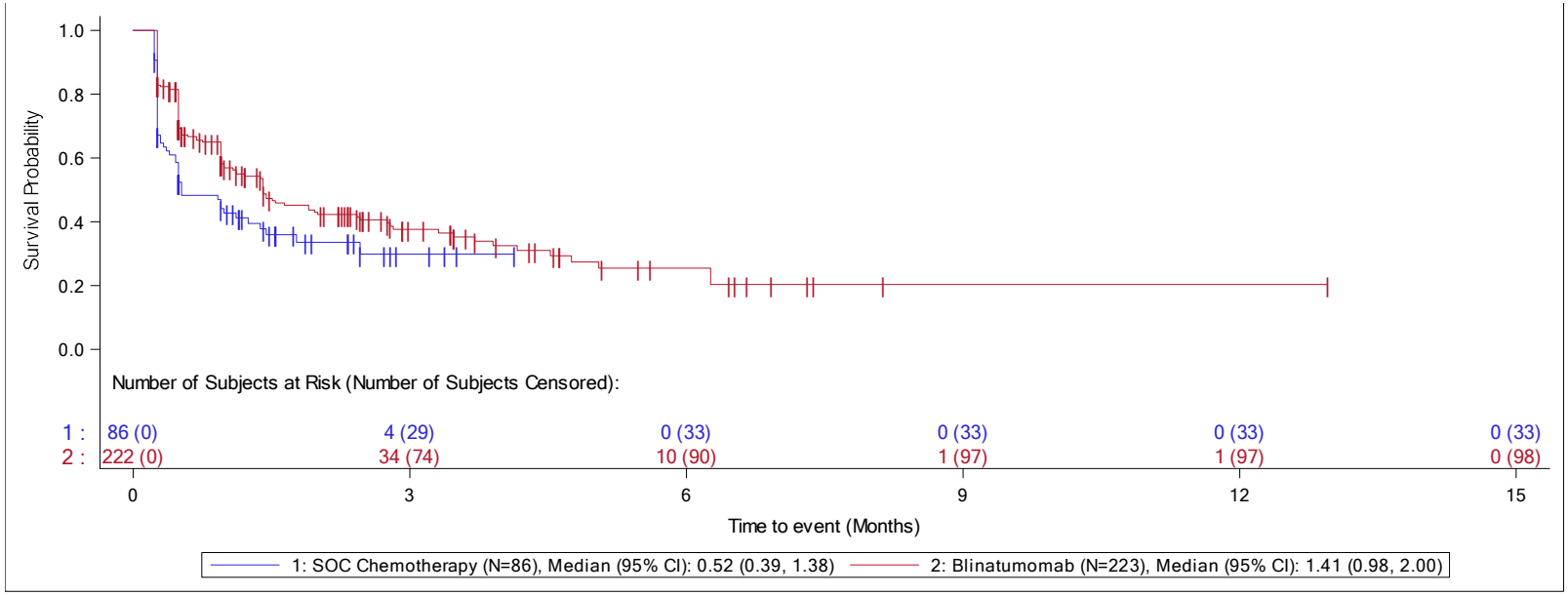
Figure 14-4.3.11. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Short of breath
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda10b-allas.sas
Output: f14-04-003-011-km-de-allss-ttda10b-allas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

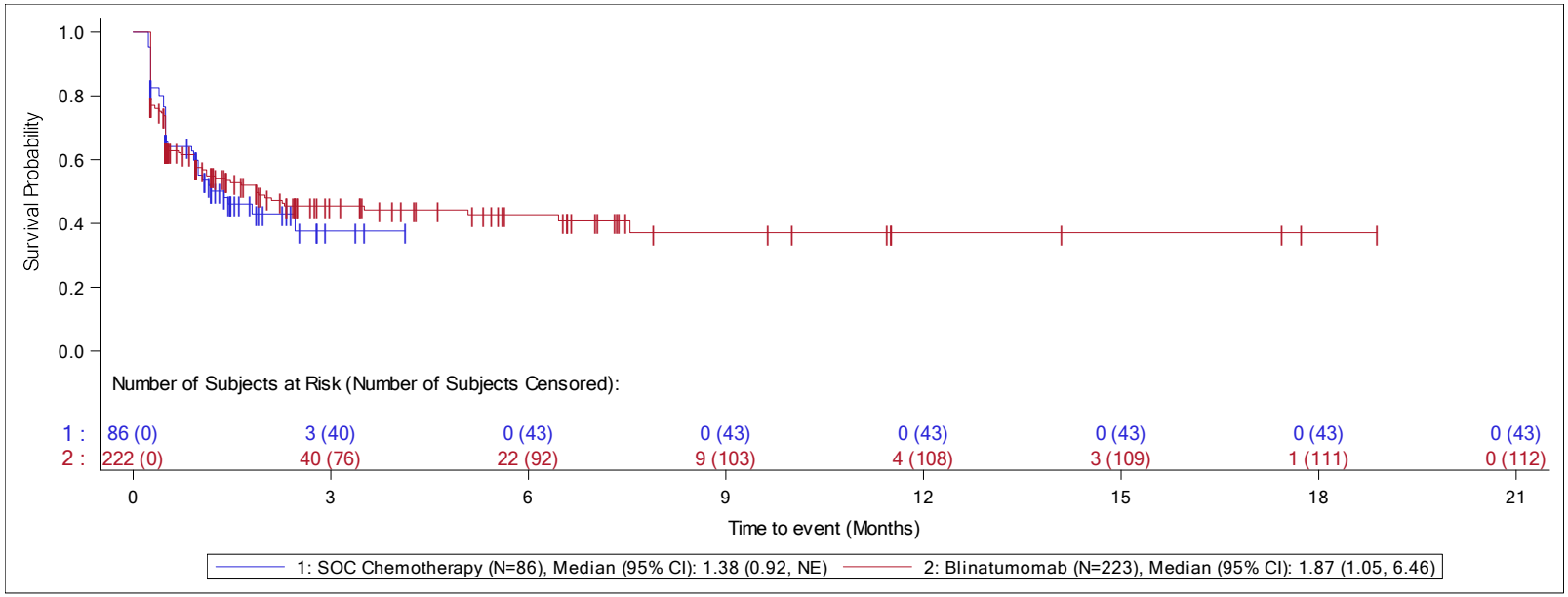
Figure 14-4.3.12. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Unable to eat (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda11e-allas.sas
Output: f14-04-003-012-km-de-allss-ttda11e-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

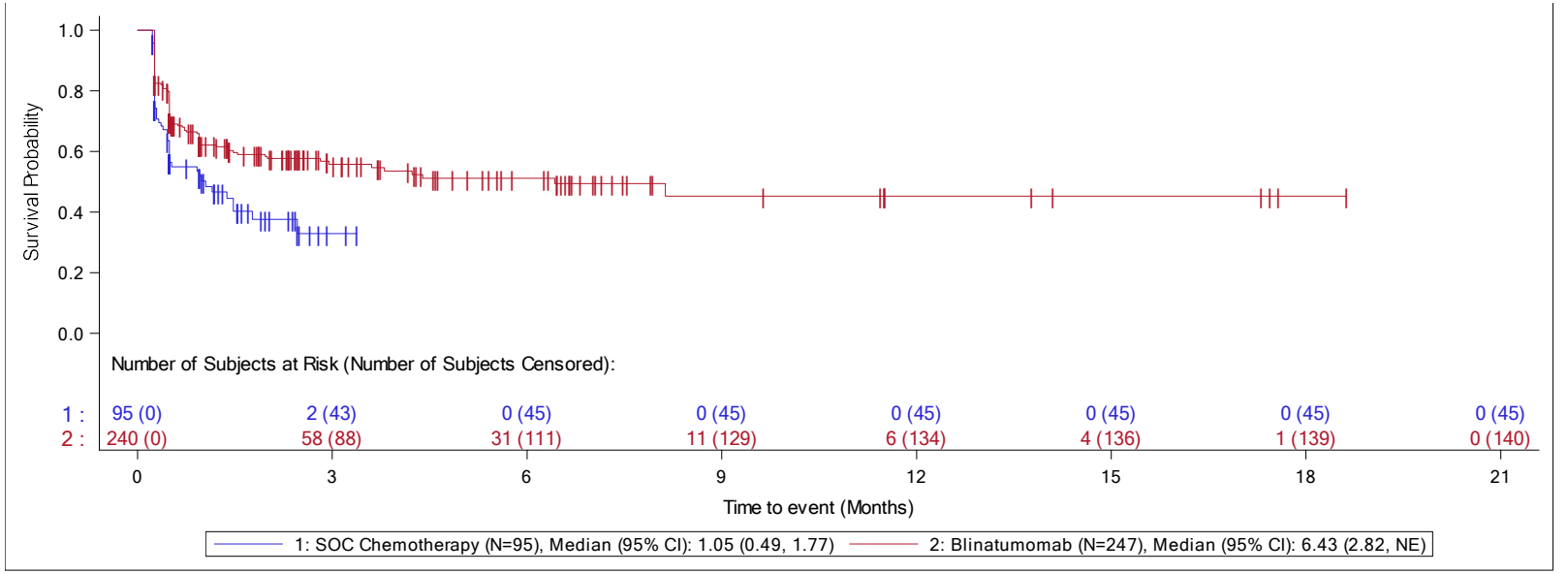
Figure 14-4.3.13. Kaplan-Meier plot for Time to First Deterioration of at least 1 point in Change from Baseline for ALLSS Night sweats
(ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-allss-ttda12s-allas.sas
Output: f14-04-003-013-km-de-allss-ttda12s-allas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

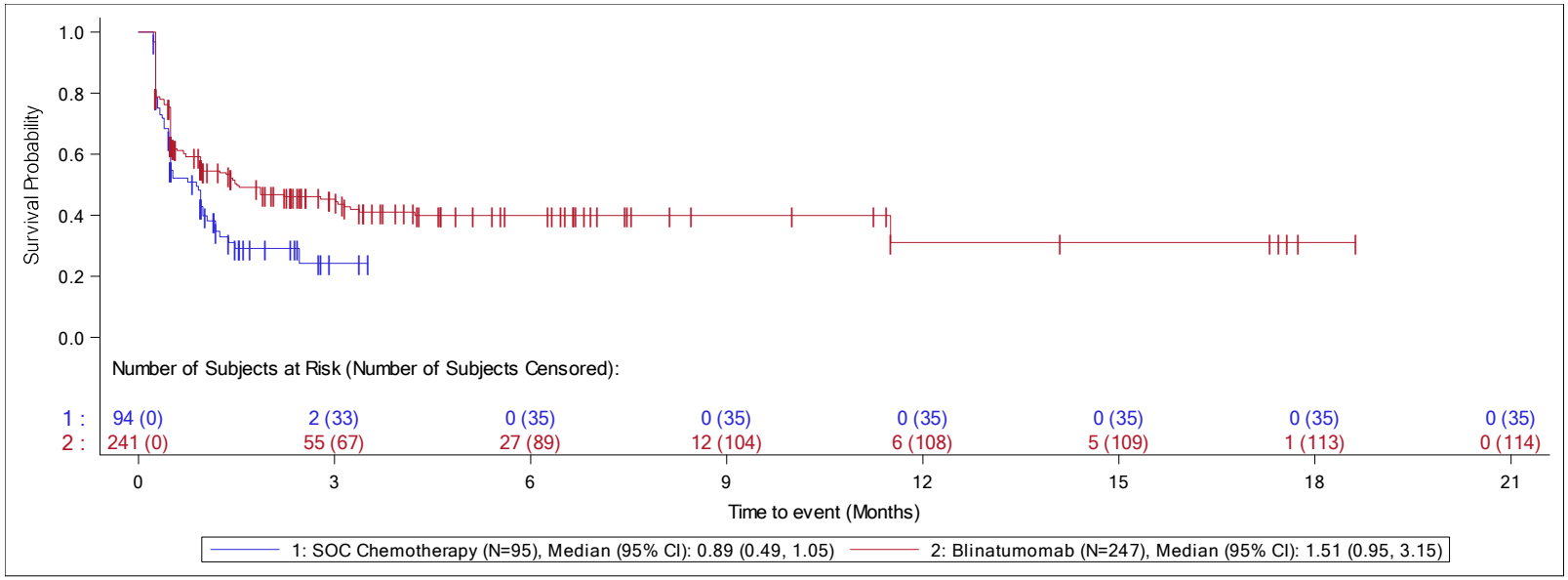
Figure 14-4.3.14. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-ghs-eqcas.sas
Output: f14-04-003-014-km-de-eortc-ghs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

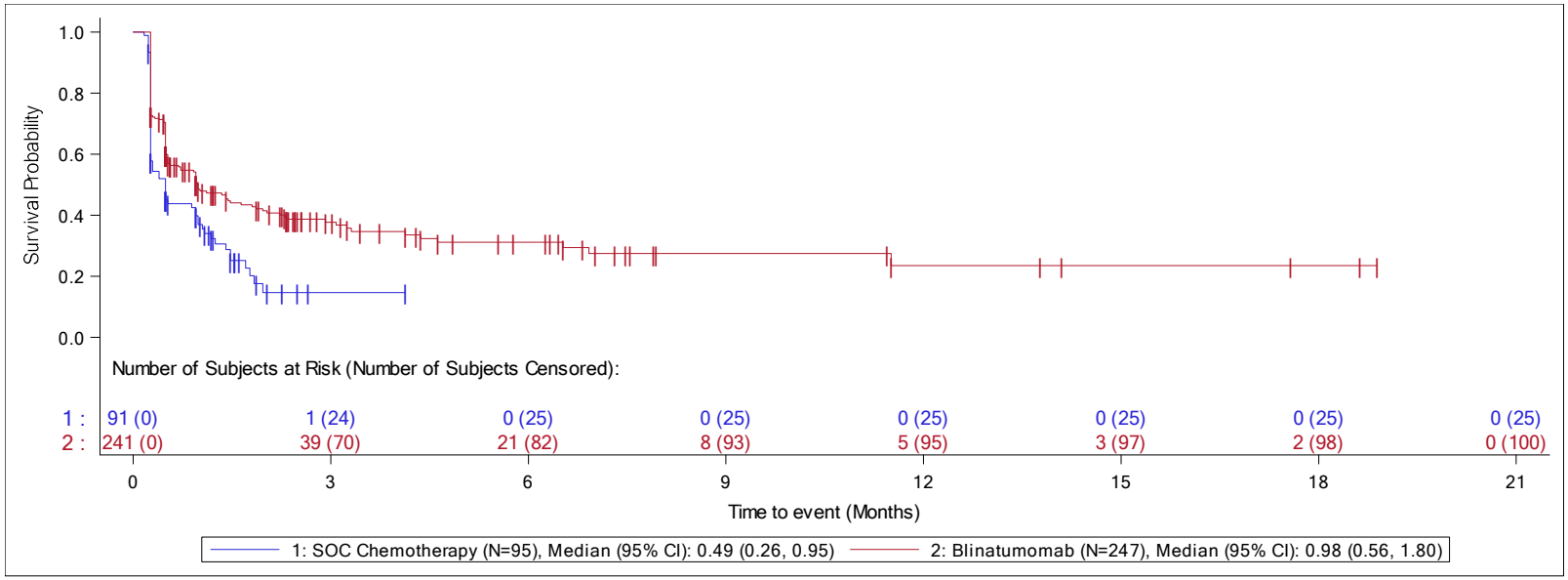
Figure 14-4.3.15. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-pf-eqcas.sas
Output: f14-04-003-015-km-de-eortc-pf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

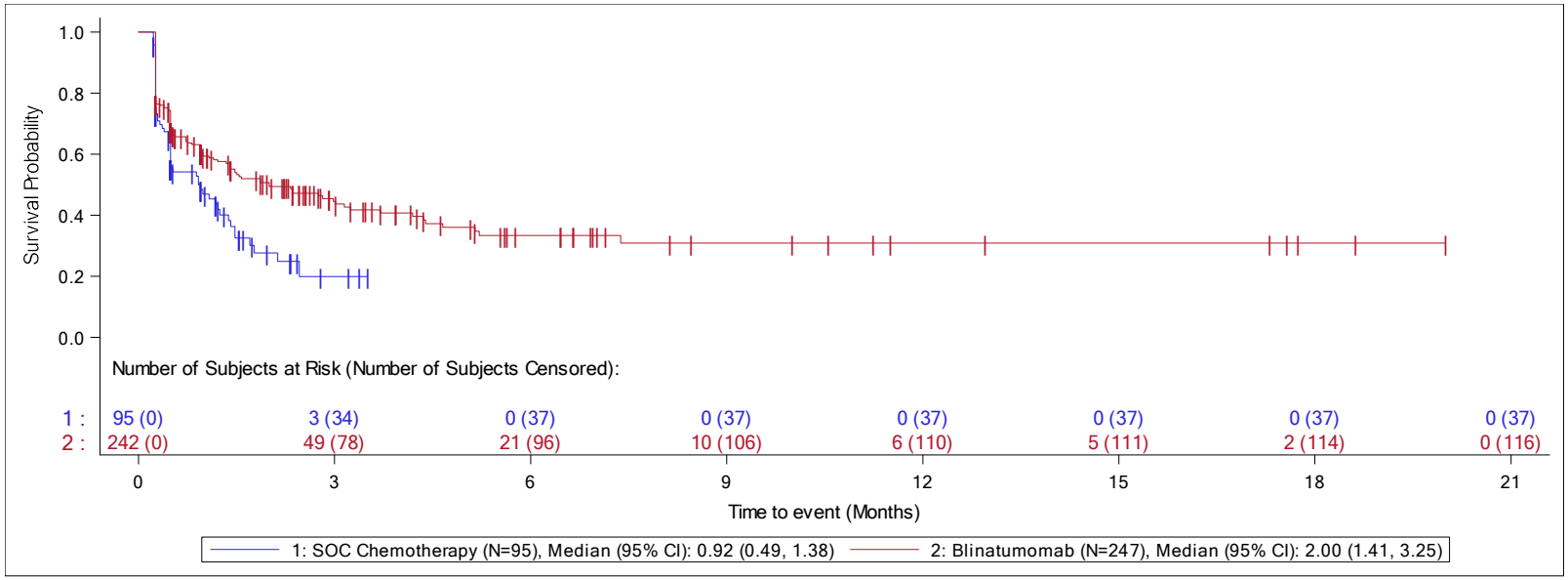
Figure 14-4.3.16. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-rf-eqcas.sas
Output: f14-04-003-016-km-de-eortc-rf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

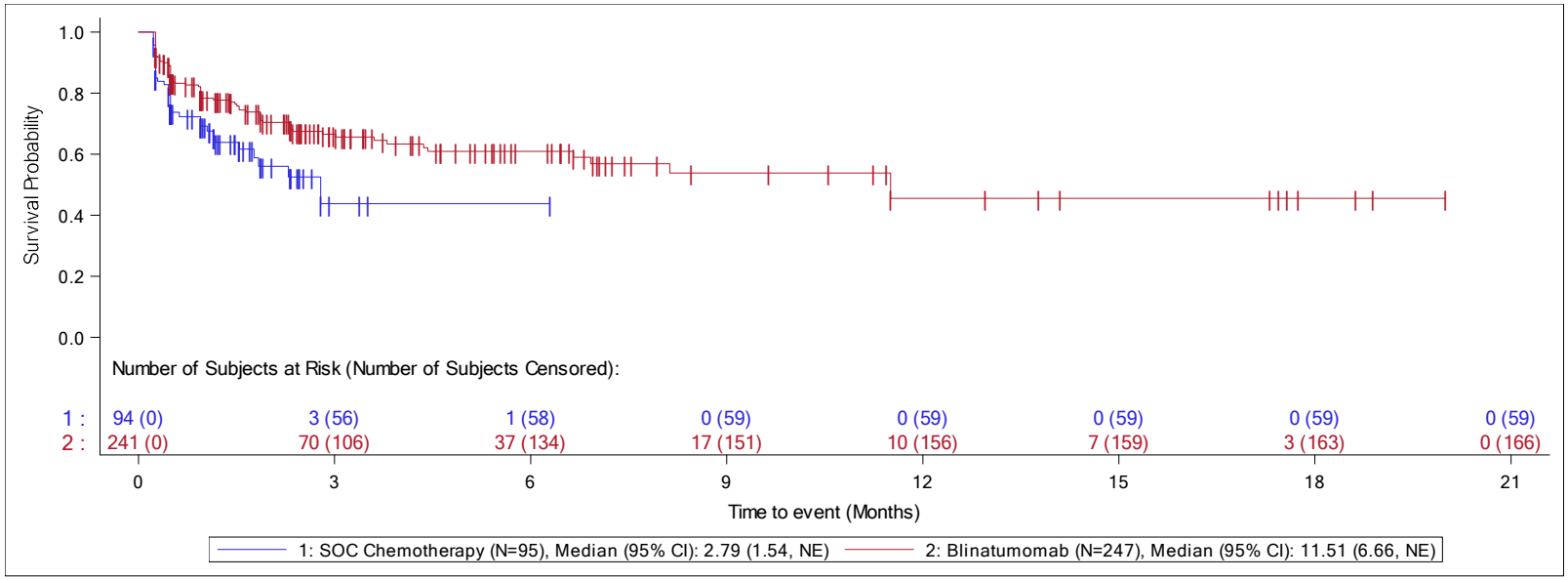
Figure 14-4.3.17. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-cf-eqcas.sas
Output: f14-04-003-017-km-de-eortc-cf-eqcas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

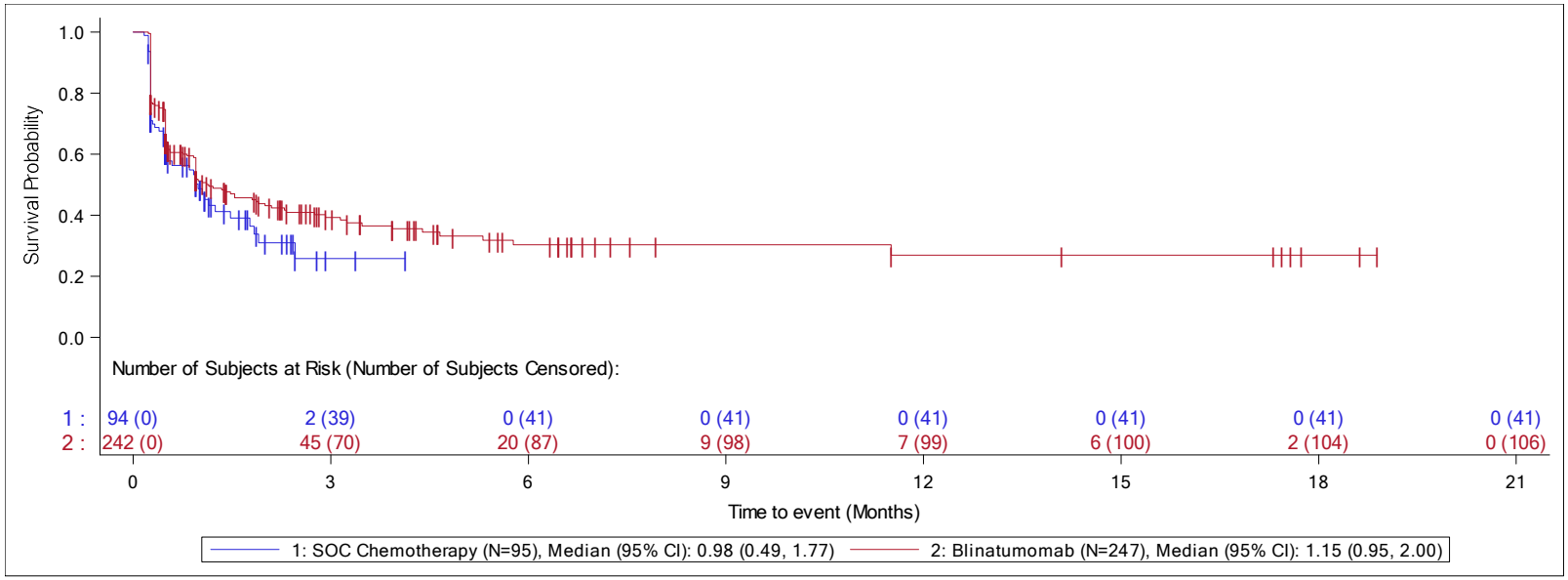
Figure 14-4.3.18. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-ef-eqcas.sas
Output: f14-04-003-018-km-de-eortc-ef-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

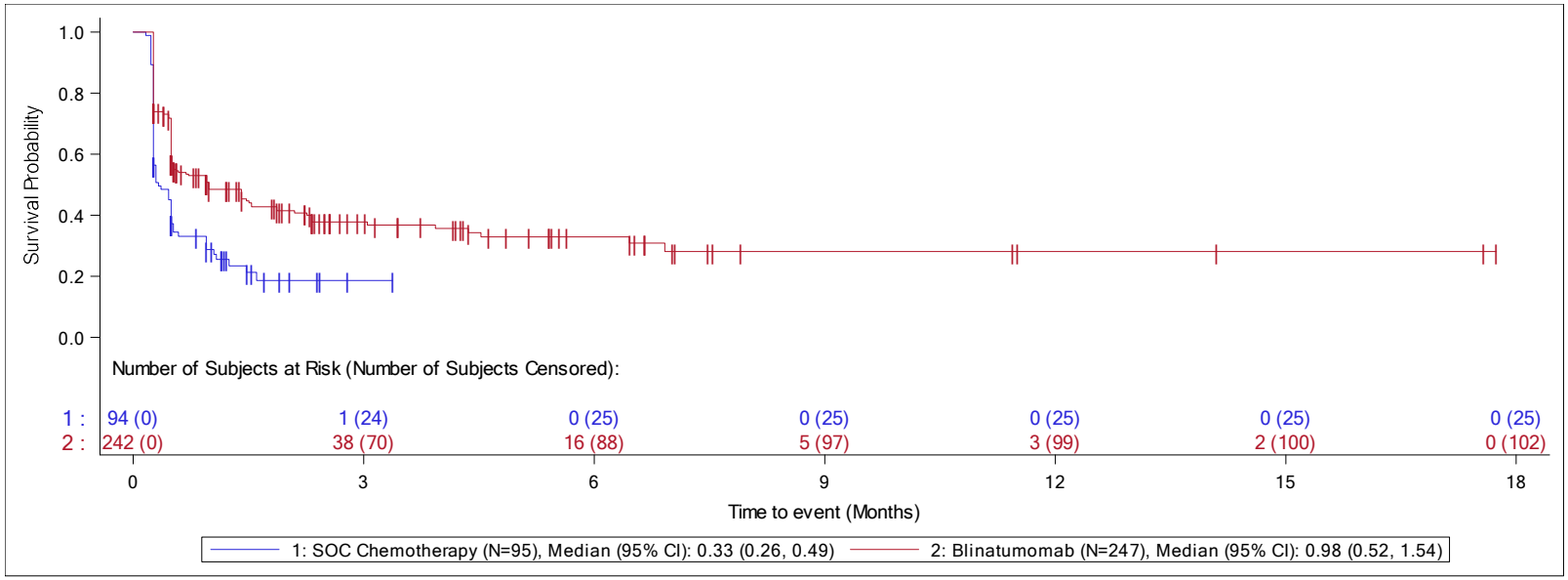
Figure 14-4.3.19. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-sf-eqcas.sas
Output: f14-04-003-019-km-de-eortc-sf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

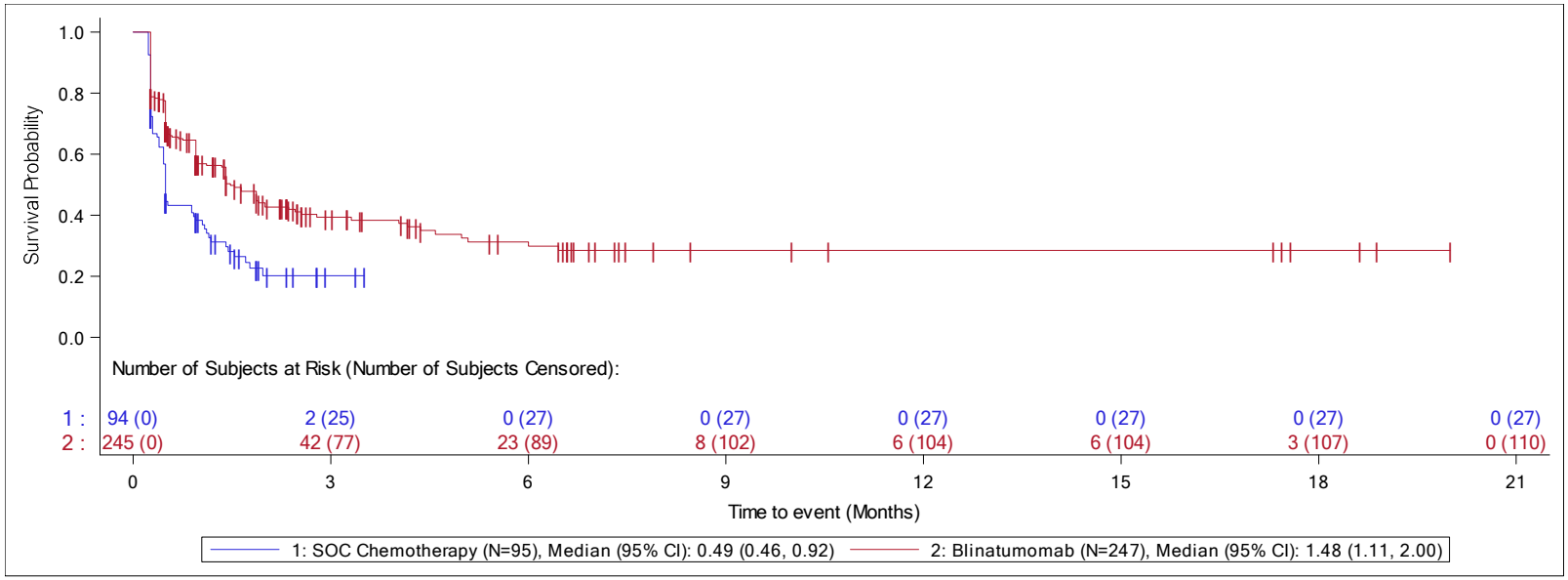
Figure 14-4.3.20. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-fs-eqcas.sas
Output: f14-04-003-020-km-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

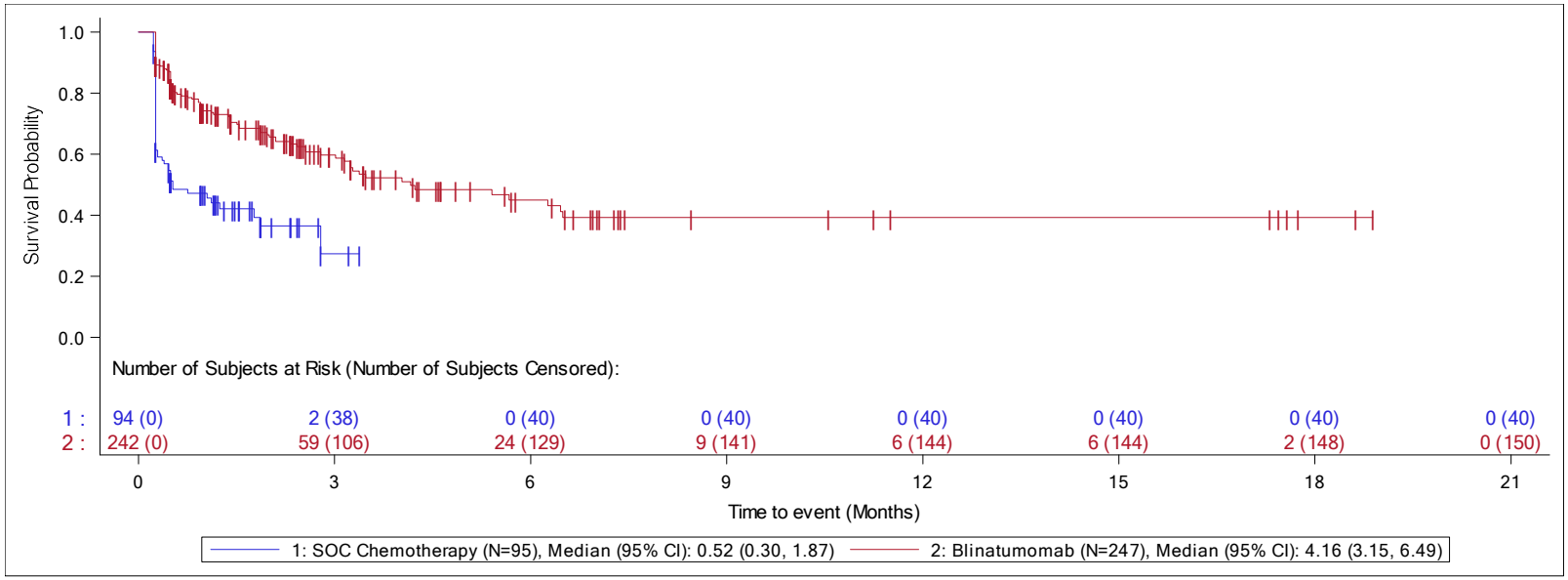
Figure 14-4.3.21. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-pas-eqcas.sas
Output: f14-04-003-021-km-de-eortc-pas-eqcas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

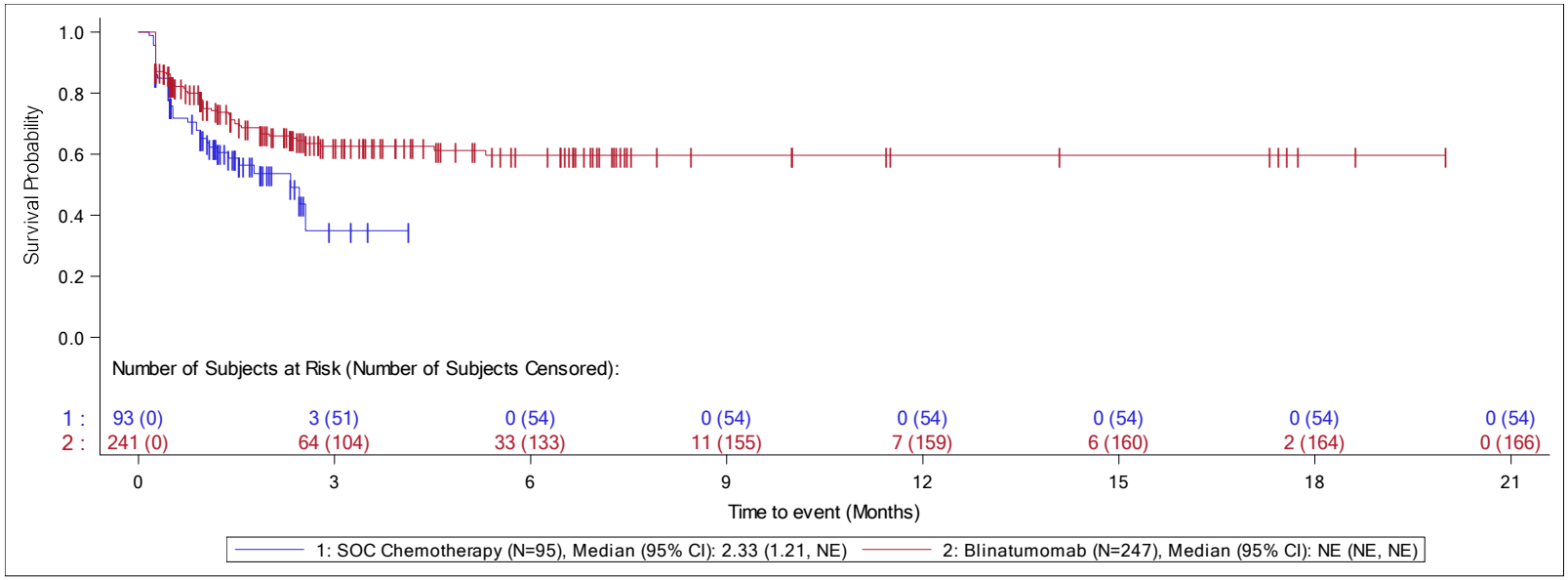
Figure 14-4.3.22. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-nvs-eqcas.sas
Output: f14-04-003-022-km-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

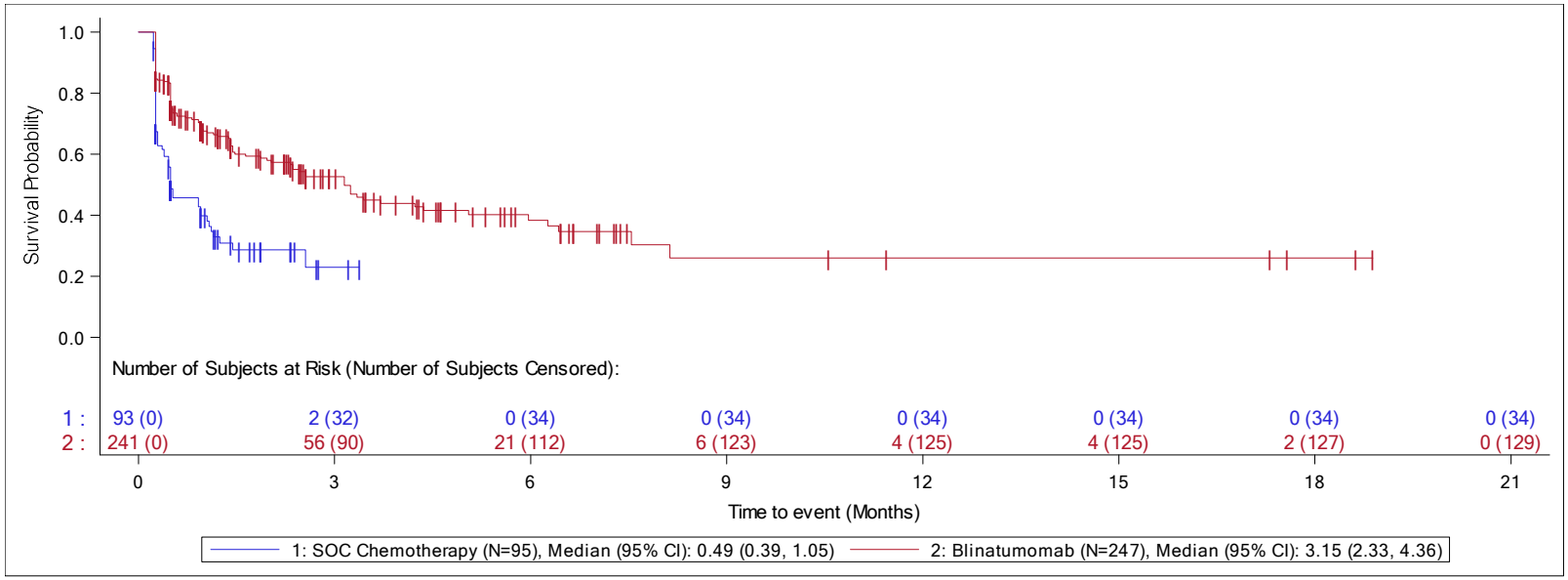
Figure 14-4.3.23. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-dys-eqcas.sas
Output: f14-04-003-023-km-de-eortc-dys-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

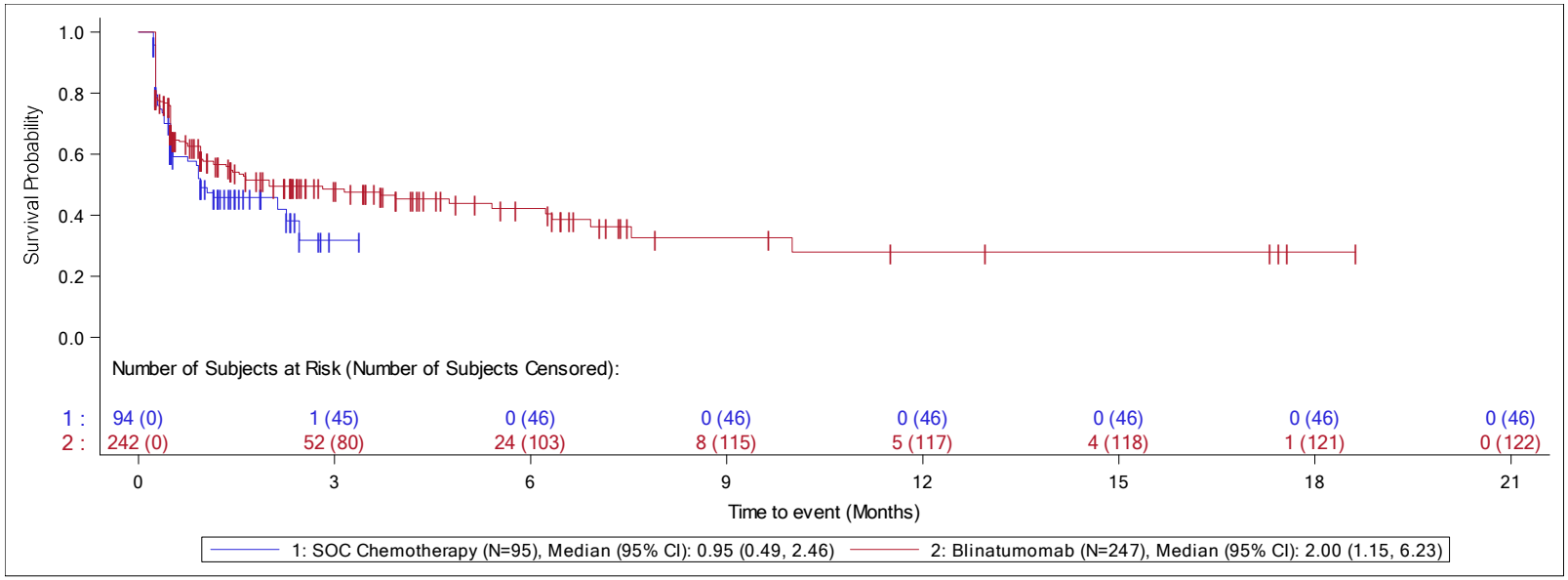
Figure 14-4.3.24. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-aps-eqcas.sas
Output: f14-04-003-024-km-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

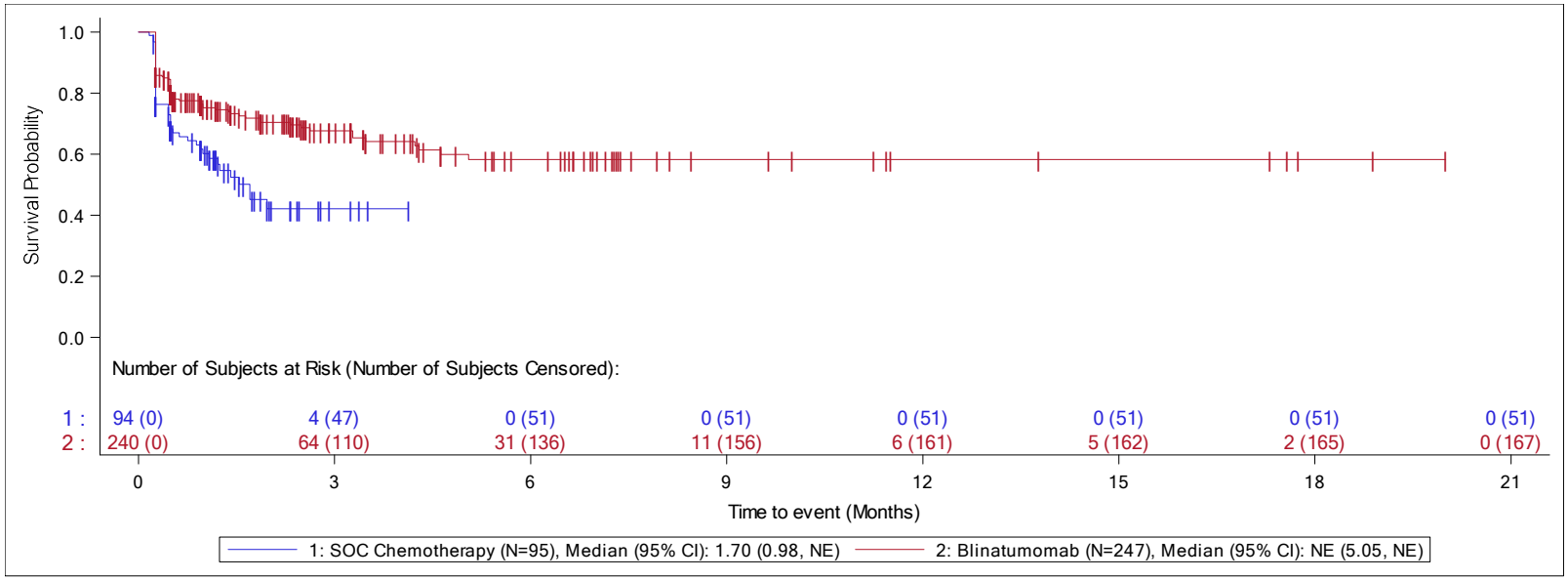
Figure 14-4.3.25. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-sls-eqcas.sas
Output: f14-04-003-025-km-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

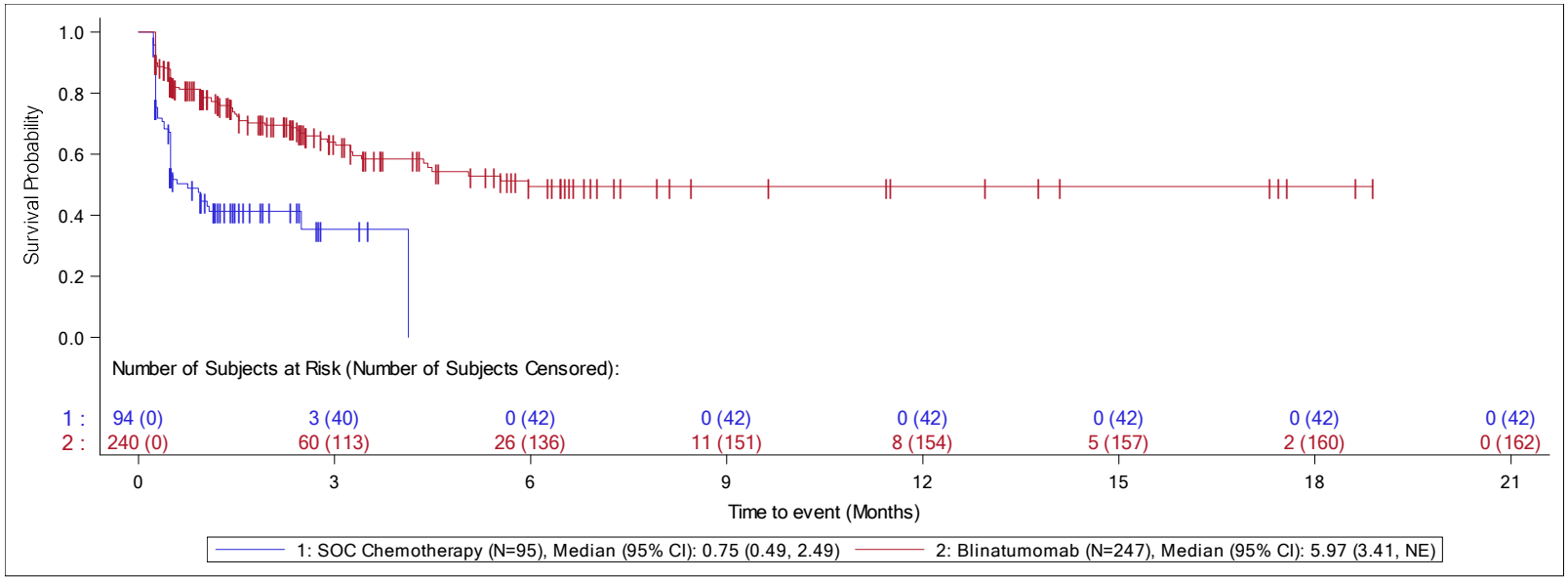
Figure 14-4.3.26. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-cos-eqcas.sas
Output: f14-04-003-026-km-de-eortc-cos-eqcas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

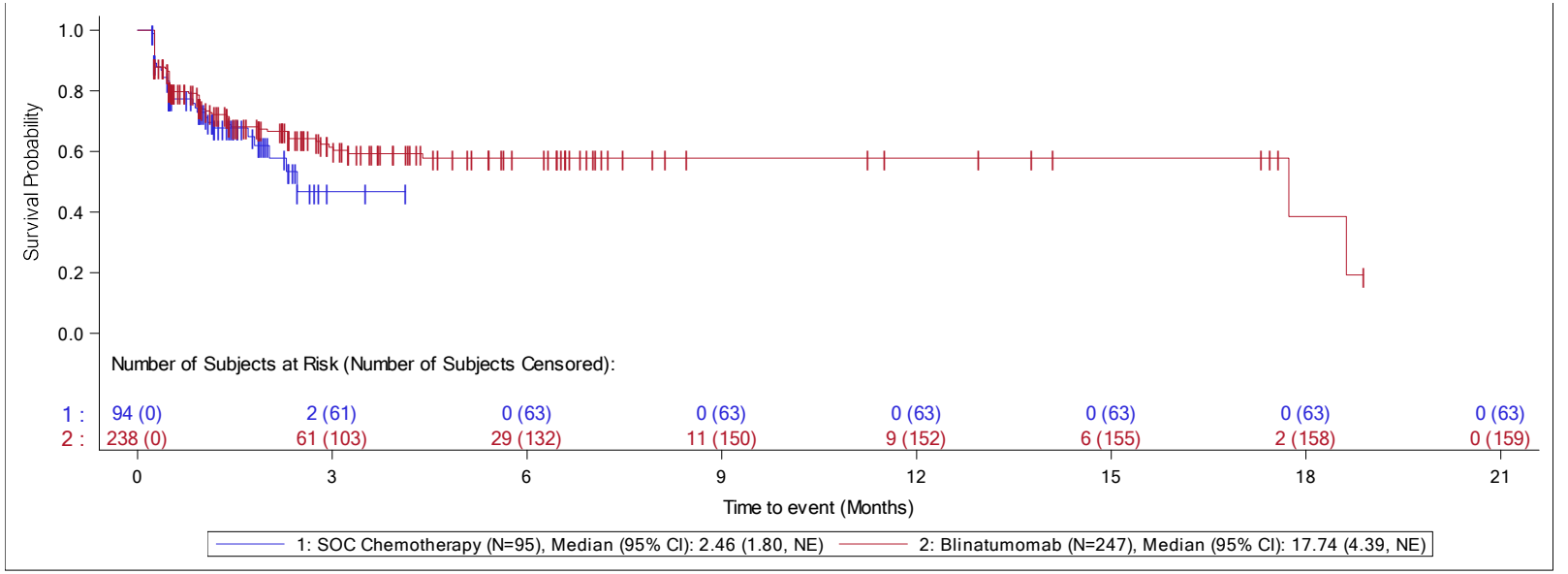
Figure 14-4.3.27. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-dis-eqcas.sas
Output: f14-04-003-027-km-de-eortc-dis-eqcas.rtf (Date Generated: 23OCT25 00:27) Source Data: adam_fa.adqs, adam_fa.adtteqs

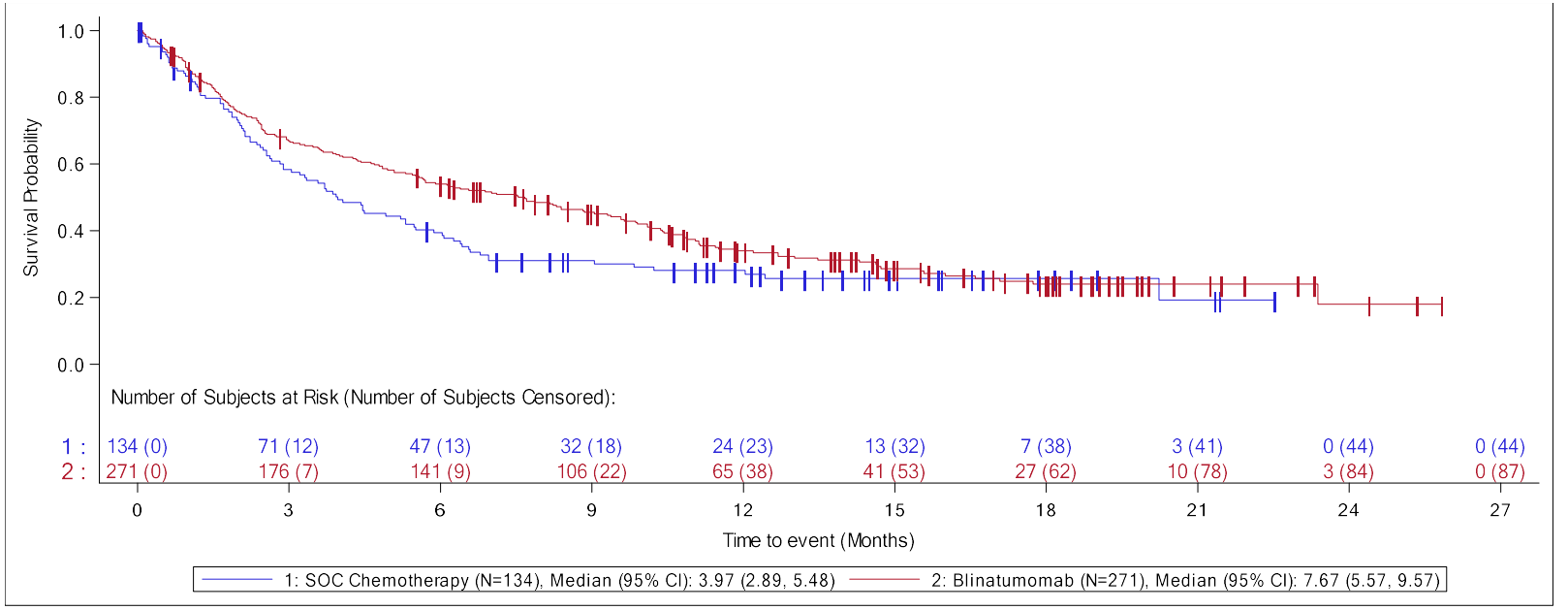
Figure 14-4.3.28. Kaplan-Meier plot for Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-de-eortc-fis-eqcas.sas
Output: f14-04-003-028-km-de-eortc-fis-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adqs, adam_fa.adtteqs

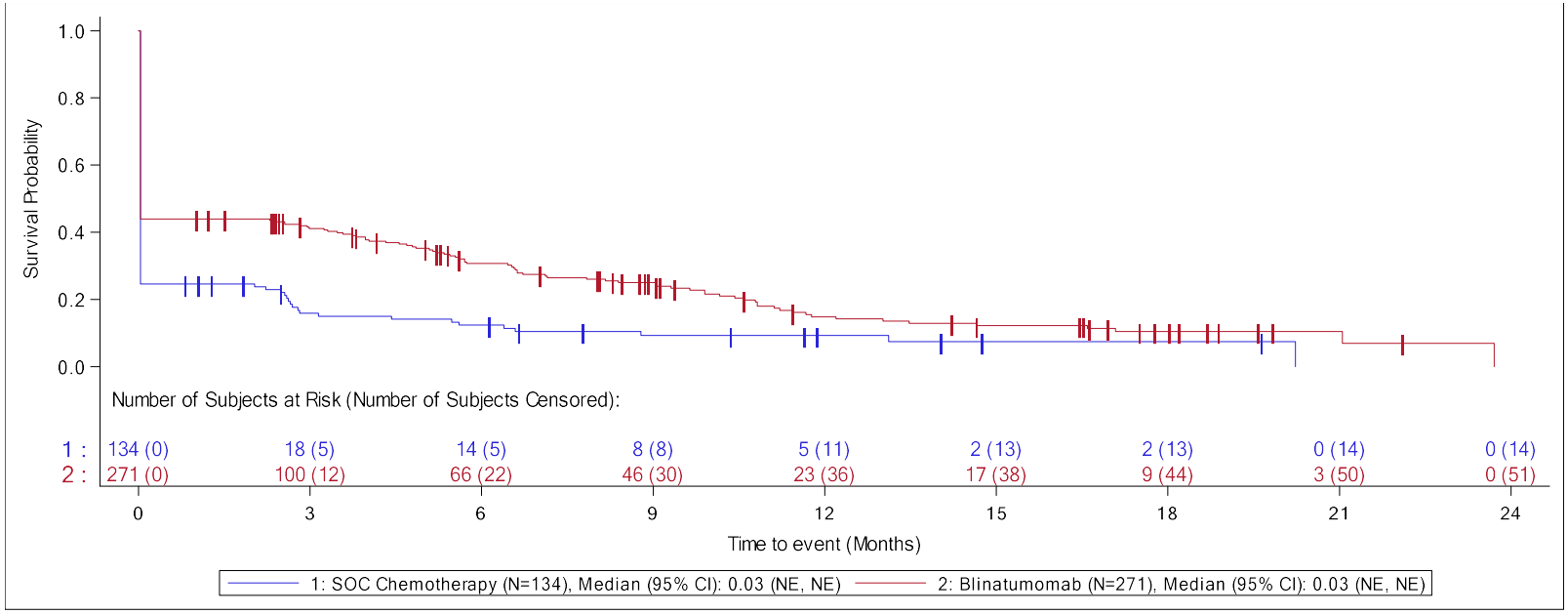
Figure 14-4.5.3. Kaplan-Meier plot for Overall Survival (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-os-fas.sas
Output: f14-04-005-003-km-os-fas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adtteeff

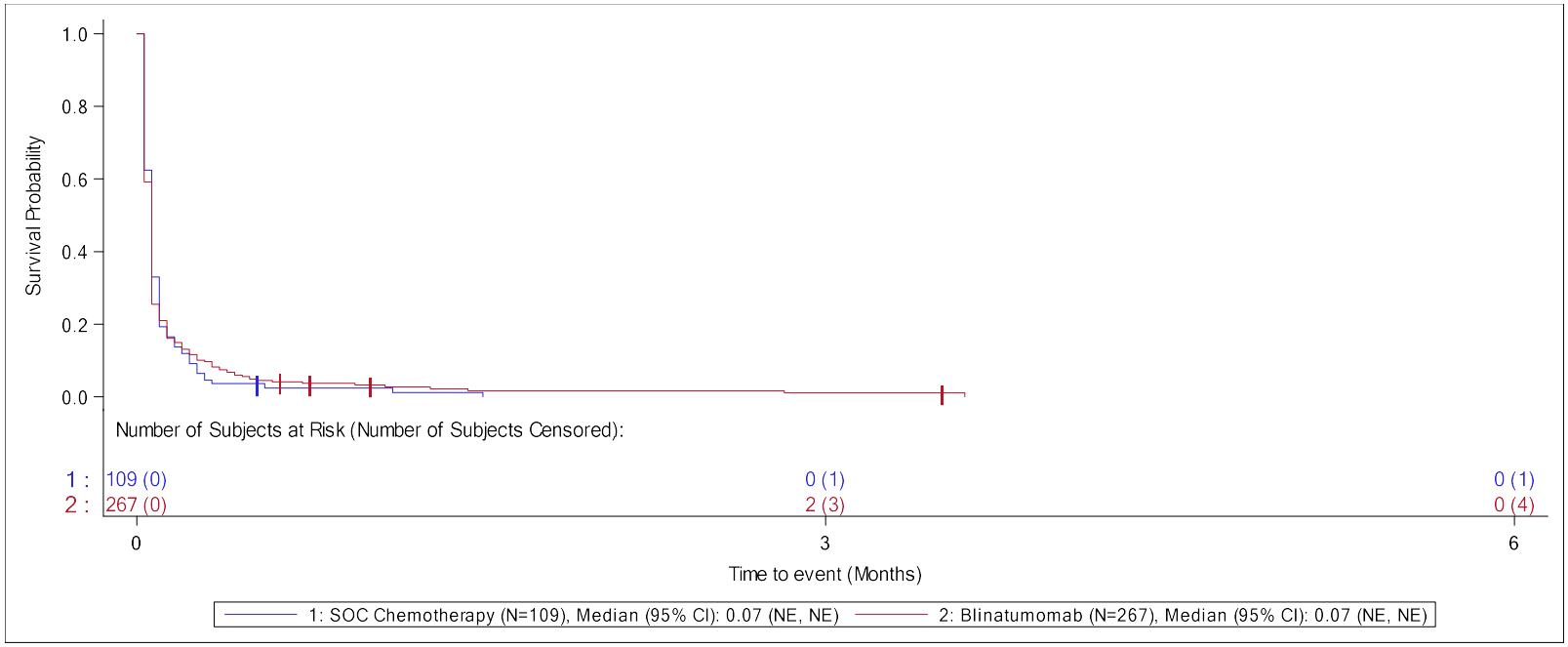
Figure 14-4.5.4. Kaplan-Meier plot for Event Free Survival (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-efs-fas.sas
Output: f14-04-005-004-km-efs-fas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adtteeff

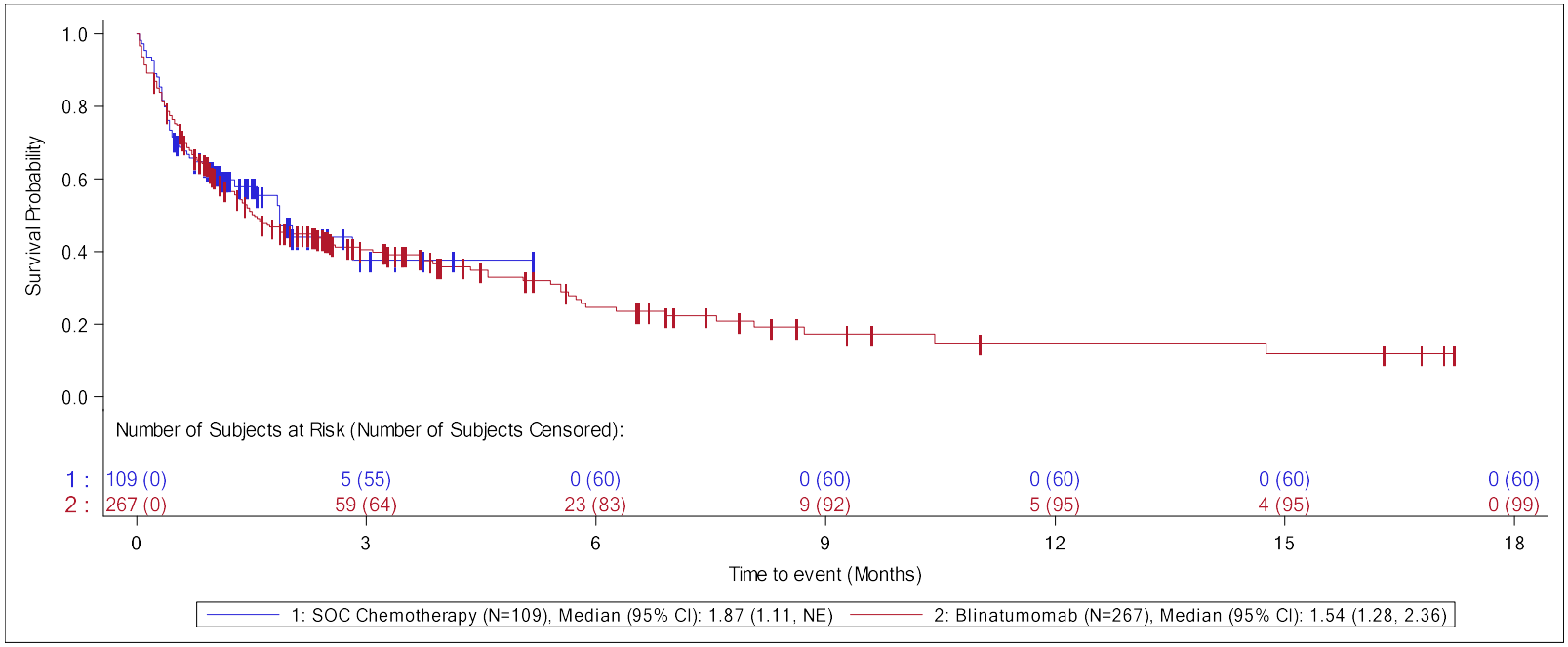
Figure 14-6.1.1. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-saf.sas
Output: f14-06-001-001-km-teae-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

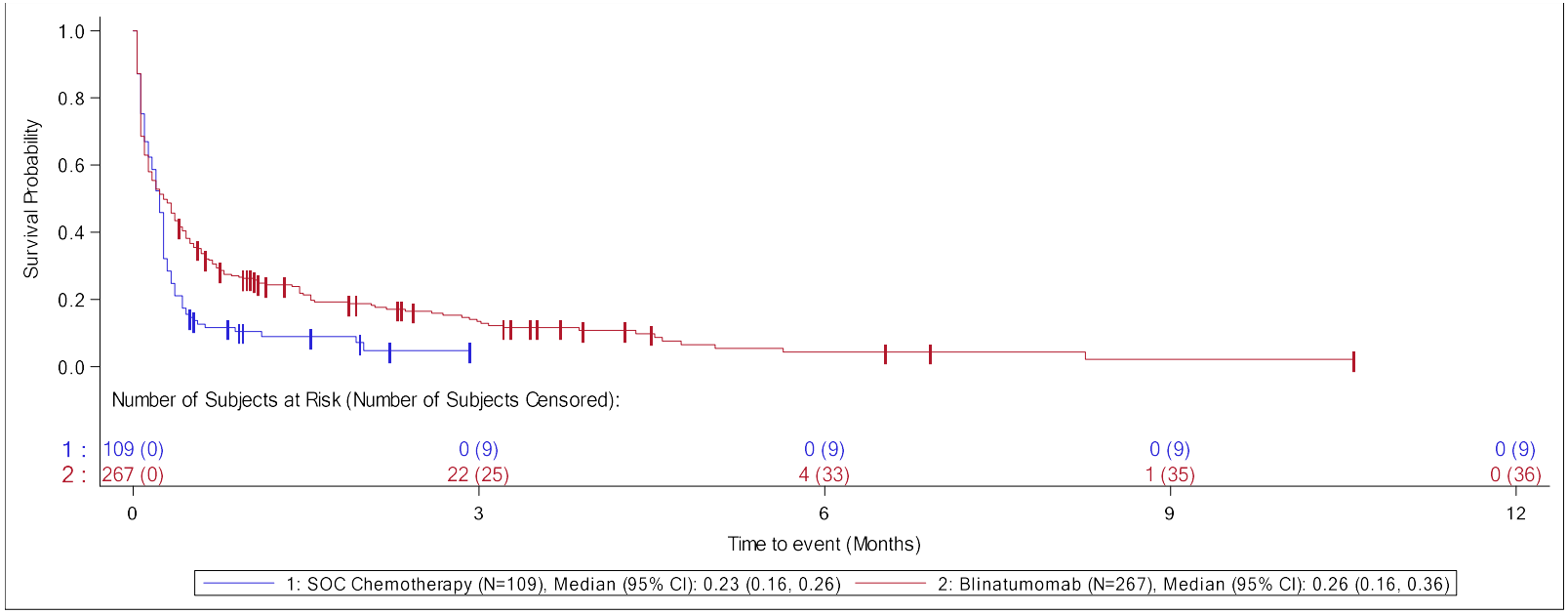
Figure 14-6.1.2. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-ser-teae-saf.sas
Output: f14-06-001-002-km-ser-teae-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam.adtteae

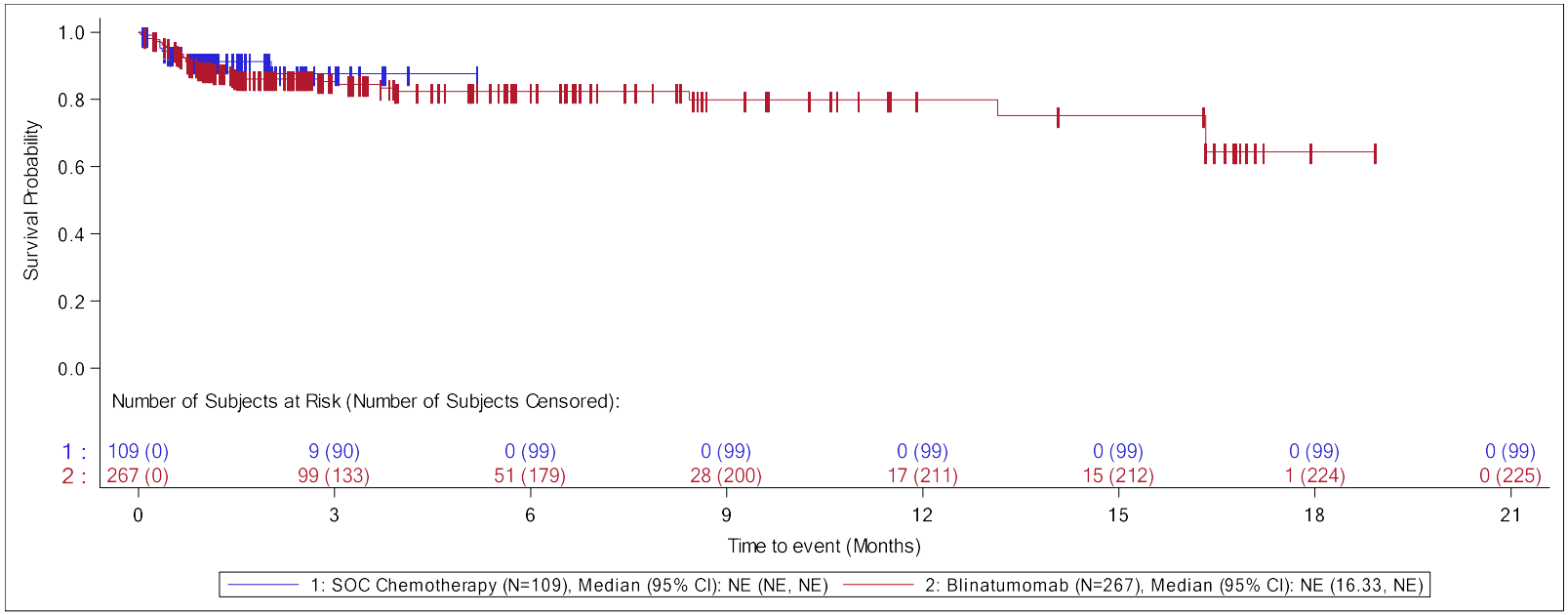
Figure 14-6.1.3. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sev-teae-saf.sas
Output: f14-06-001-003-km-sev-teae-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam.adtteae

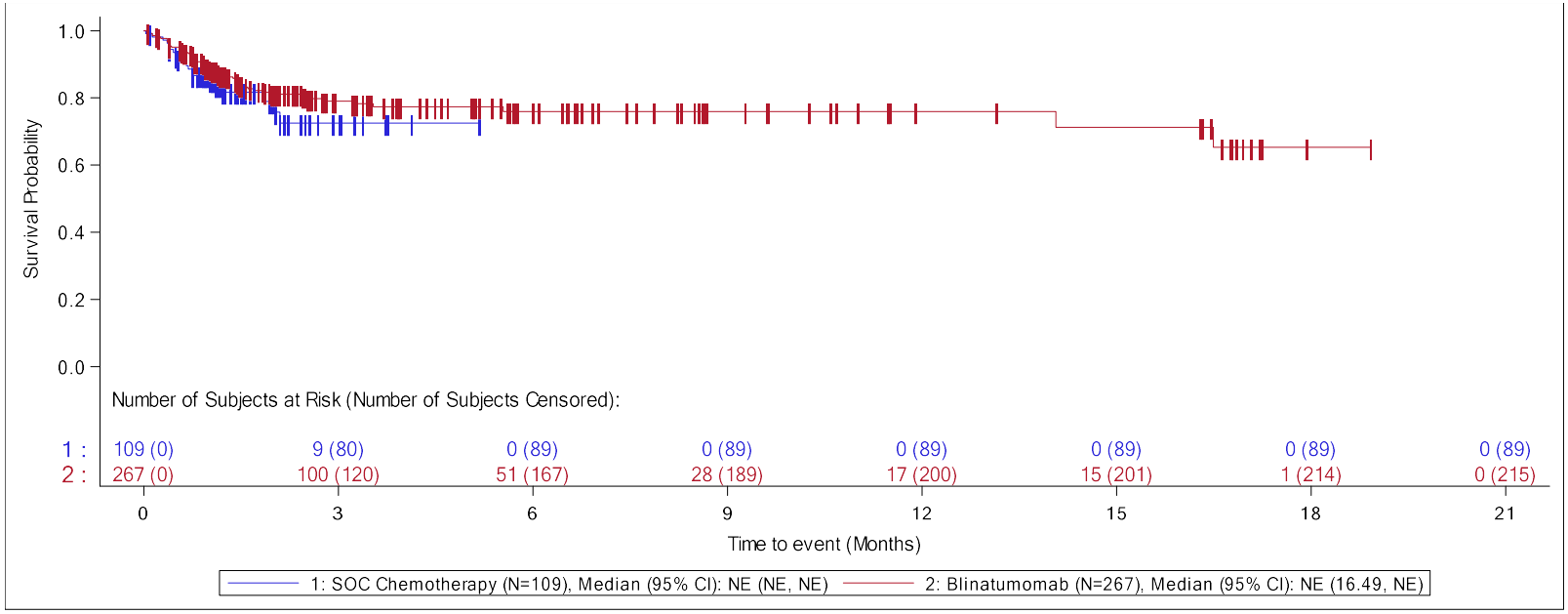
Figure 14-6.1.4. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-trt-disc-saf.sas
Output: f14-06-001-004-km-teae-trt-disc-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, adam.adtteae

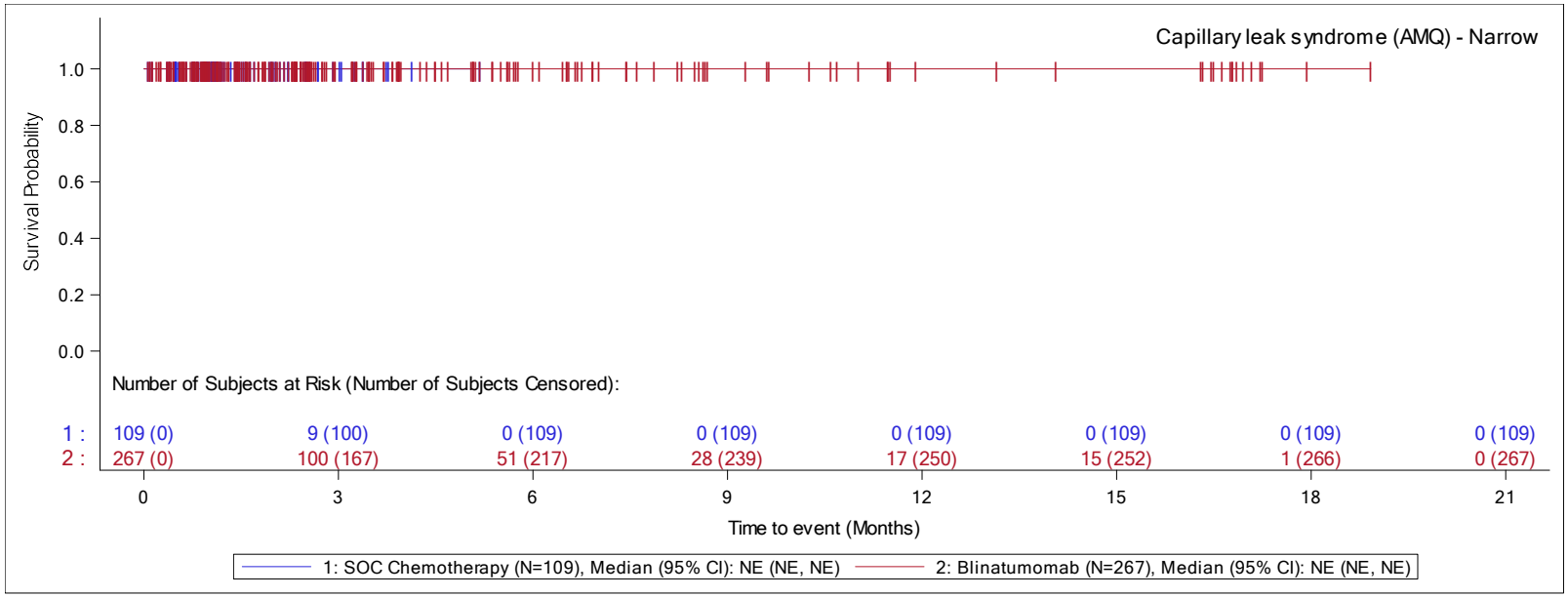
Figure 14-6.1.5. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event Leading to Death (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-fatal-saf.sas
Output: f14-06-001-005-km-teae-fatal-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

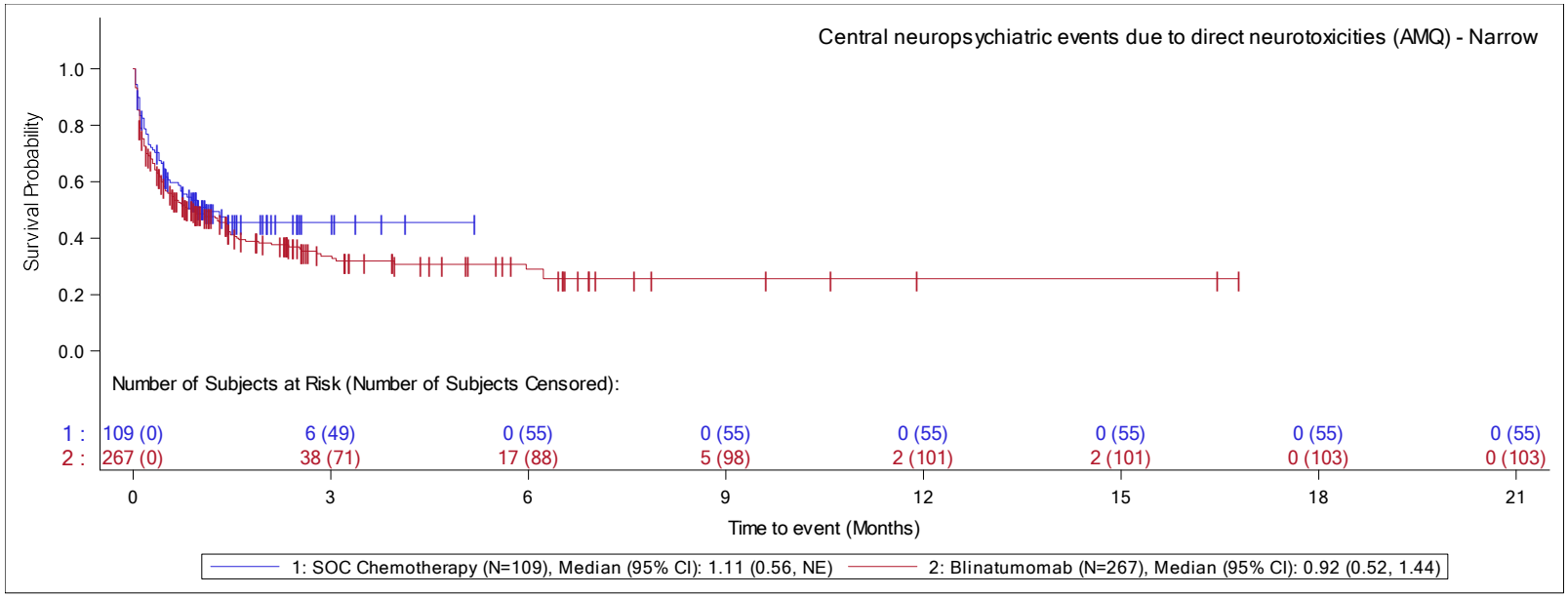
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

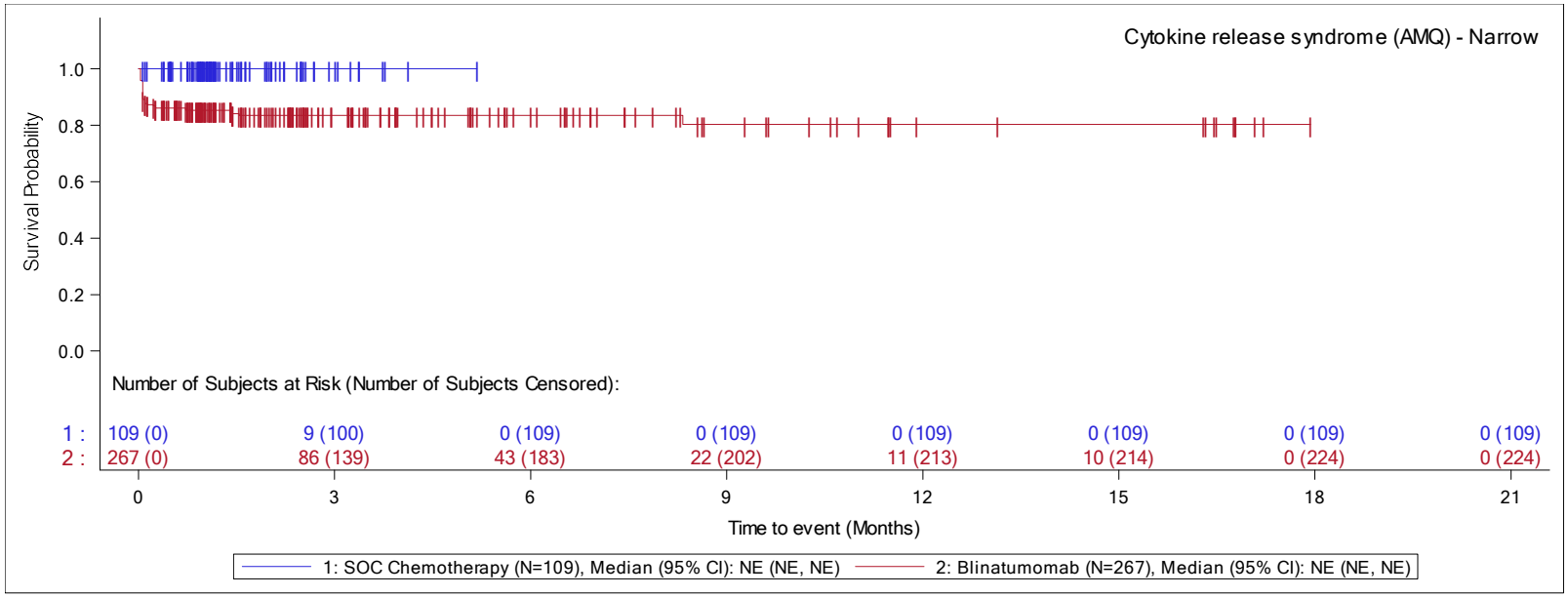
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

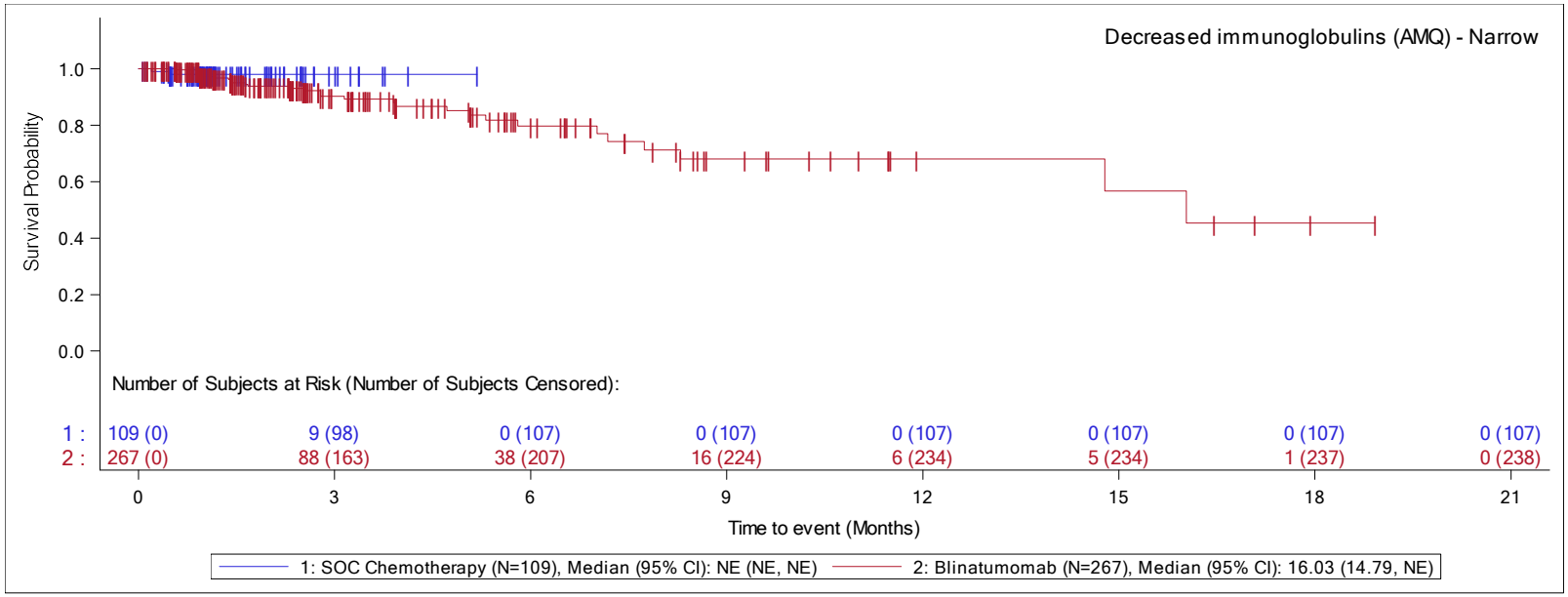
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

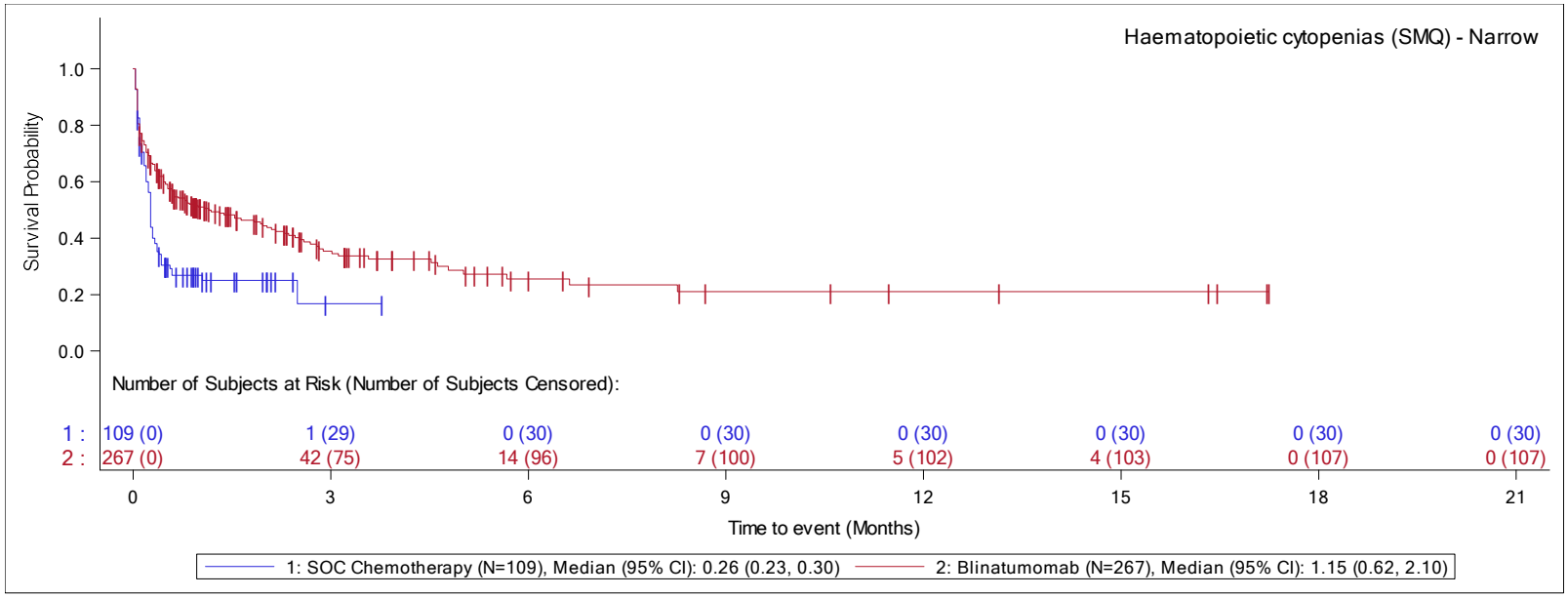
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

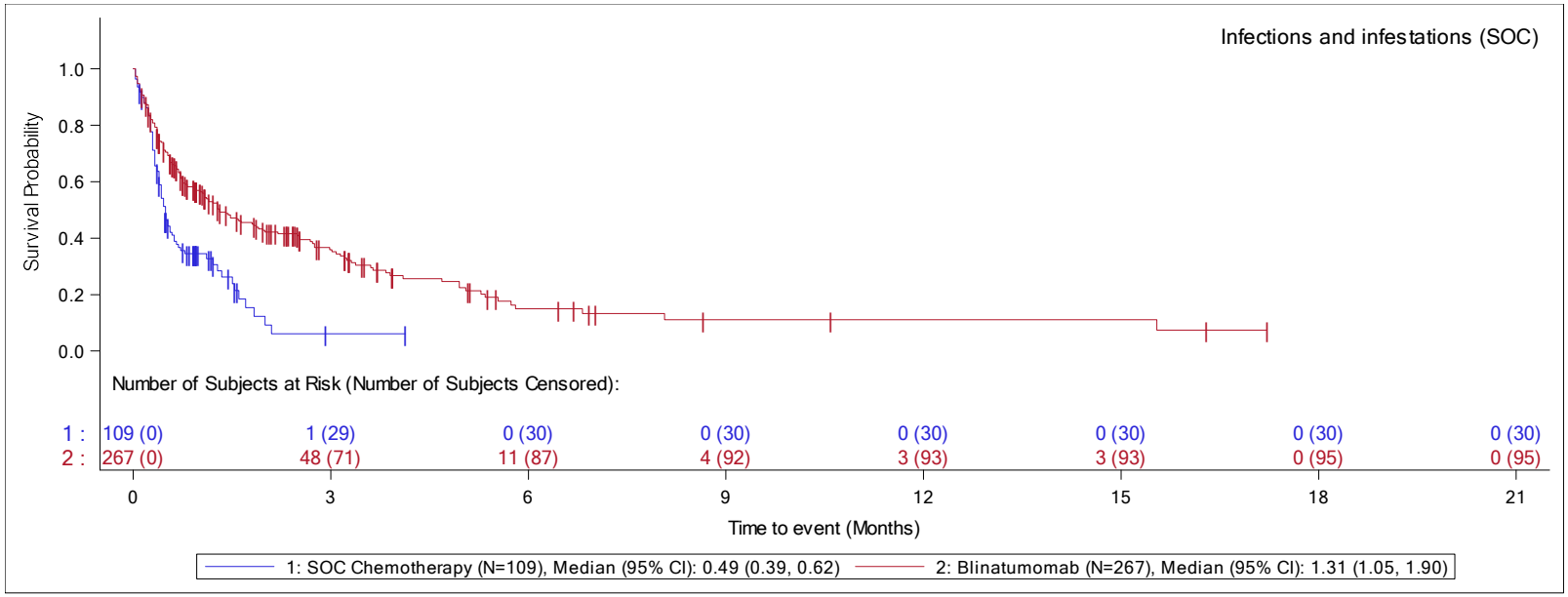
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

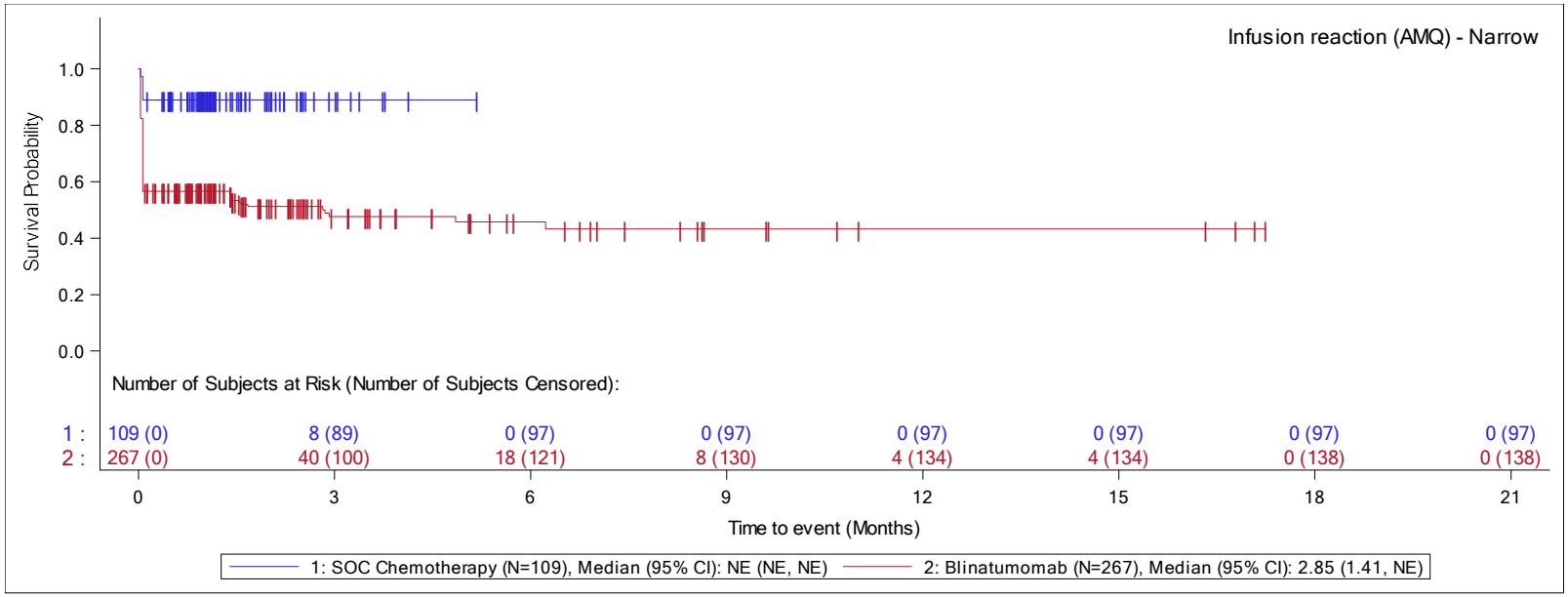
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

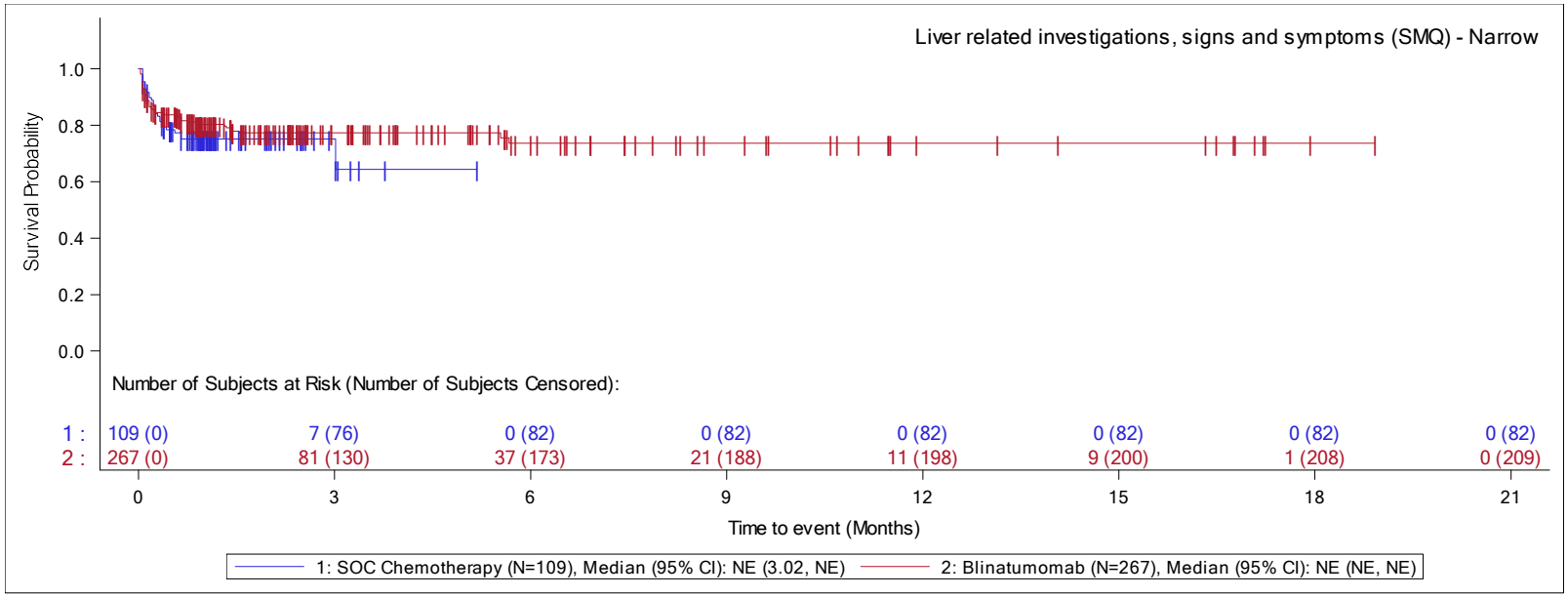
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

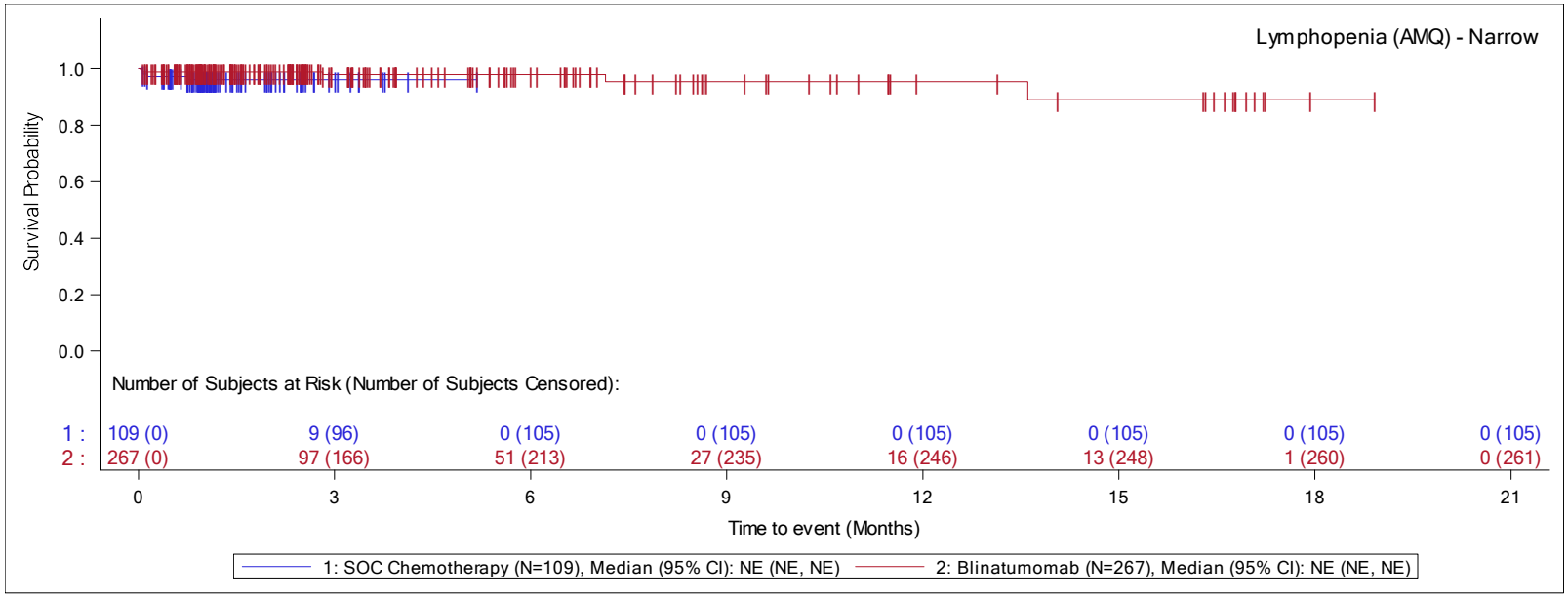
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

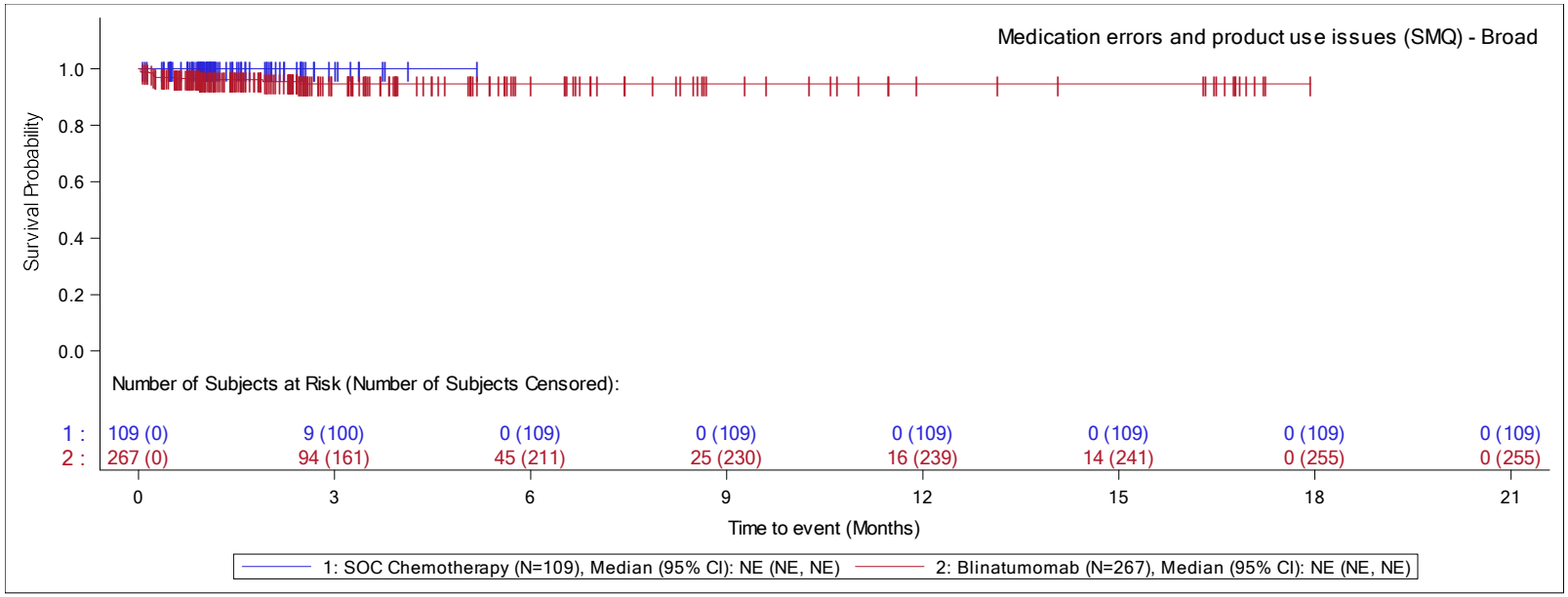
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

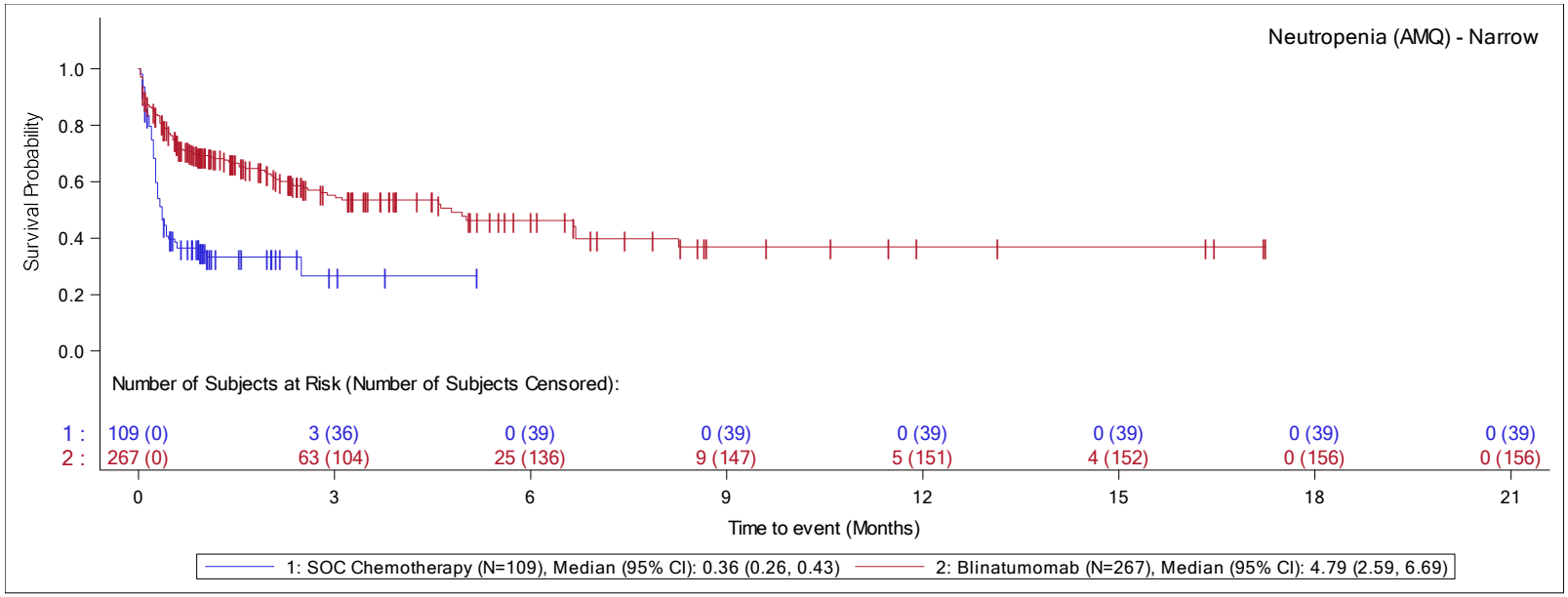
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

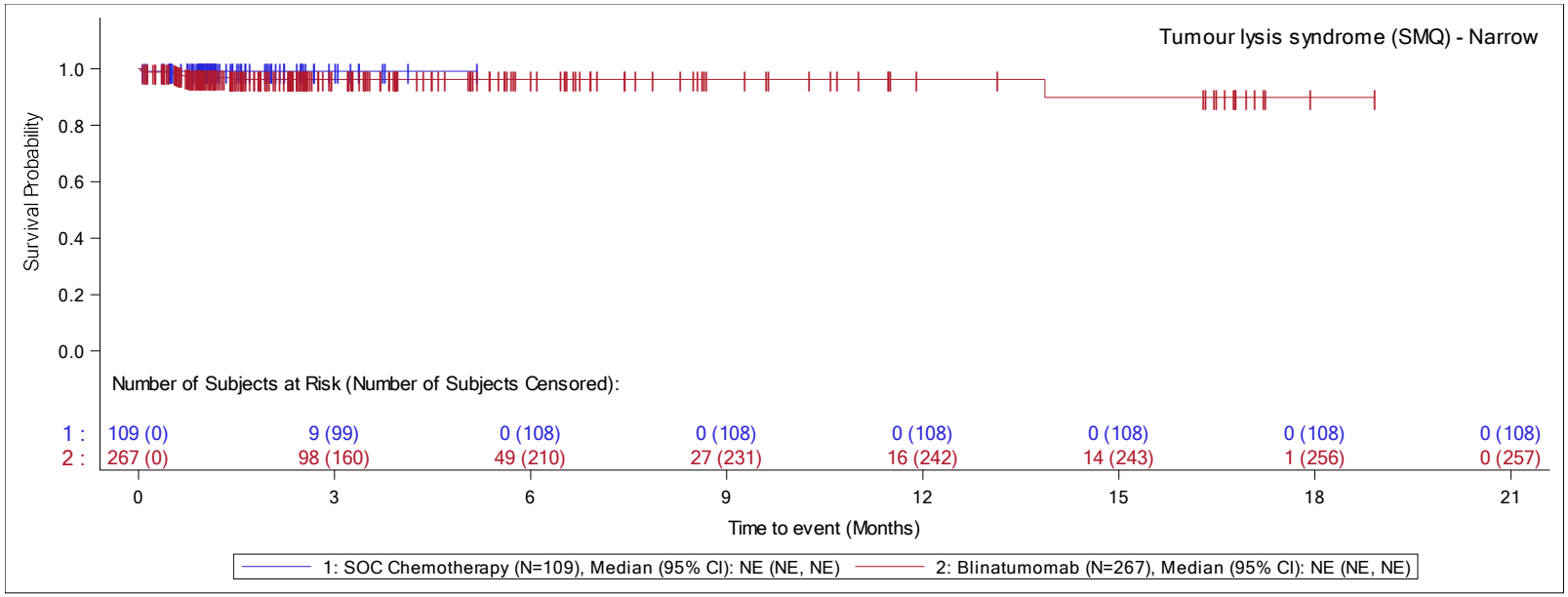
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

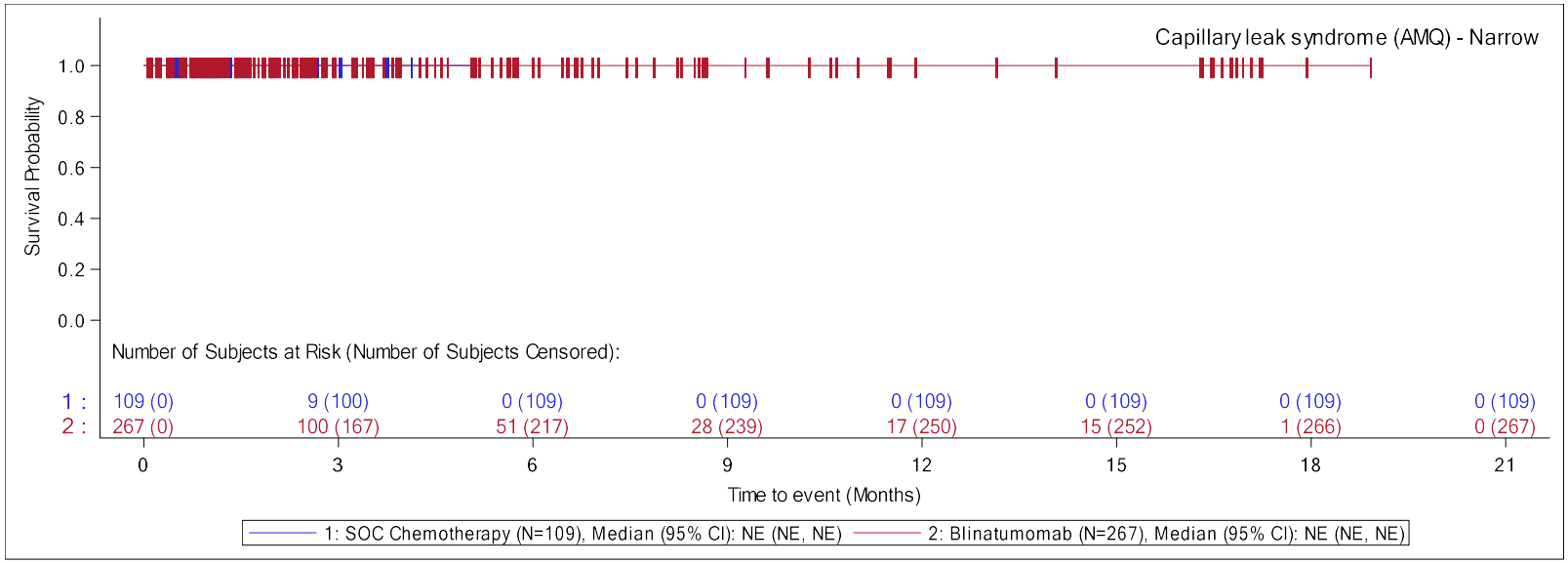
Figure 14-6.1.6. Kaplan-Meier plot for Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-aesi-saf.sas
Output: f14-06-001-006-km-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam.adtteae

Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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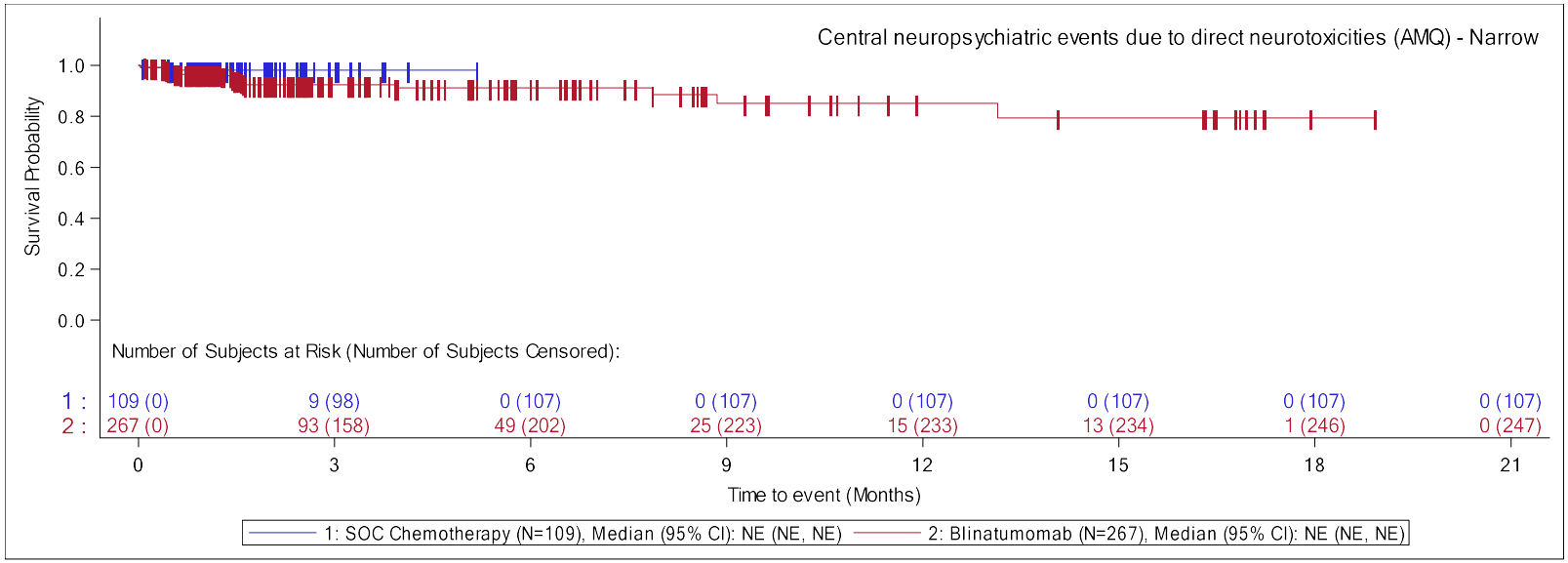
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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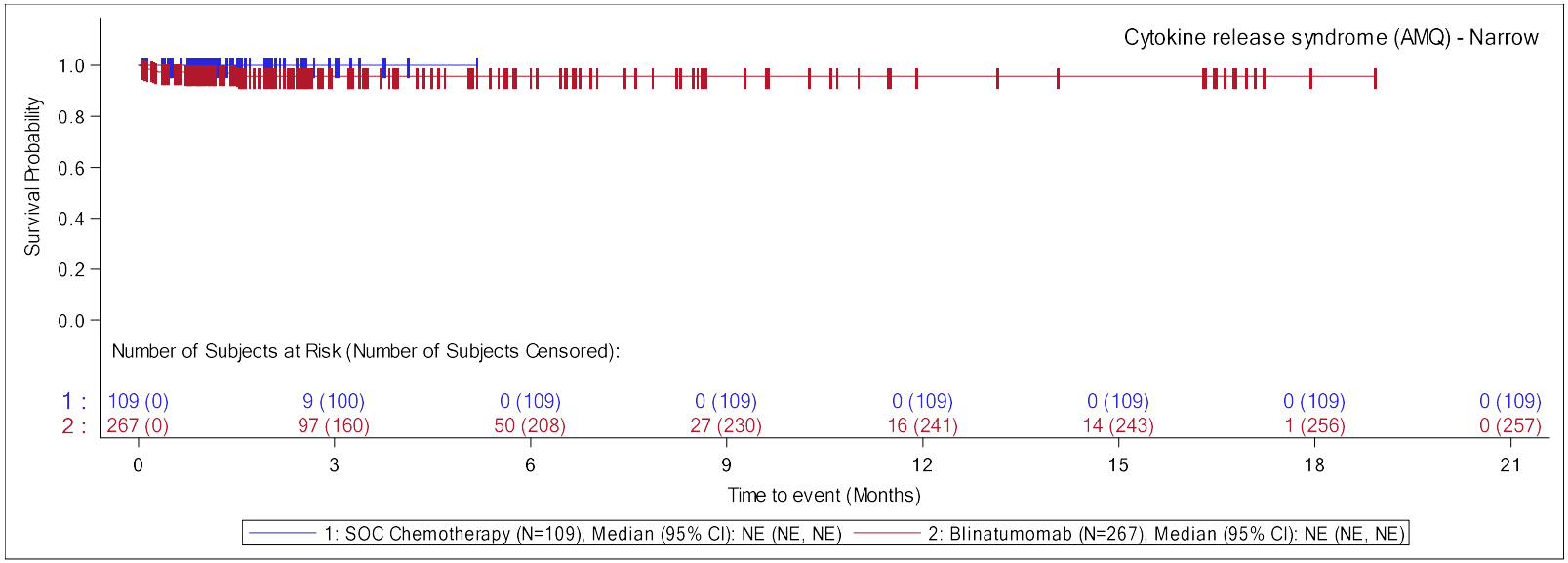

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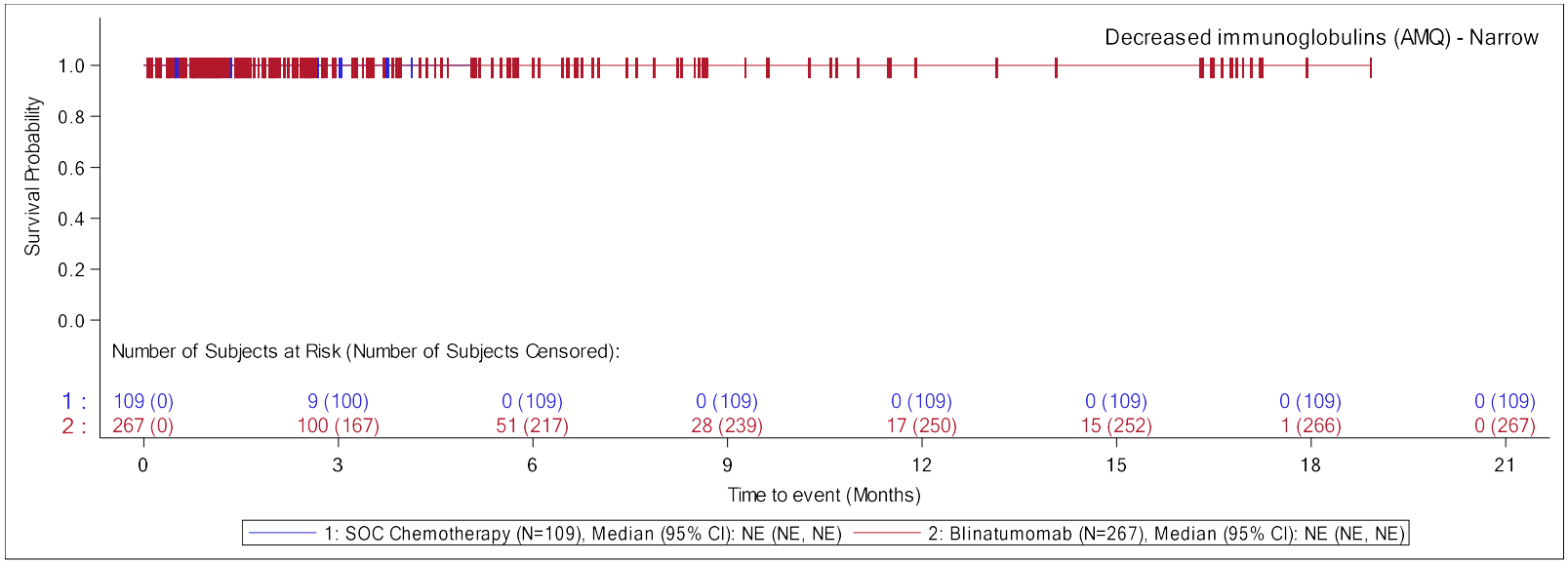
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

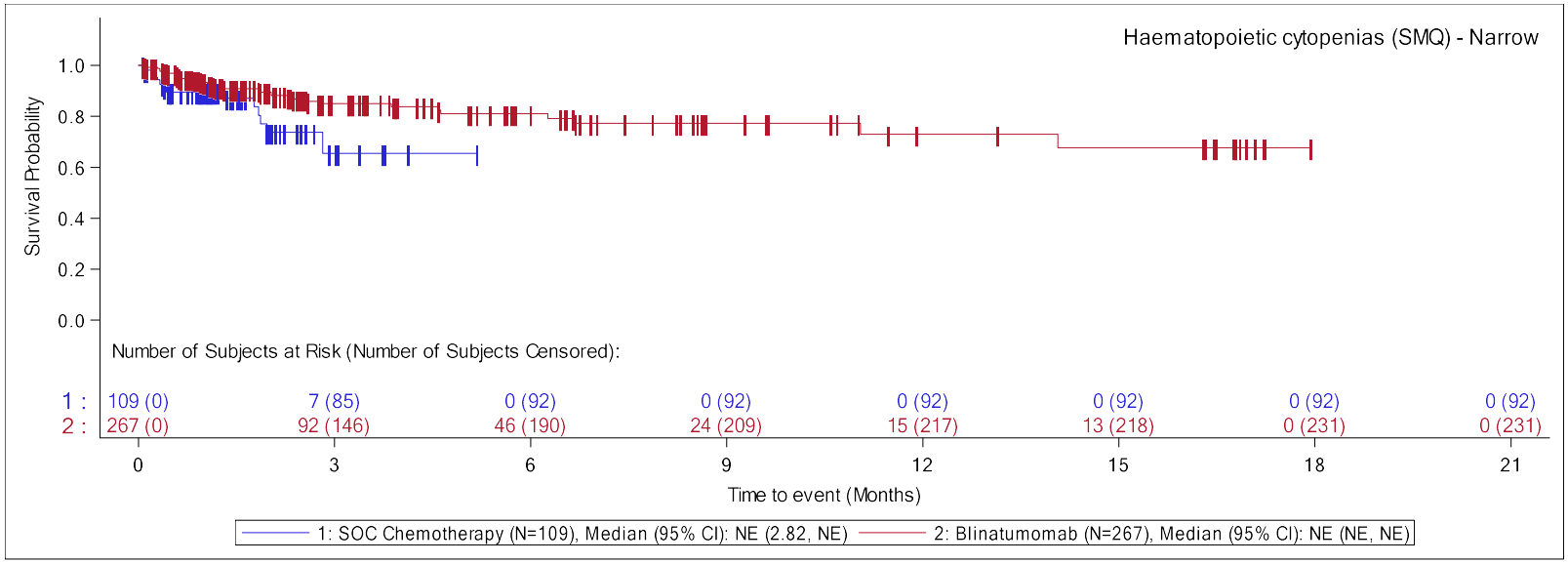

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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

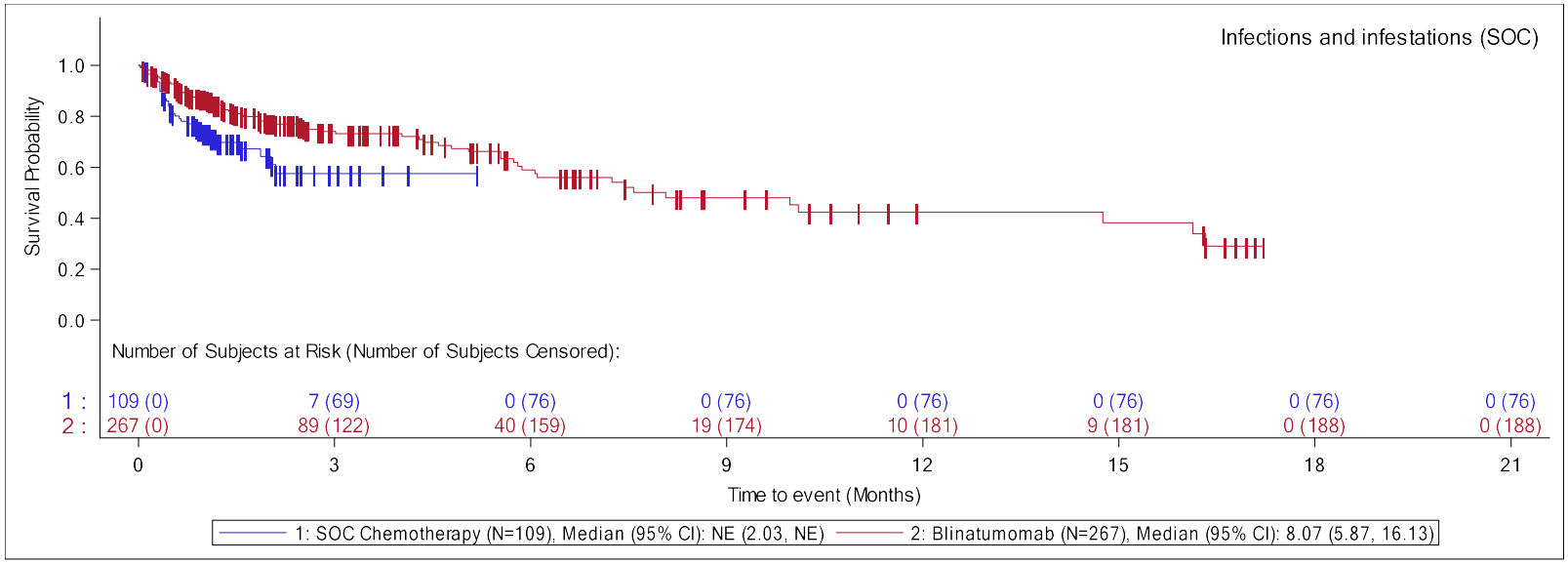

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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

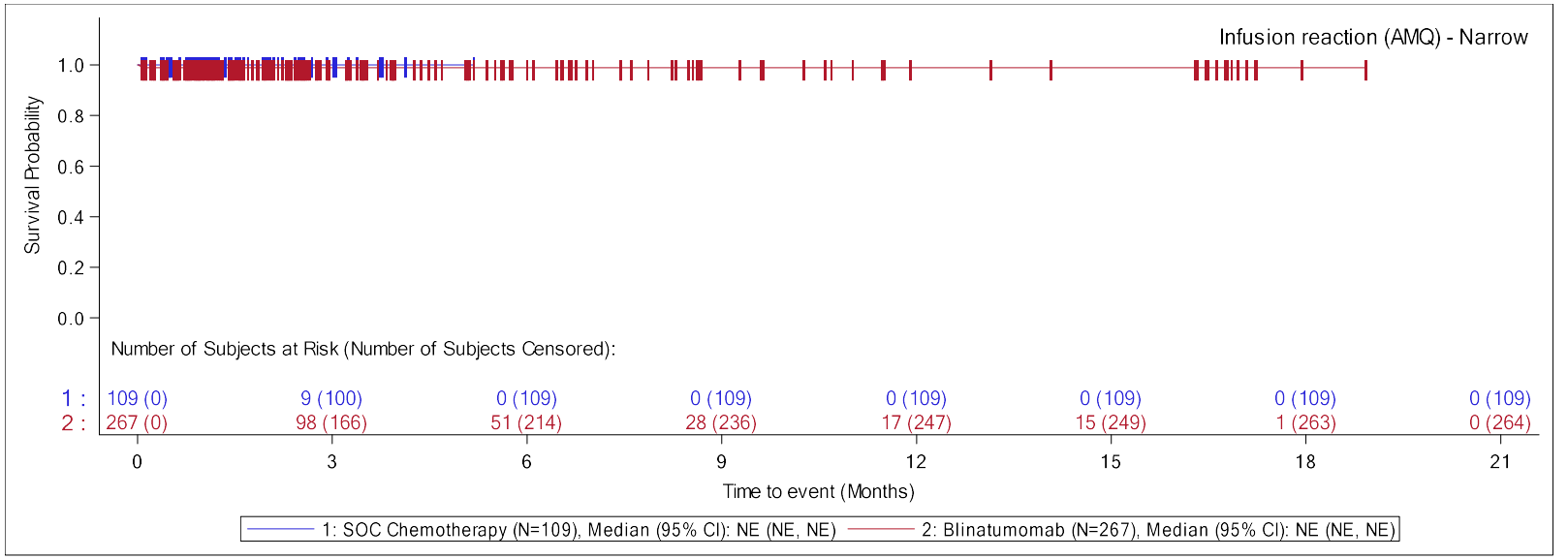

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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

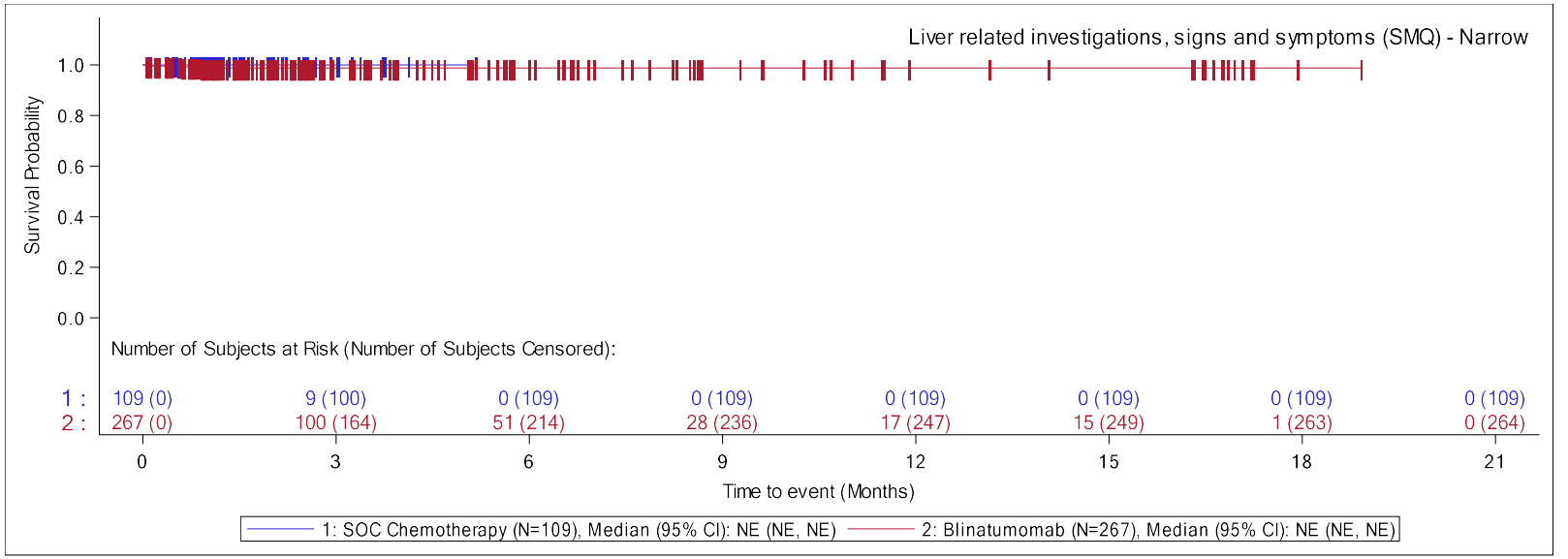

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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

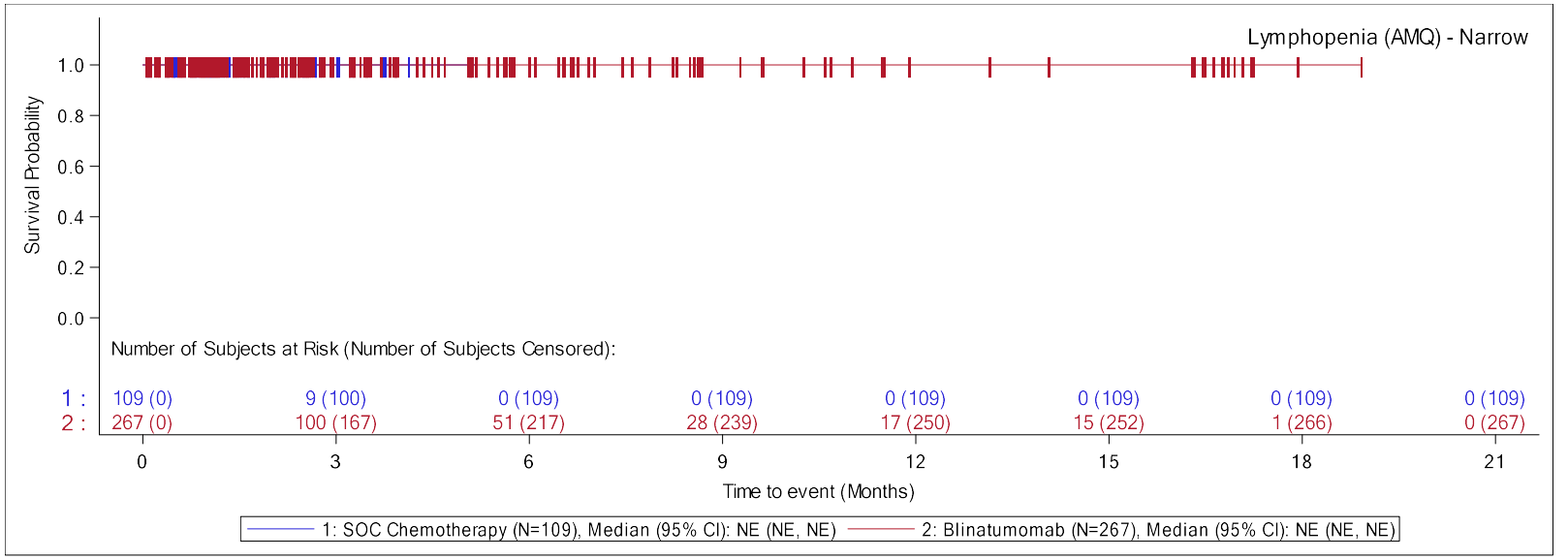

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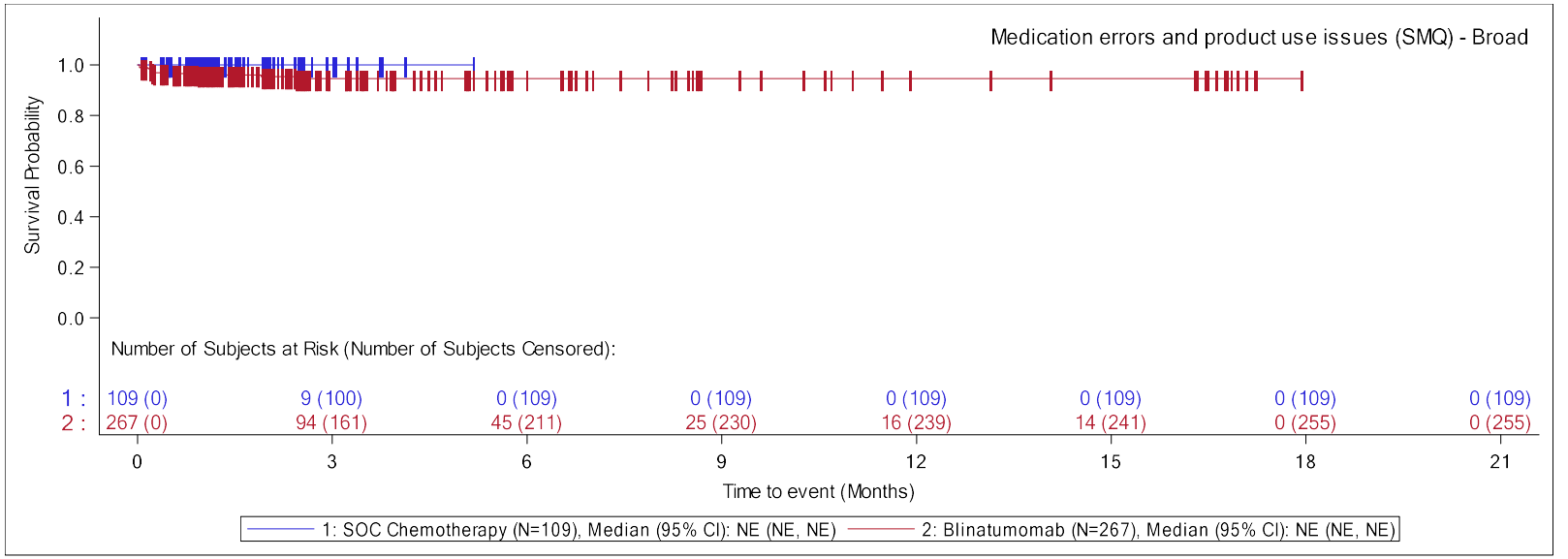
Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

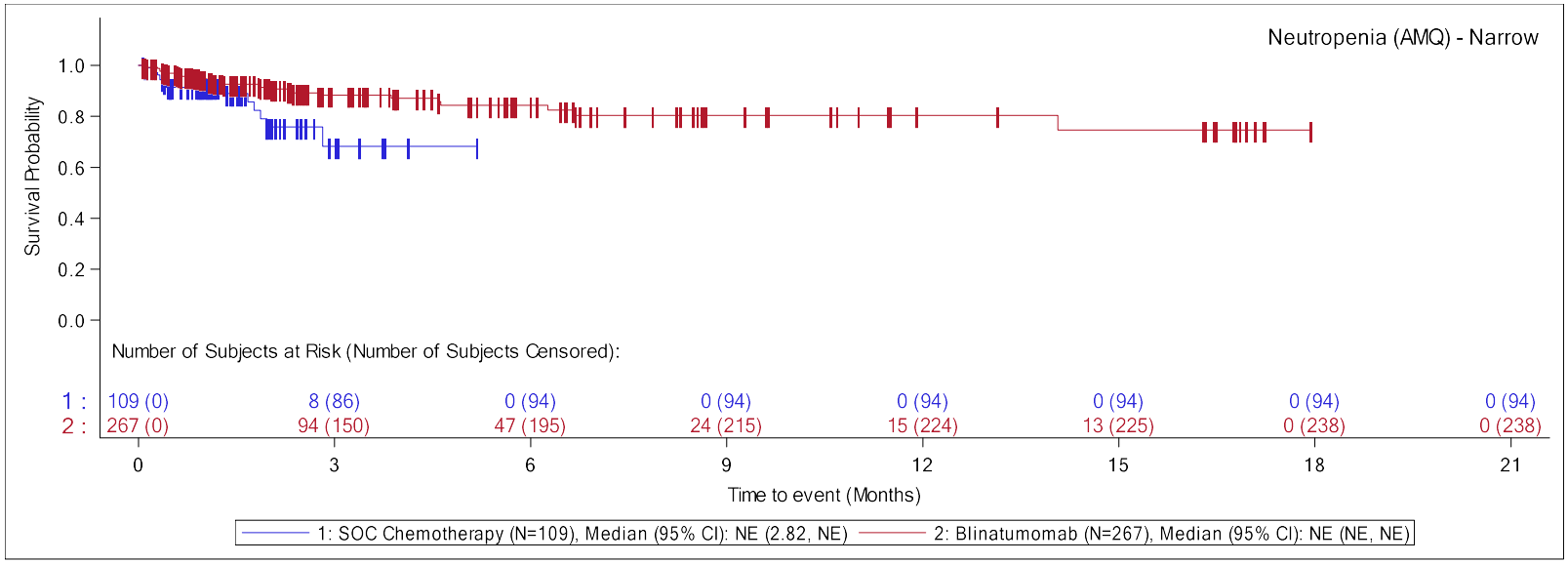

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Figure 14-6.1.7. Kaplan-Meier plot for Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

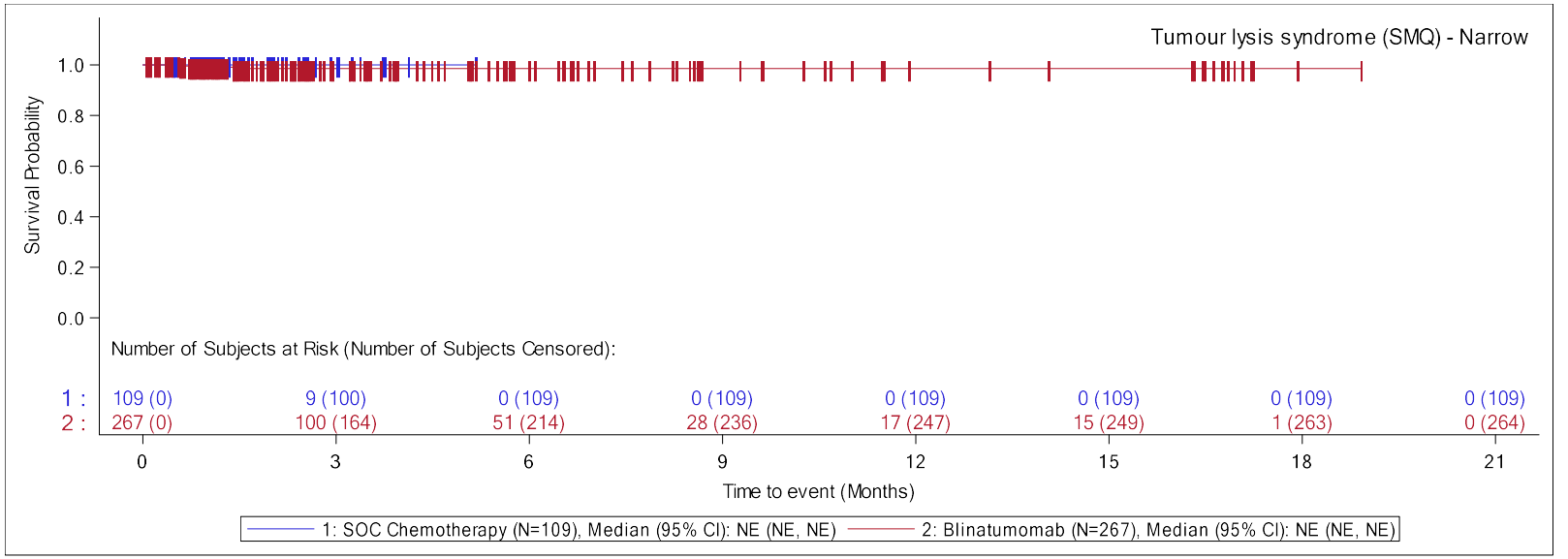

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Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest
(Safety Analysis Set)

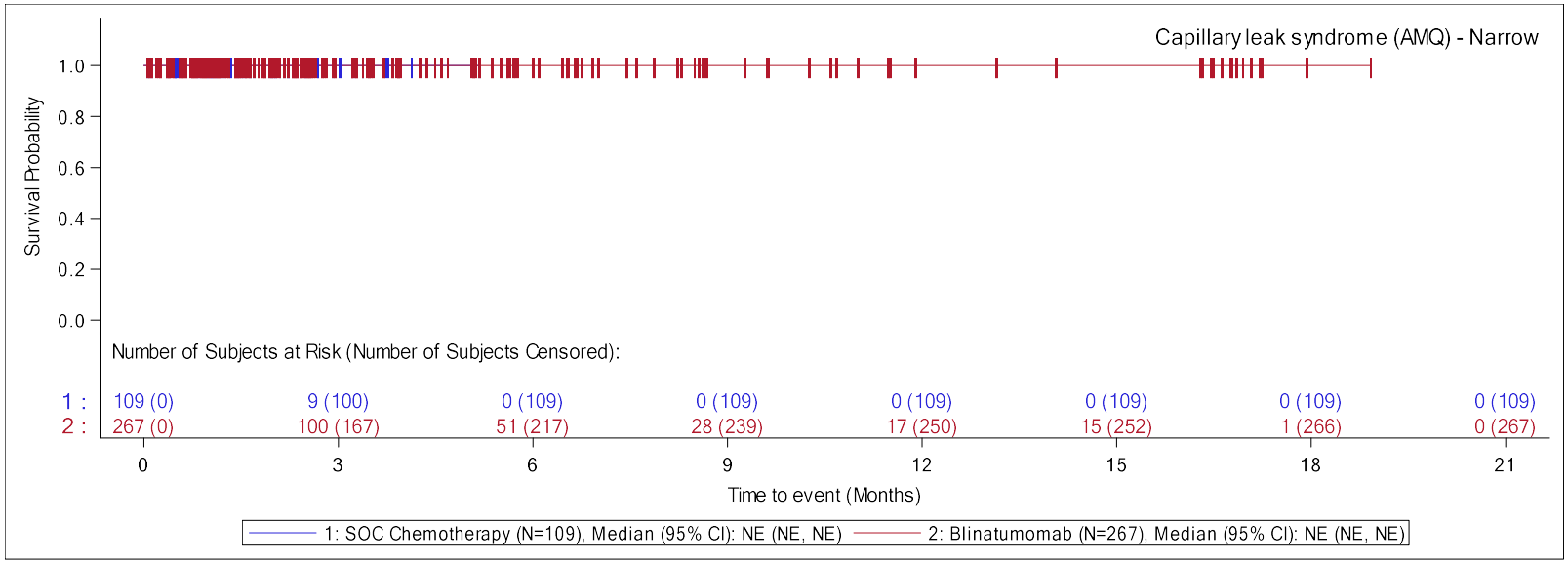

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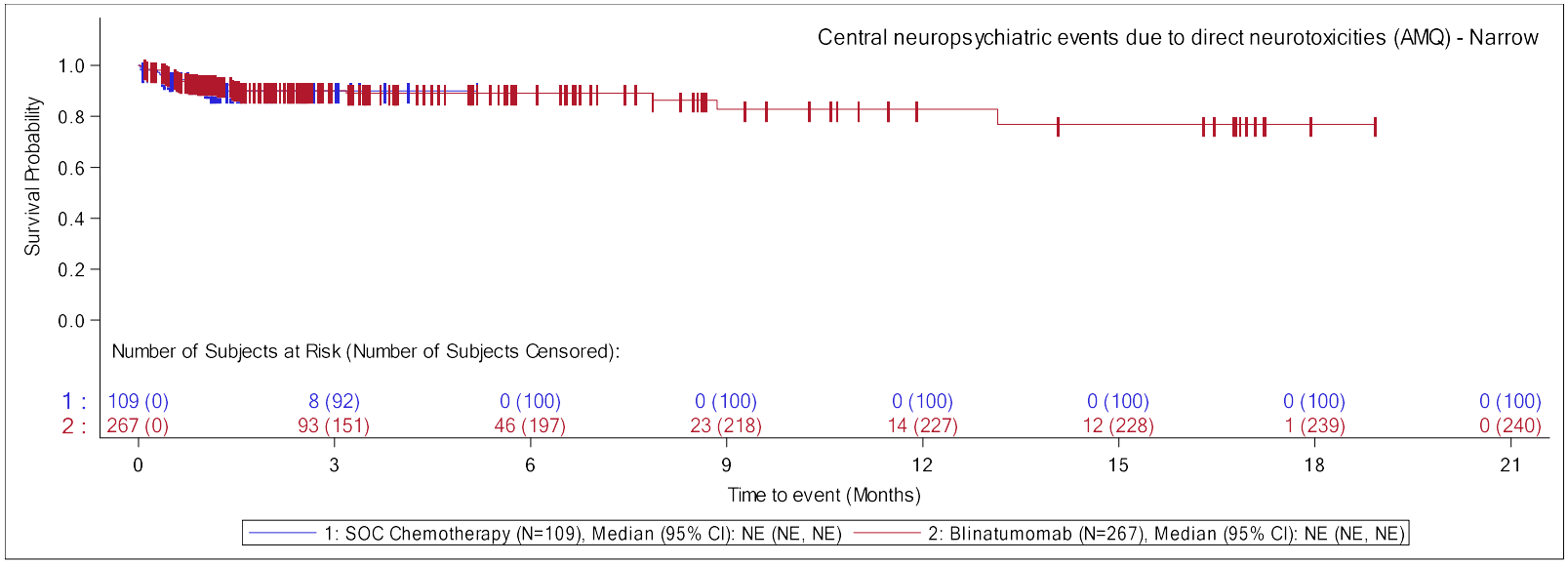
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



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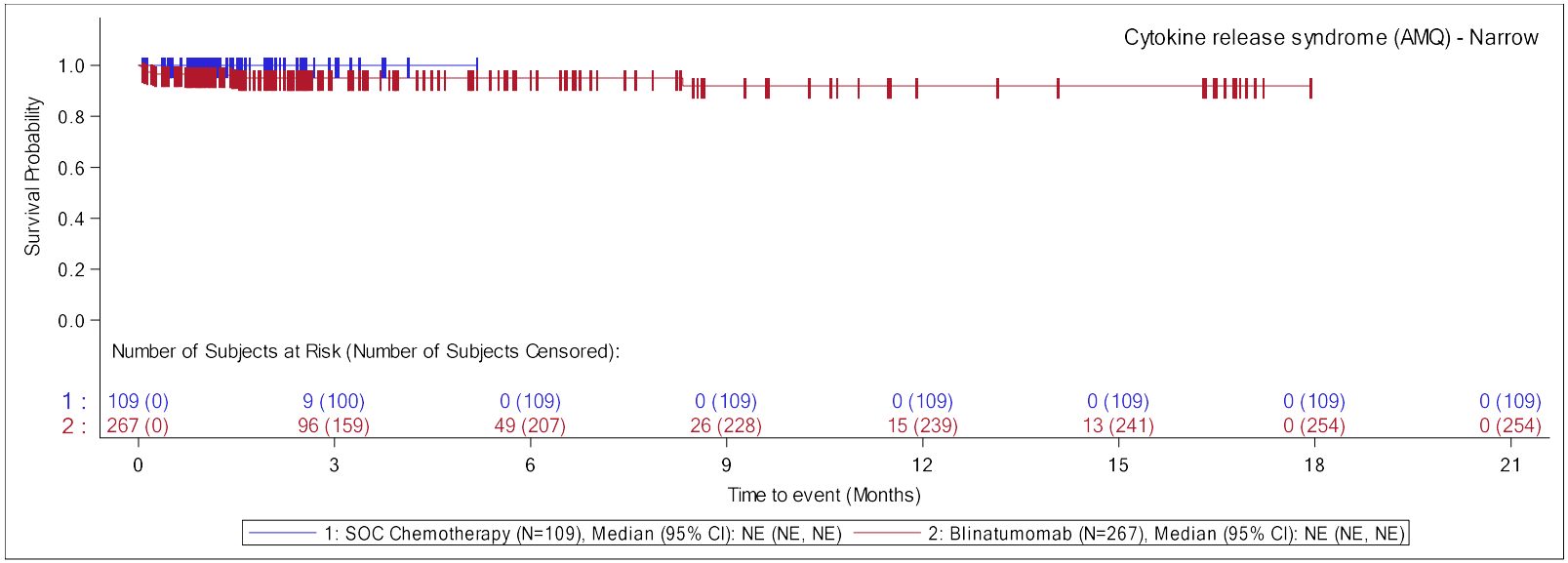

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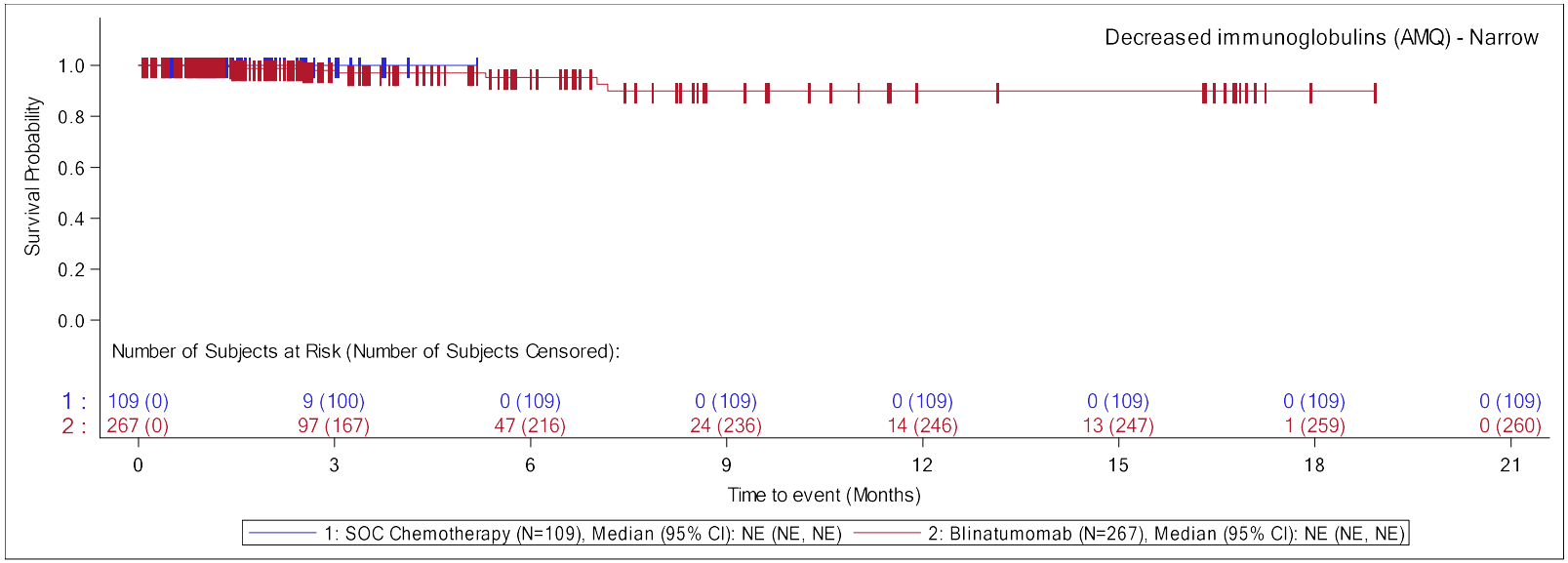
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



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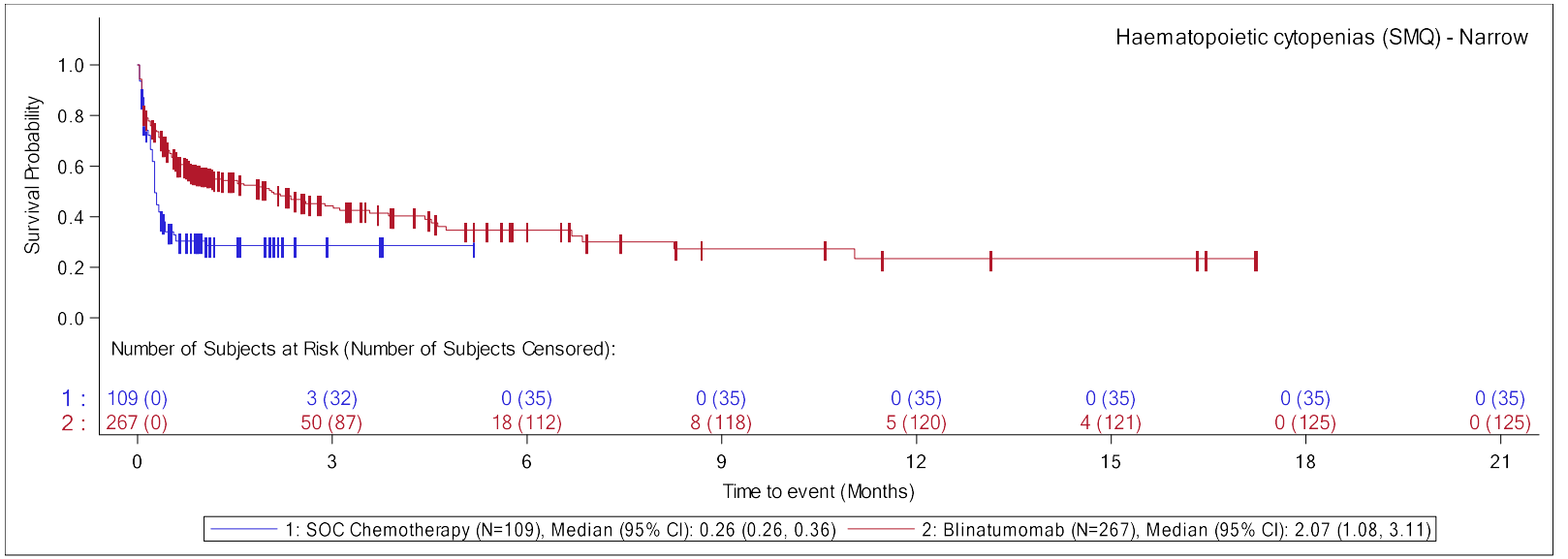

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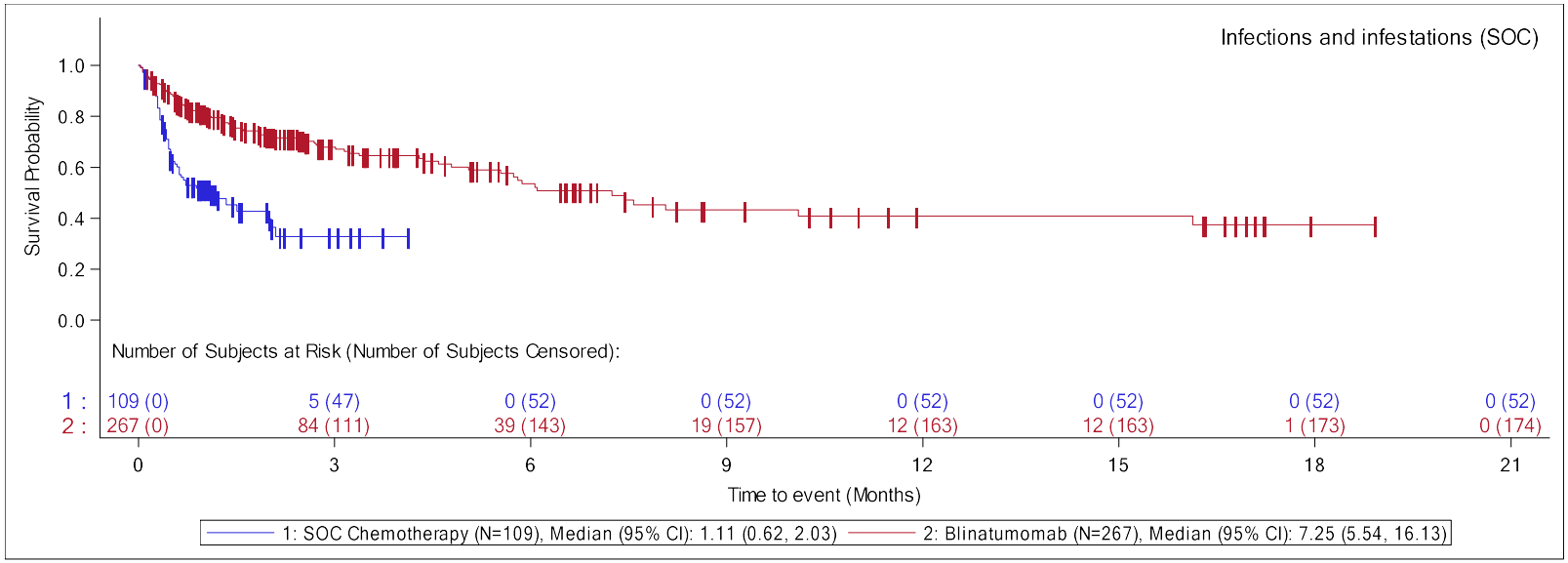

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Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

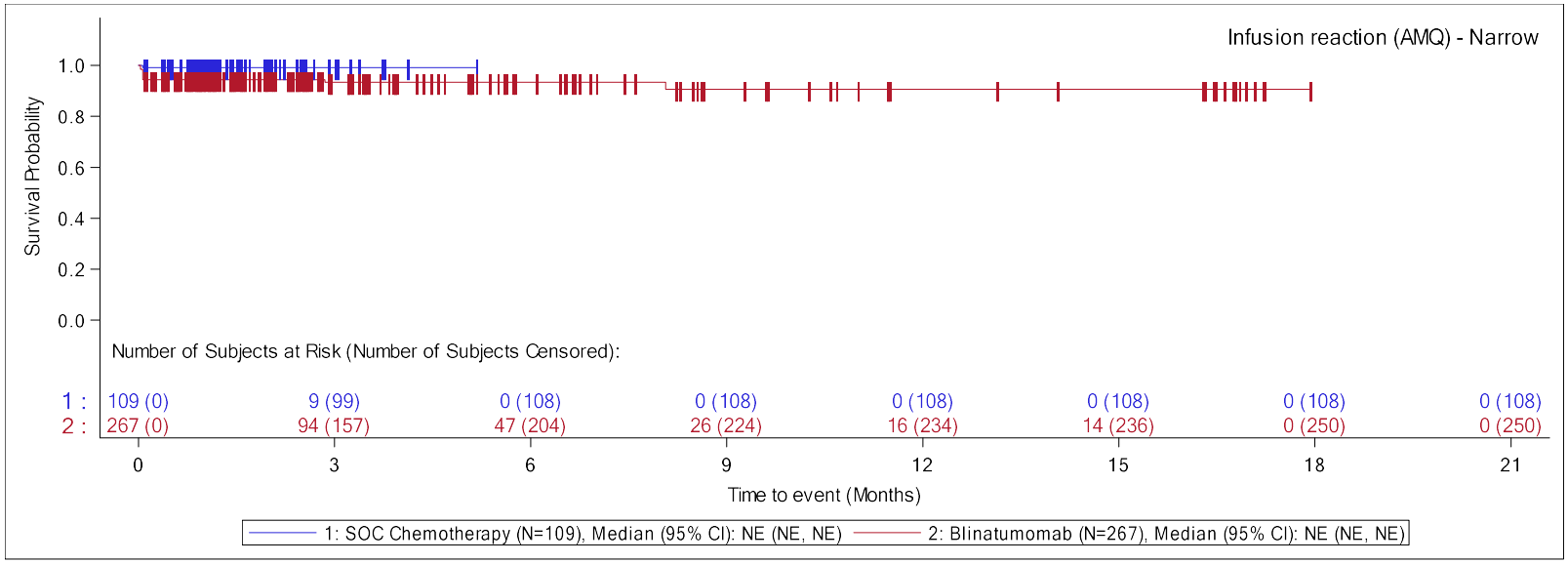

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Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

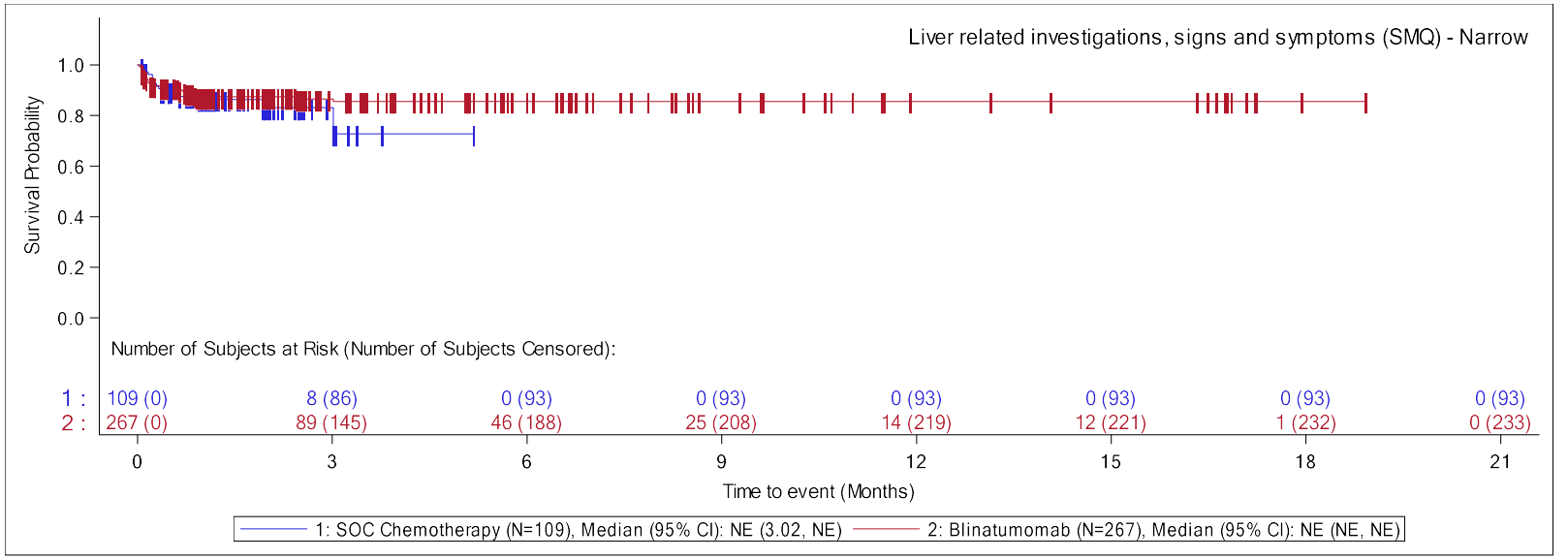

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Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

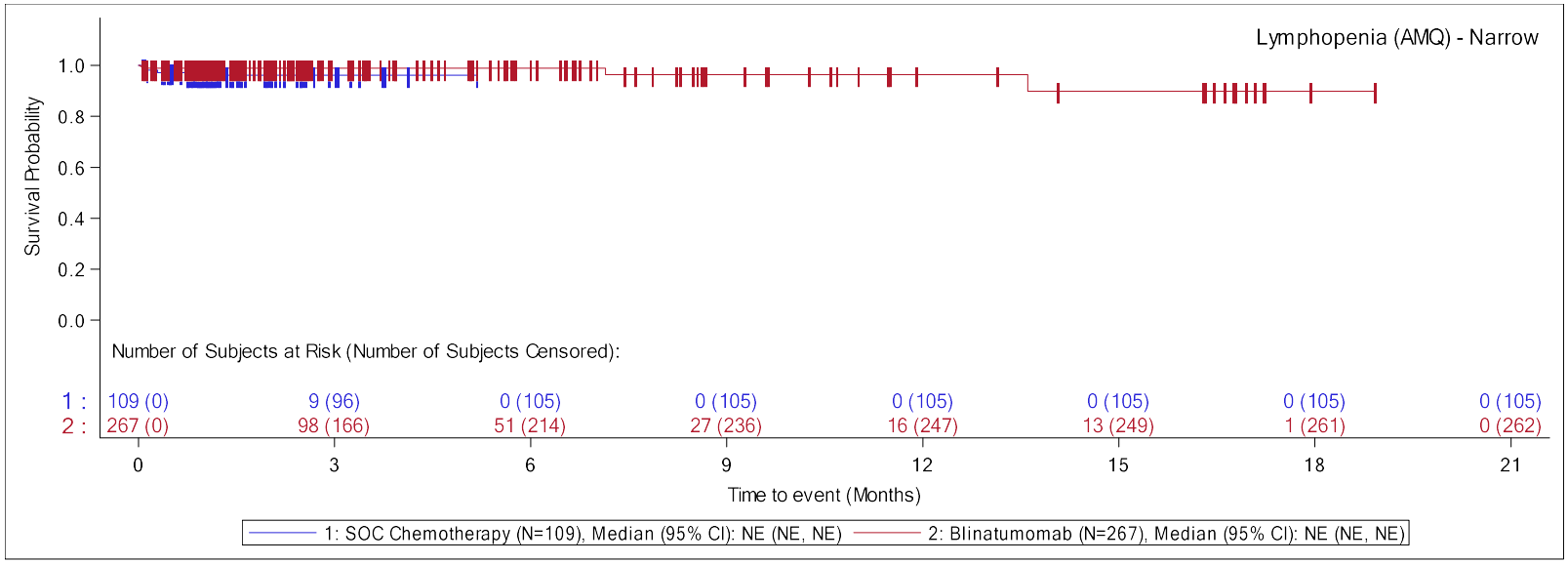

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Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

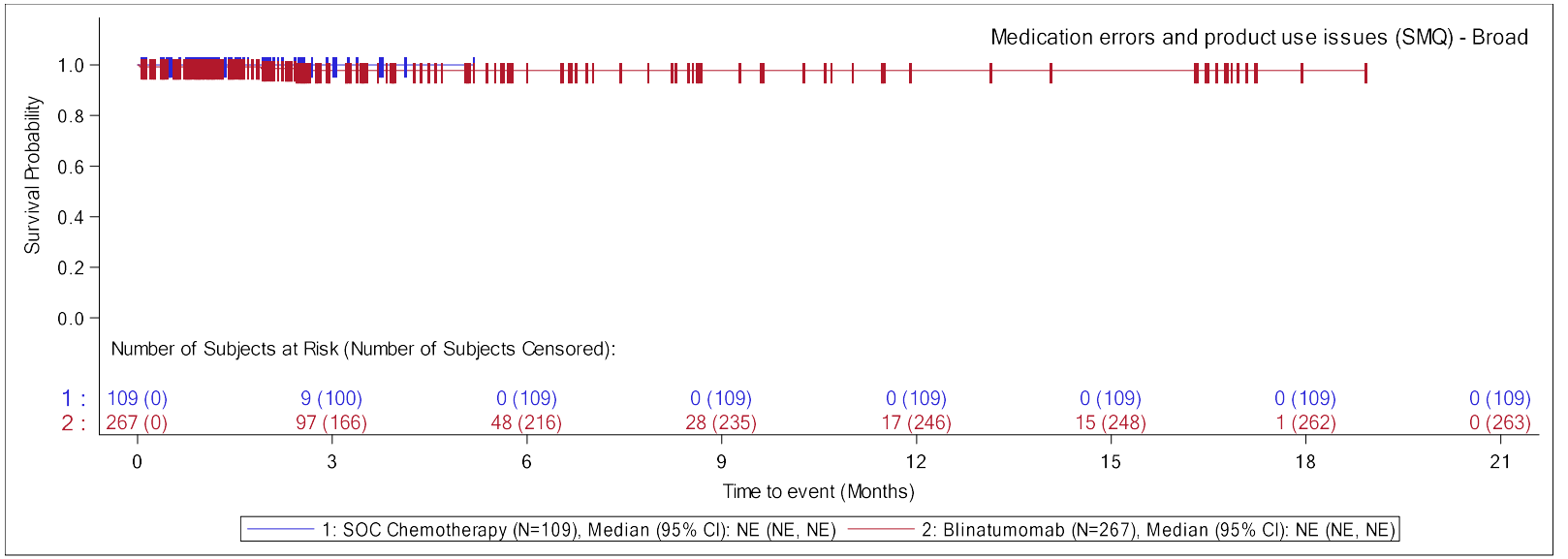

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Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

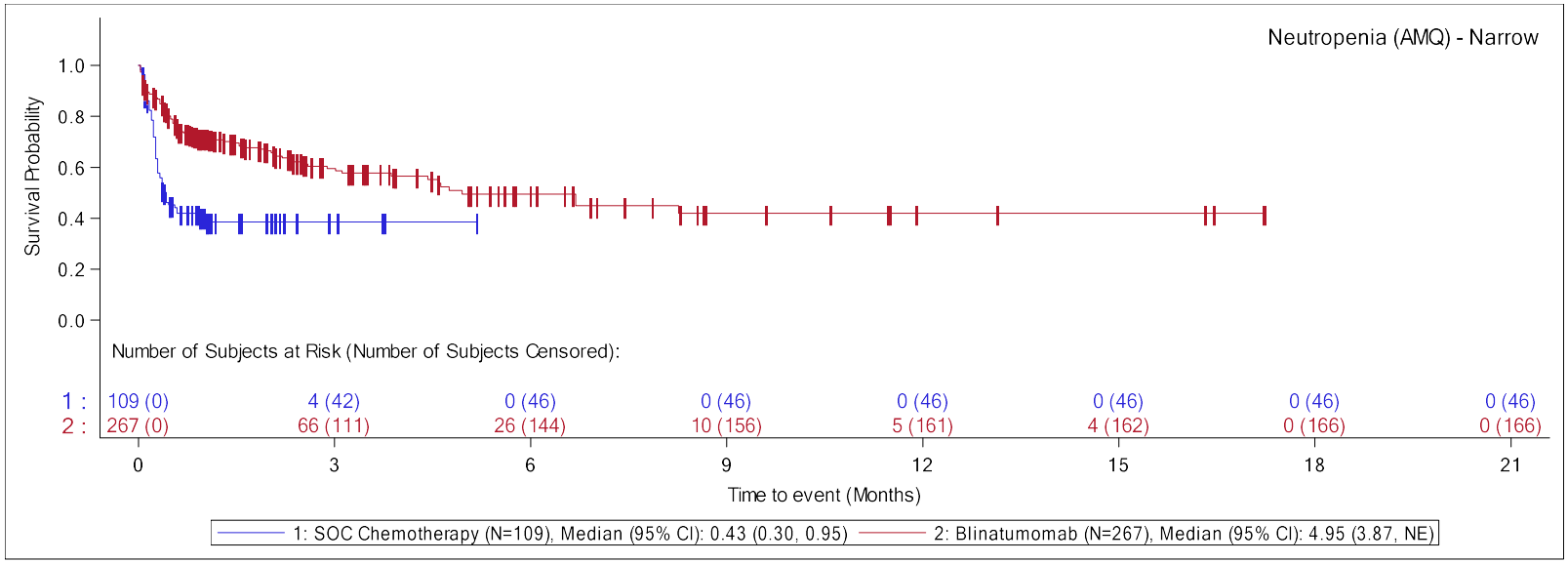

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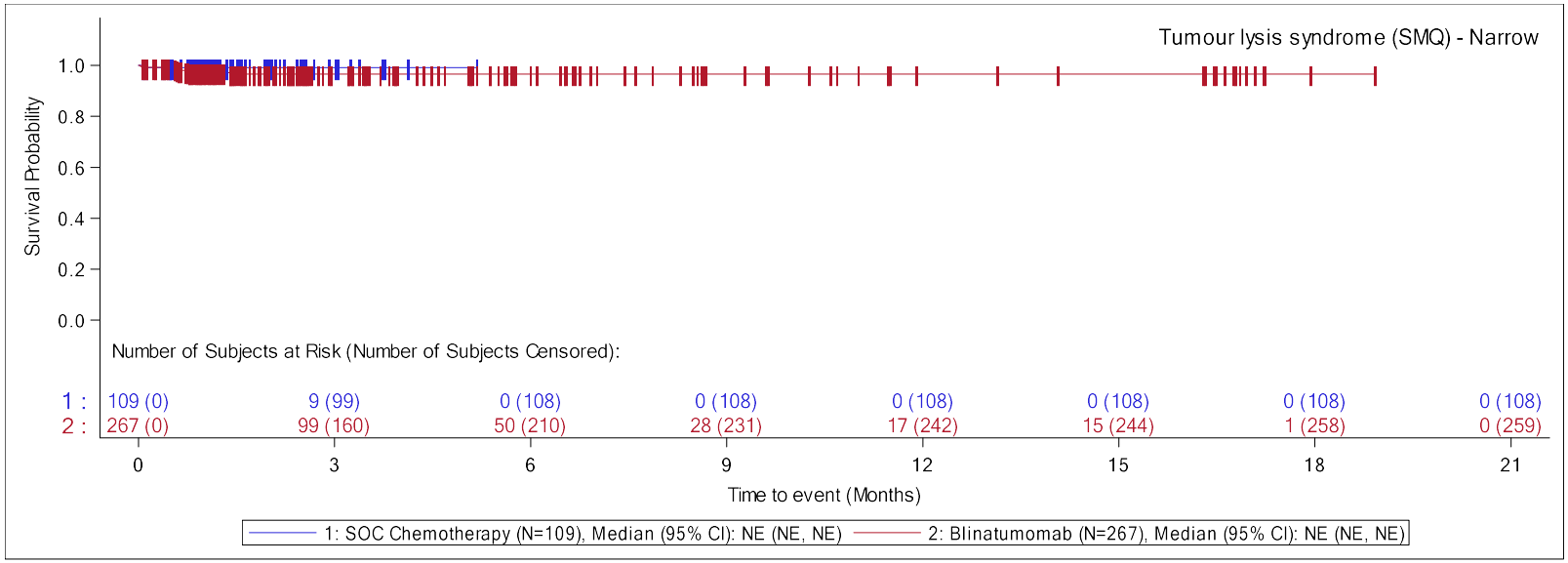
Figure 14-6.1.8. Kaplan-Meier plot for Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



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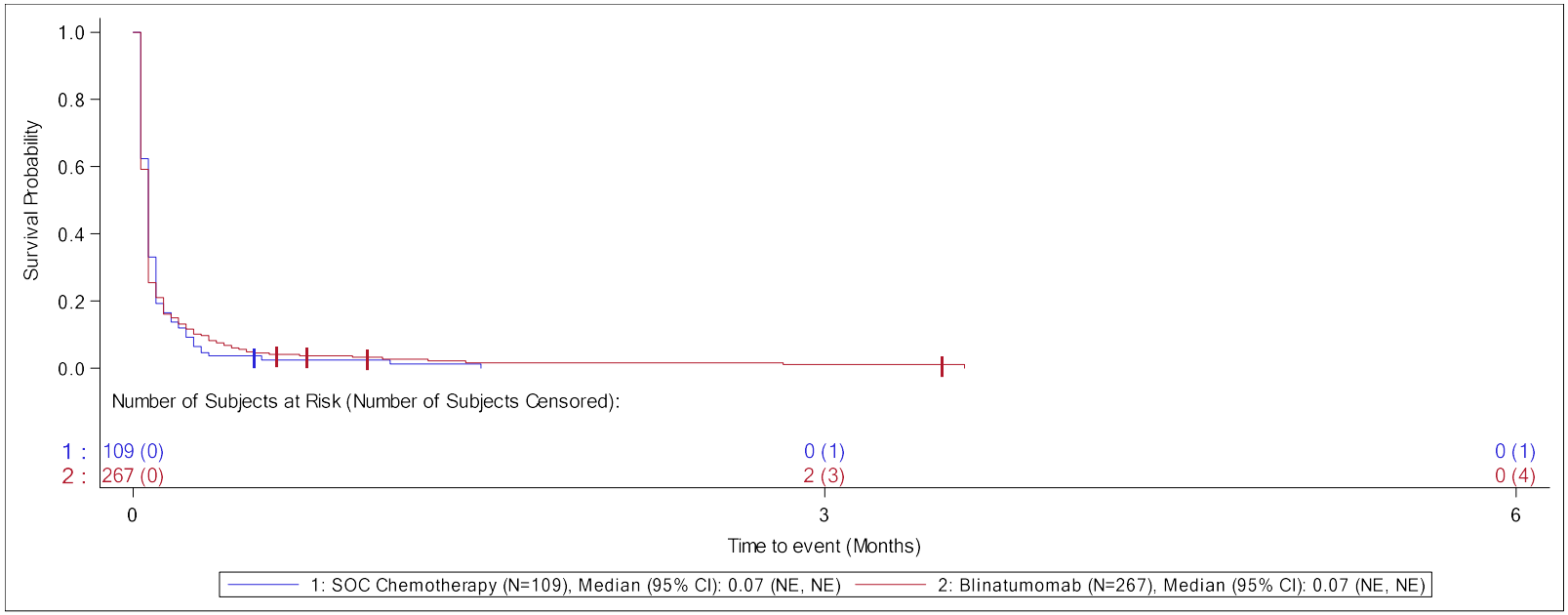
Output: f14-06-001-008-km-sev-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam.adtteae

Figure 14-6.1.9. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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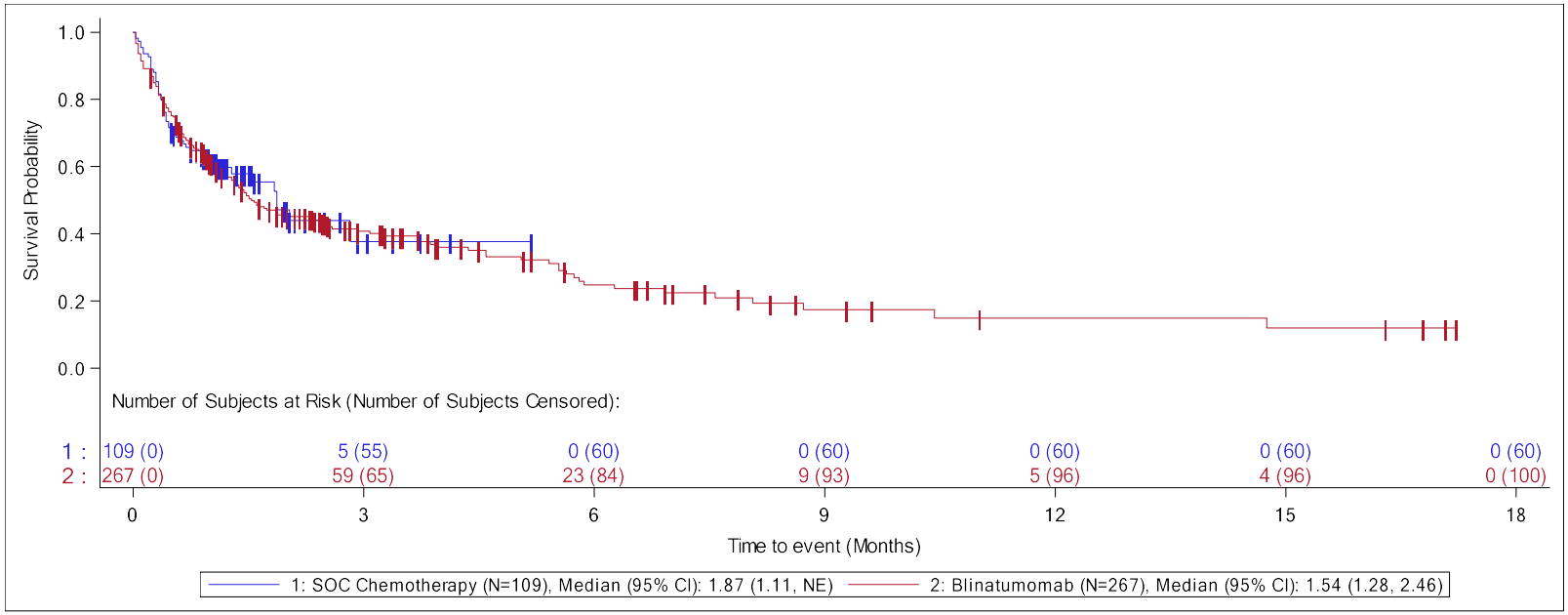
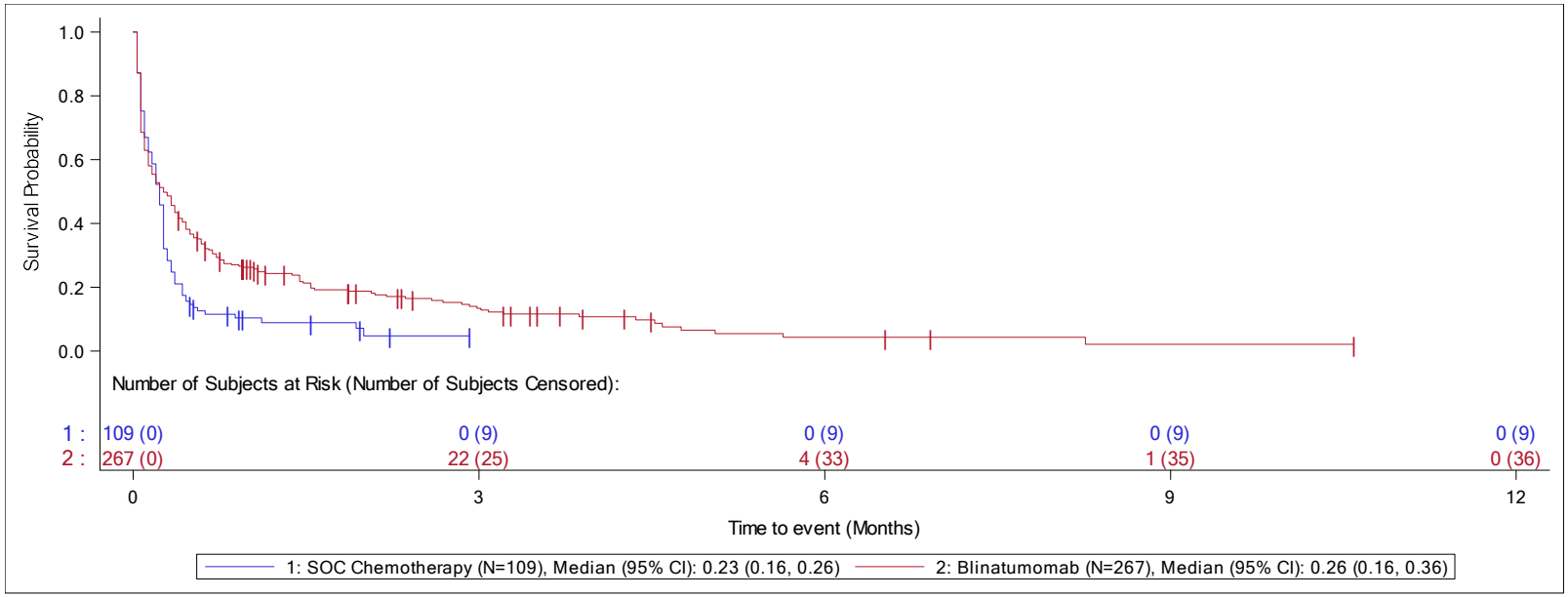
Figure 14-6.1.10. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-ser-teae-edp-saf.sas
Output: f14-06-001-010-km-ser-teae-edp-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam.adtteae

Figure 14-6.1.11. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval.
Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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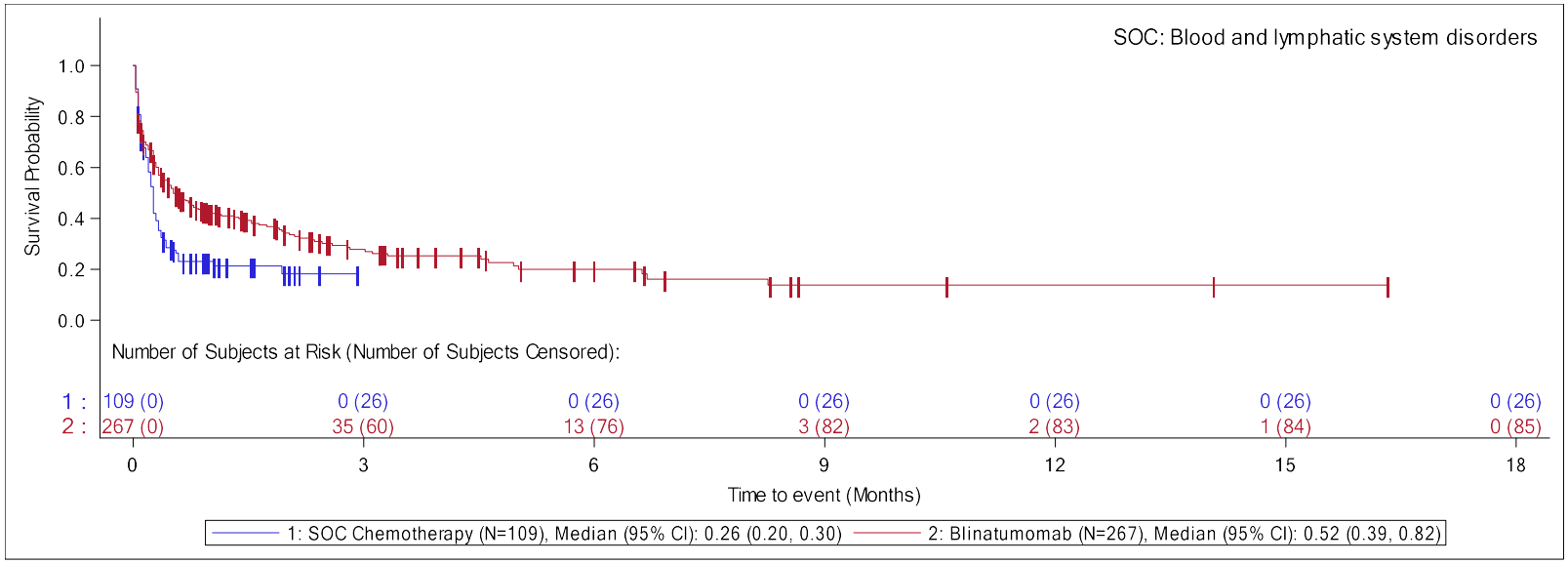
Output: f14-06-001-011-km-sev-teae-edp-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam.adtteae

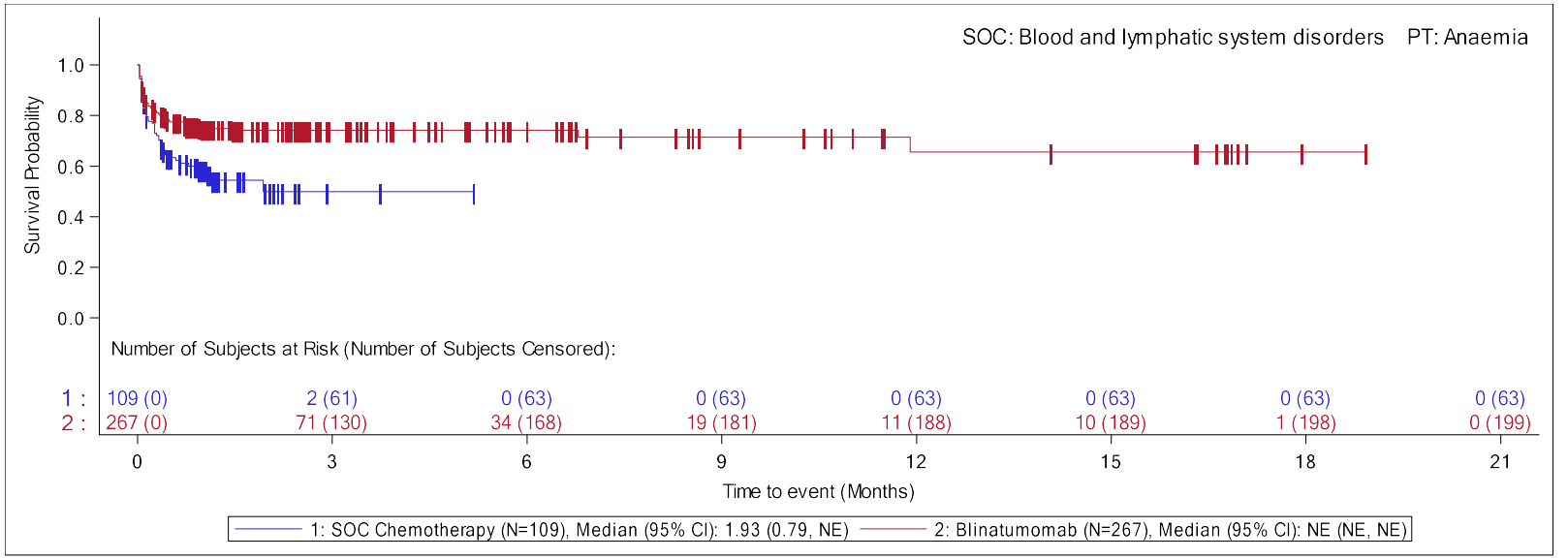
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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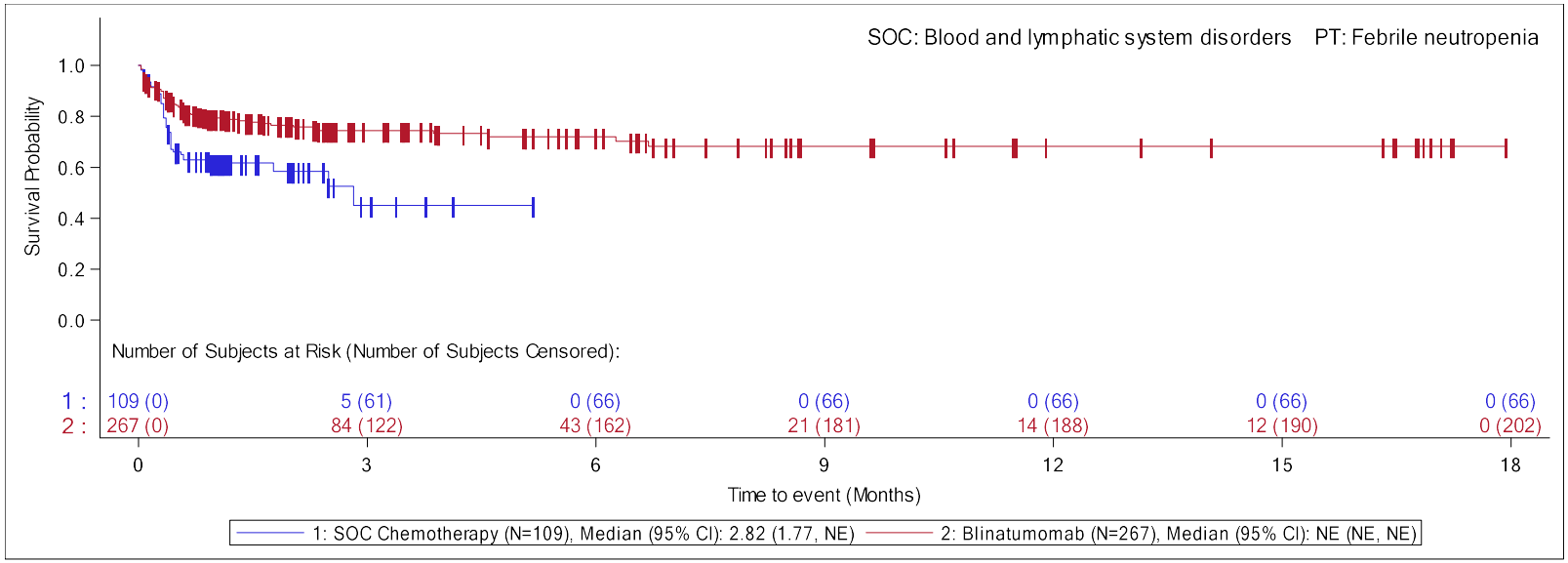
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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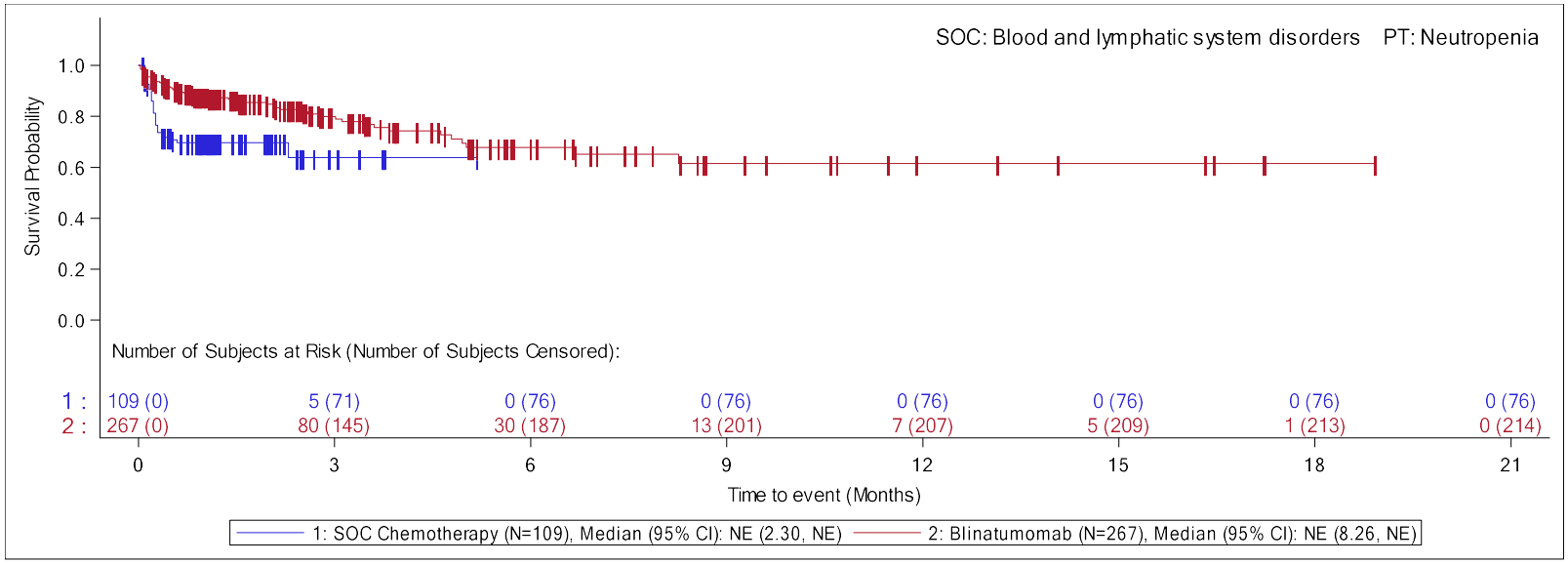
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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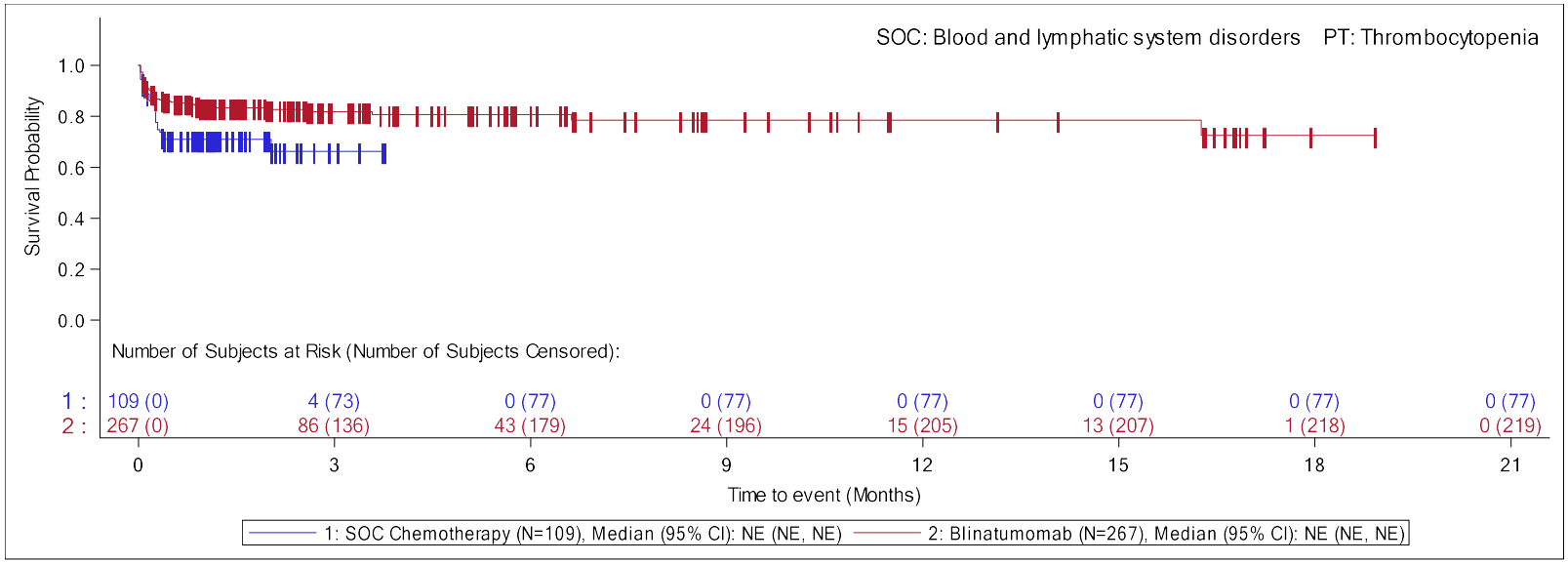
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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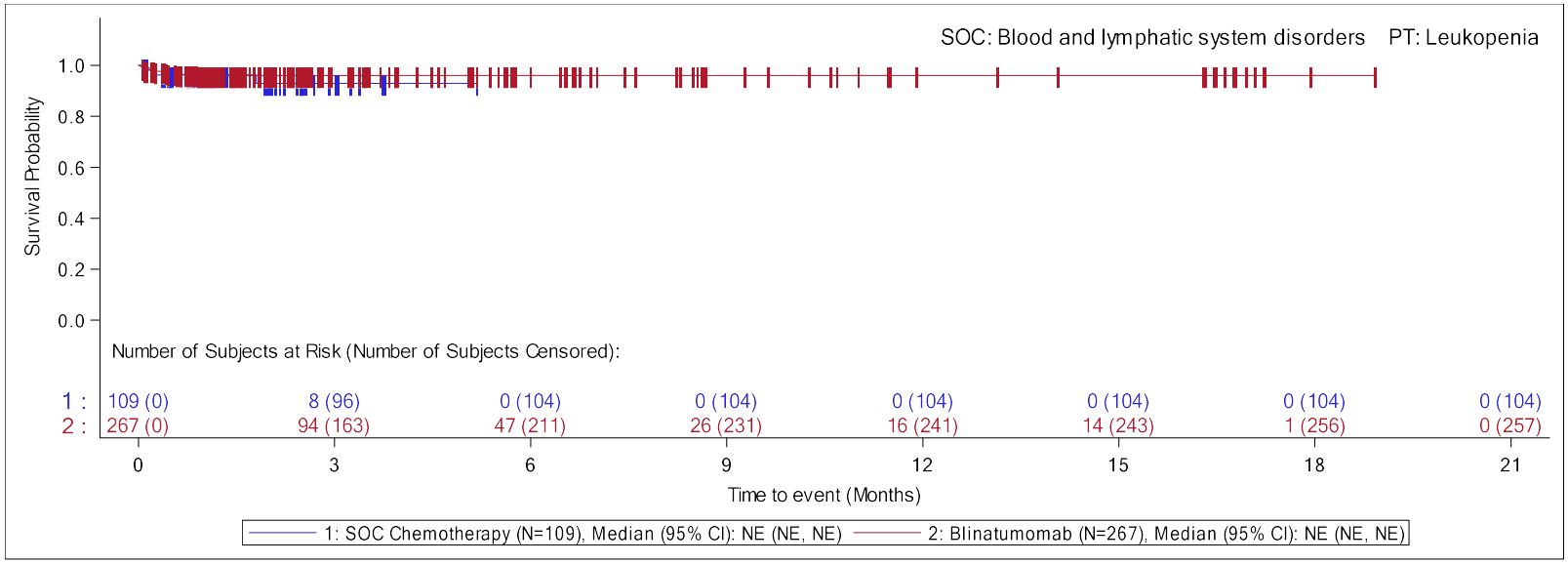
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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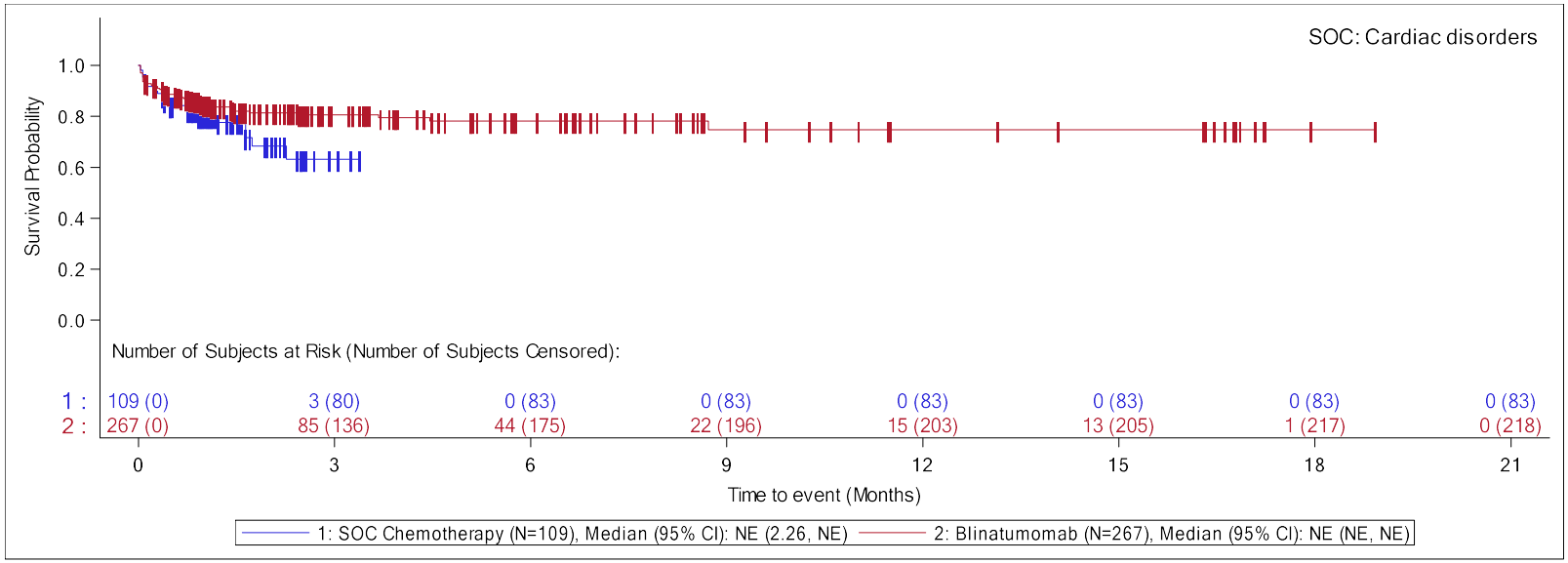
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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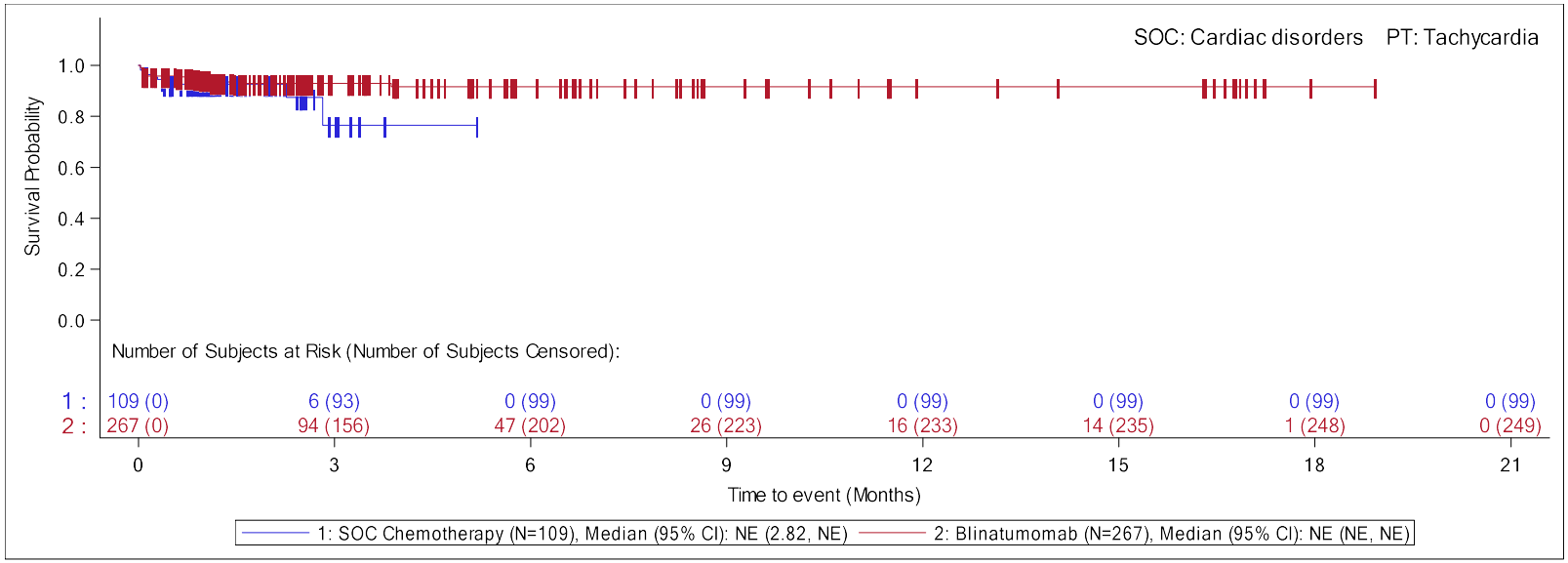
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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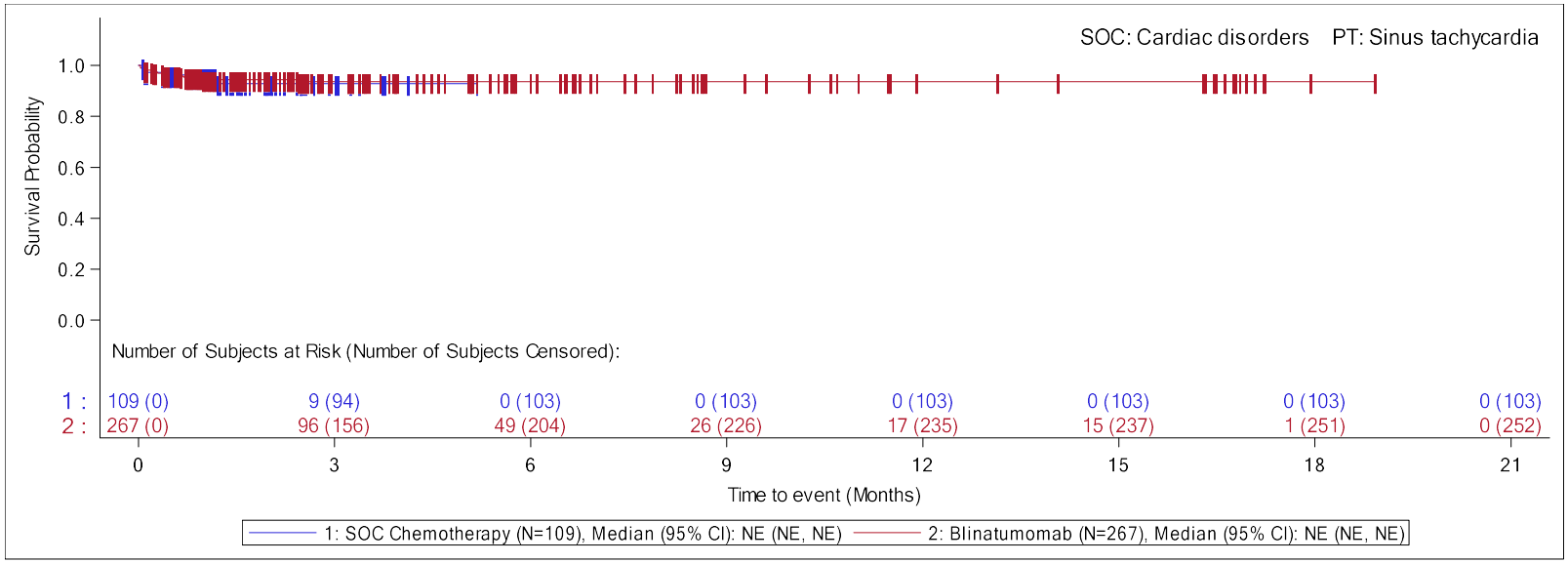
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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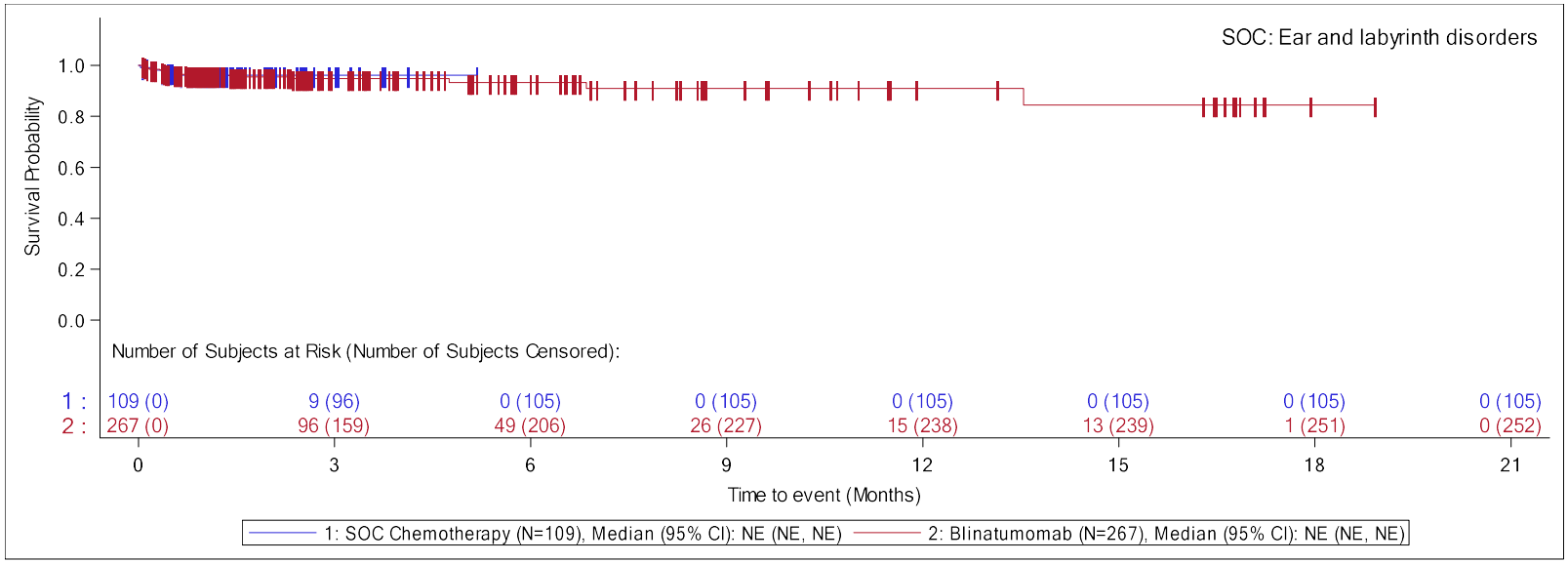
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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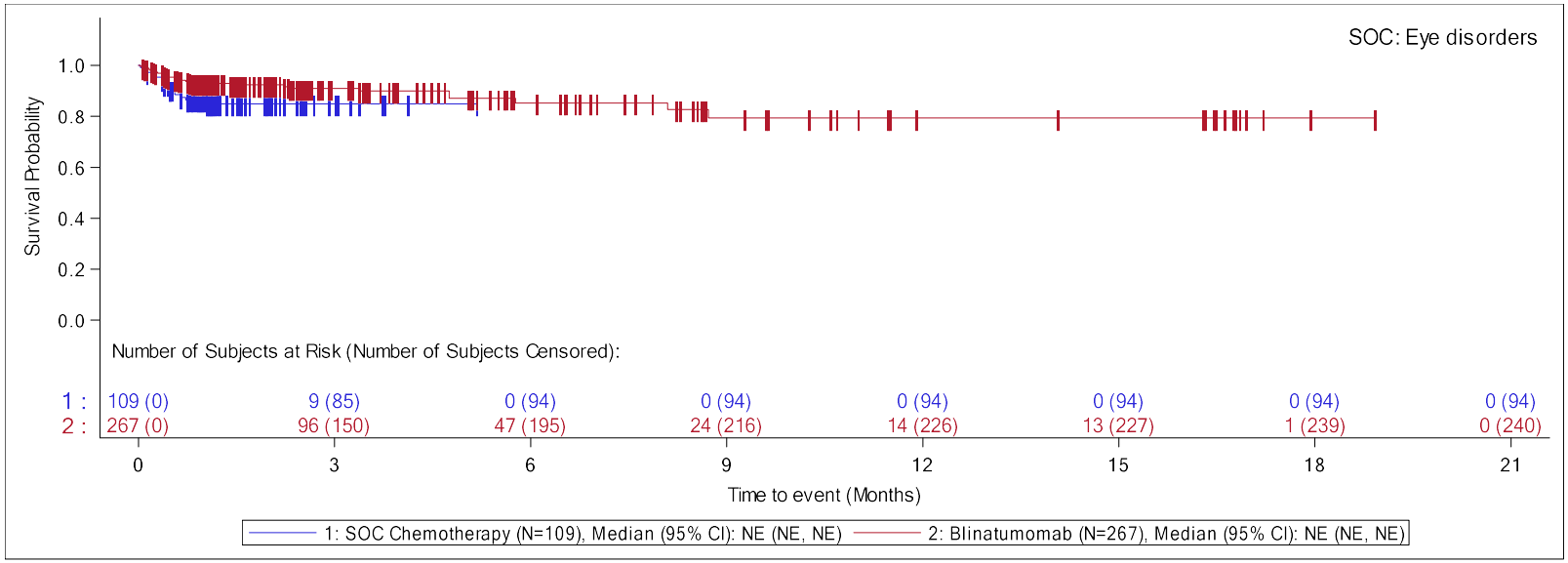
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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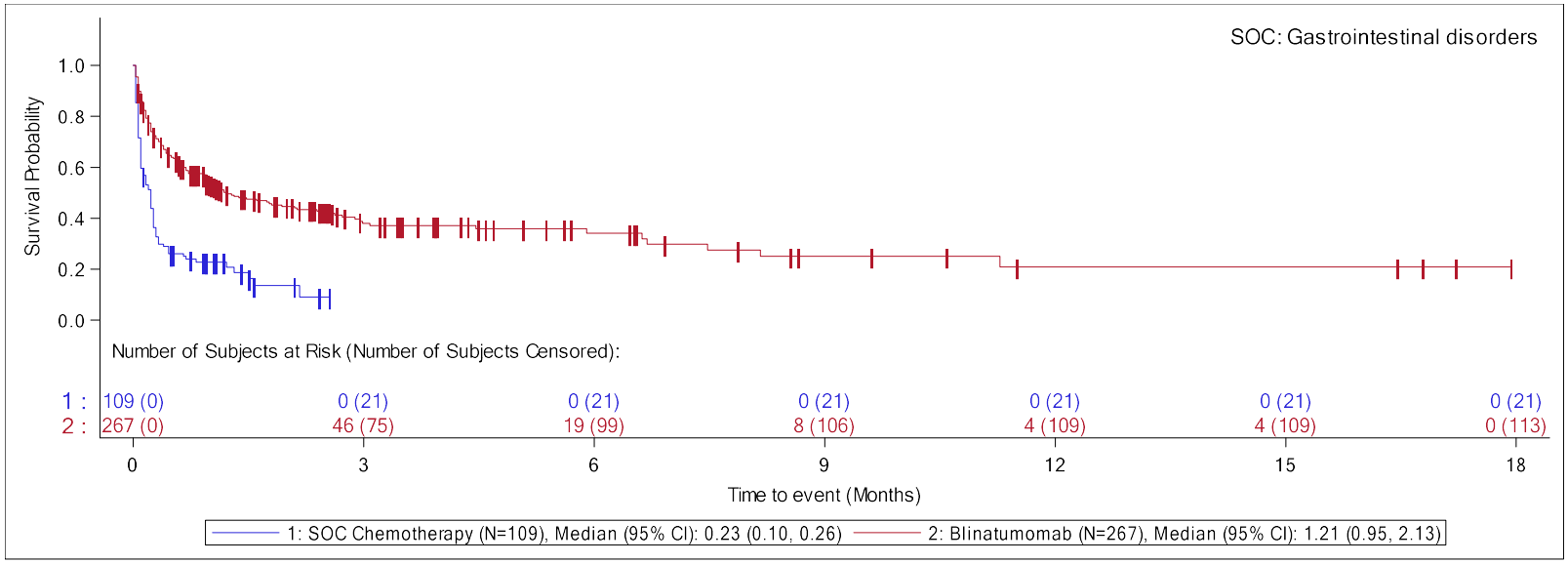
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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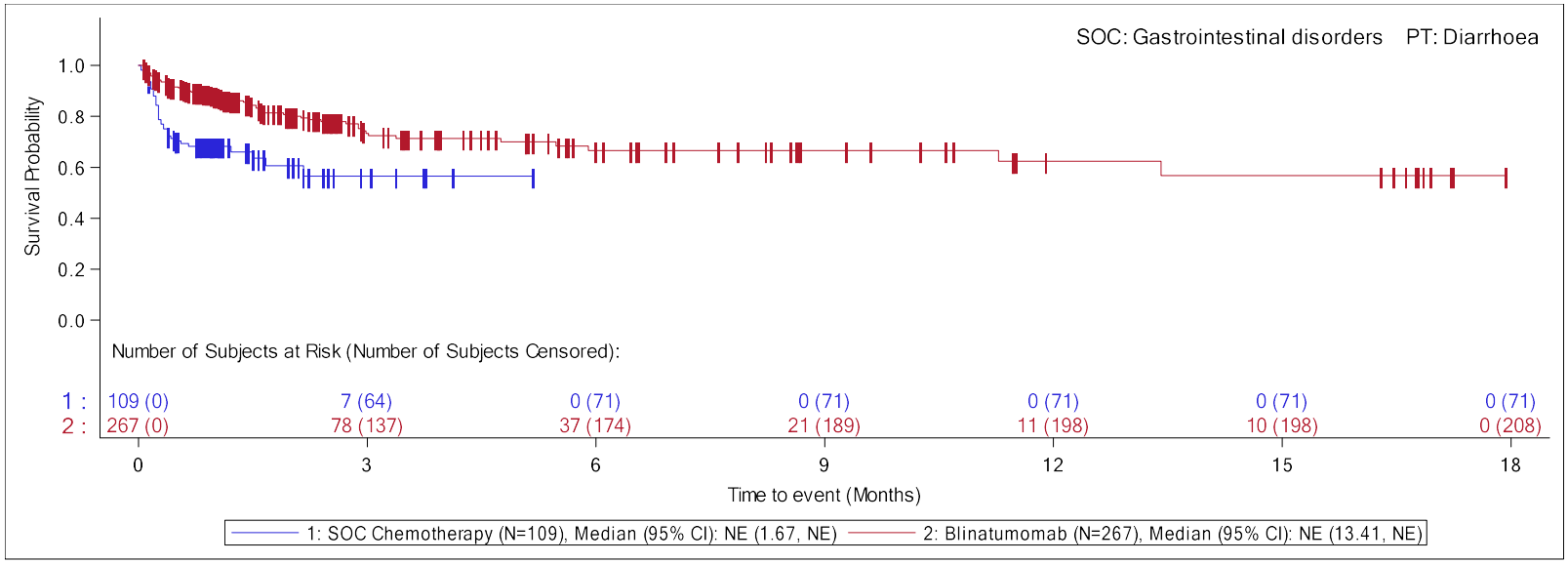
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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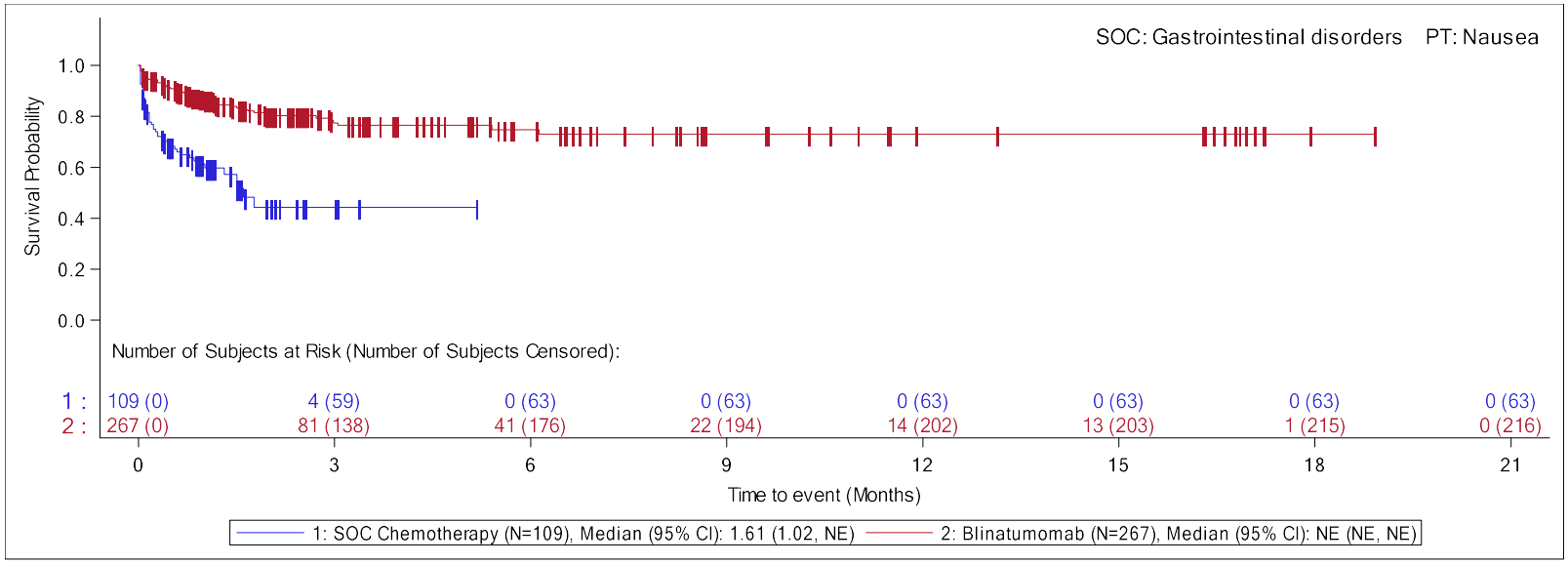
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
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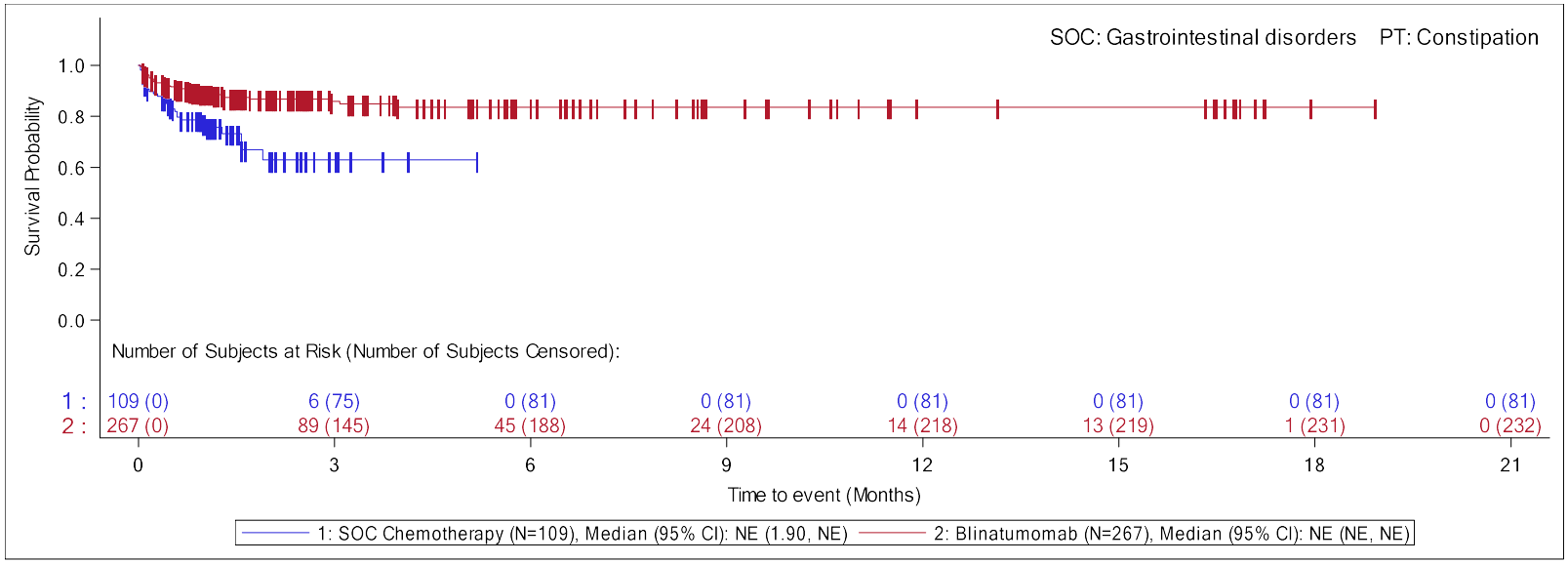
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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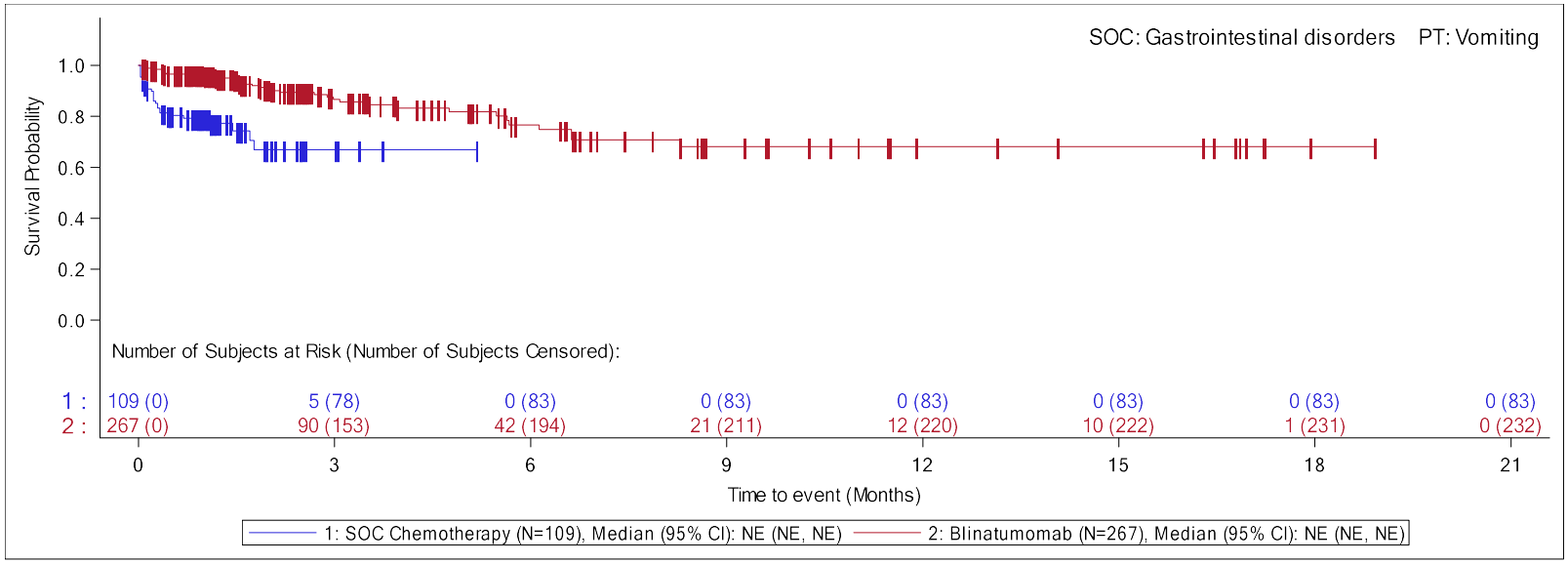
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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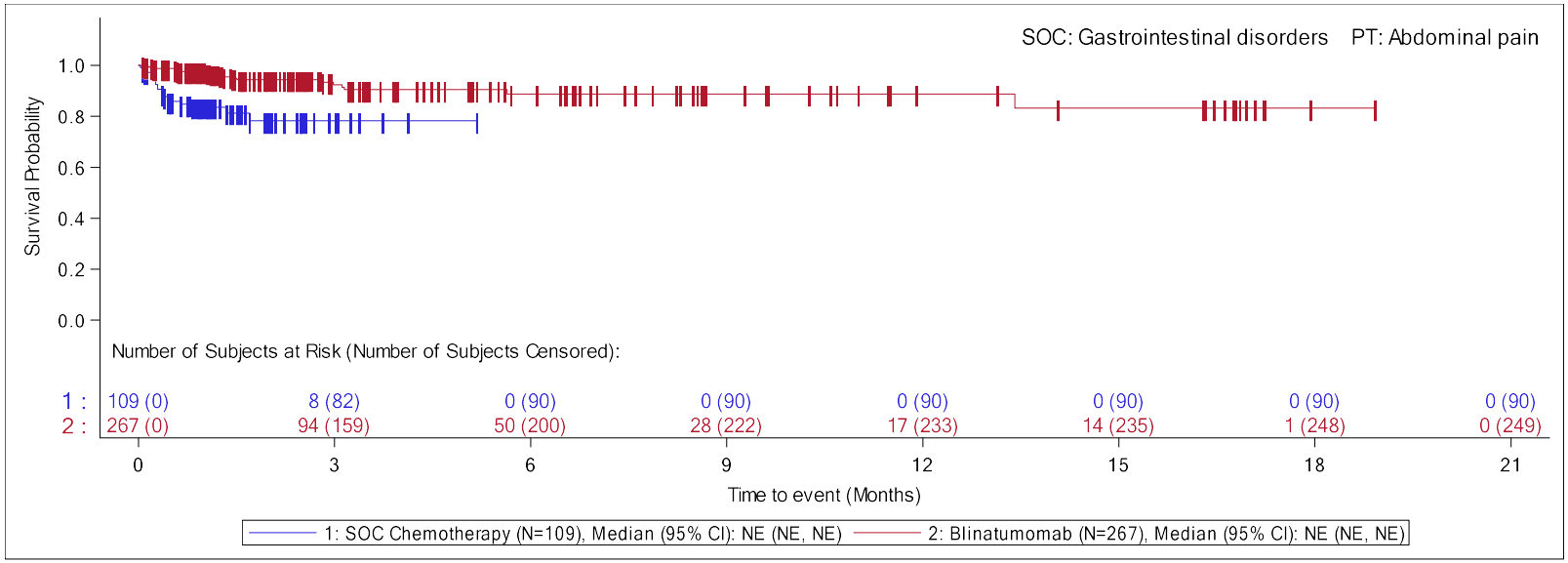
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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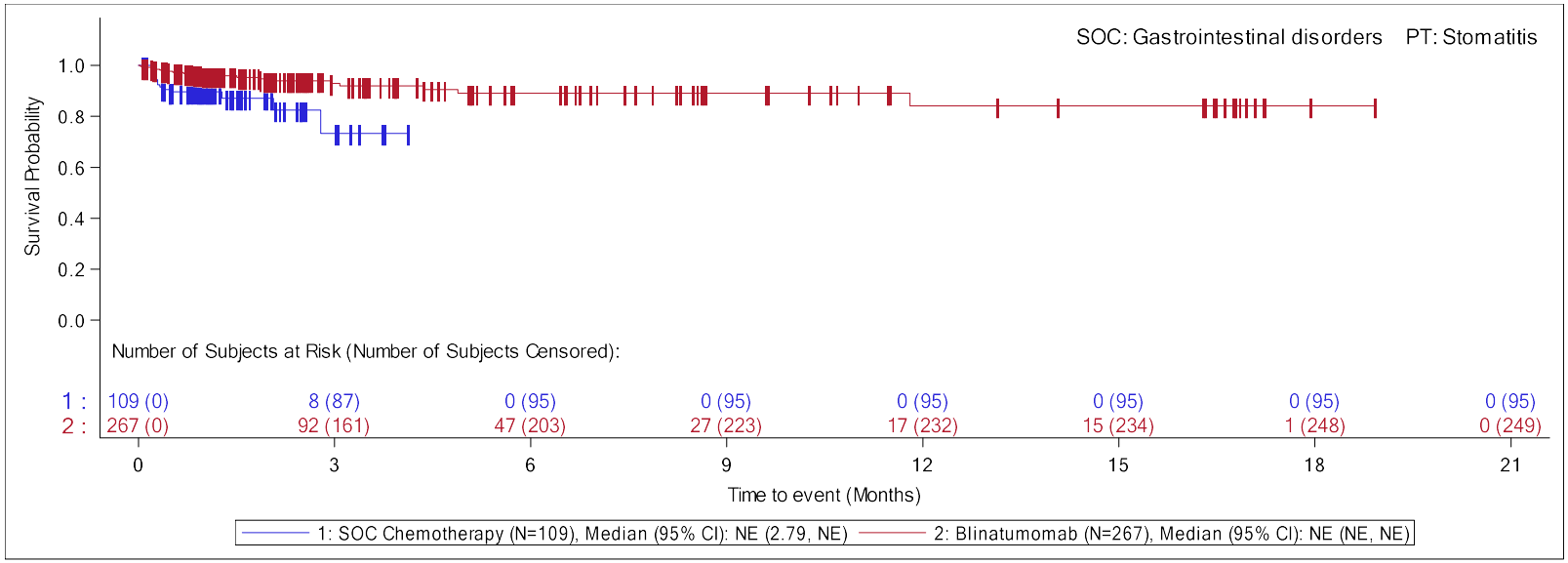
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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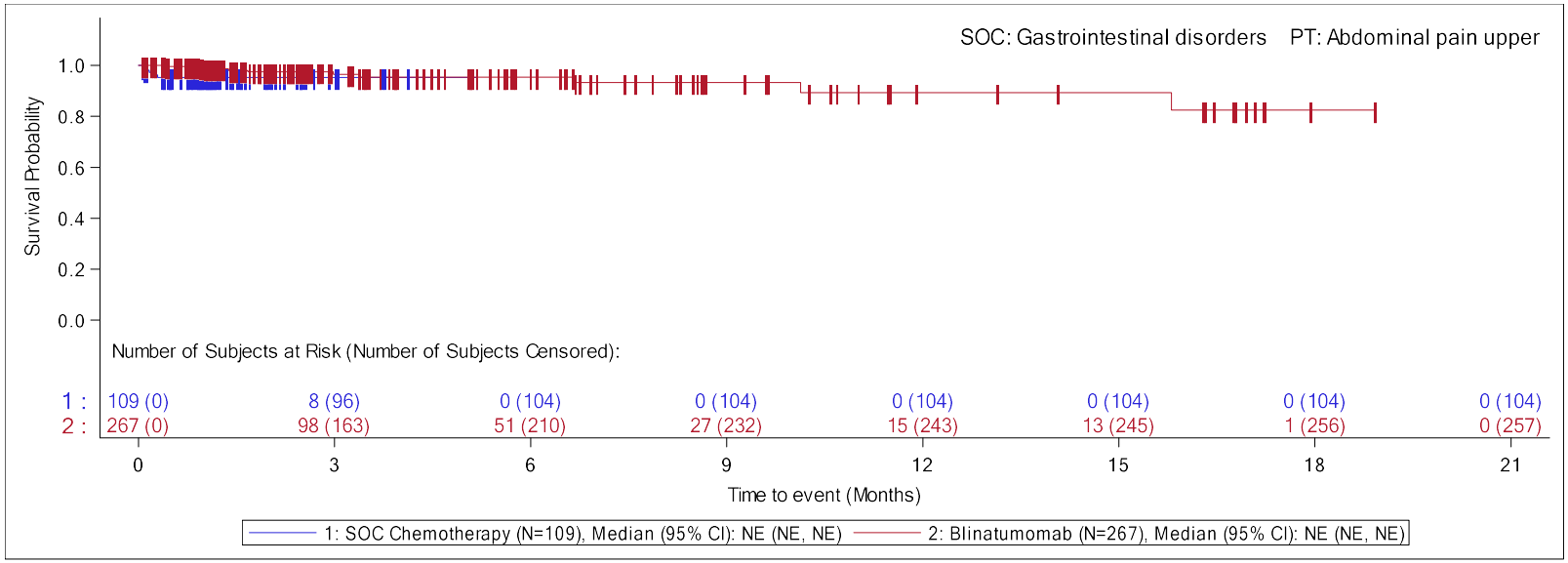
Output: f14-06-001-012-km-teae-soc-pt-saf.rtf (Date Generated: 23OCT25 00:30) Source Data: adam_fa.adsl, outtab.t_aette_socpref

Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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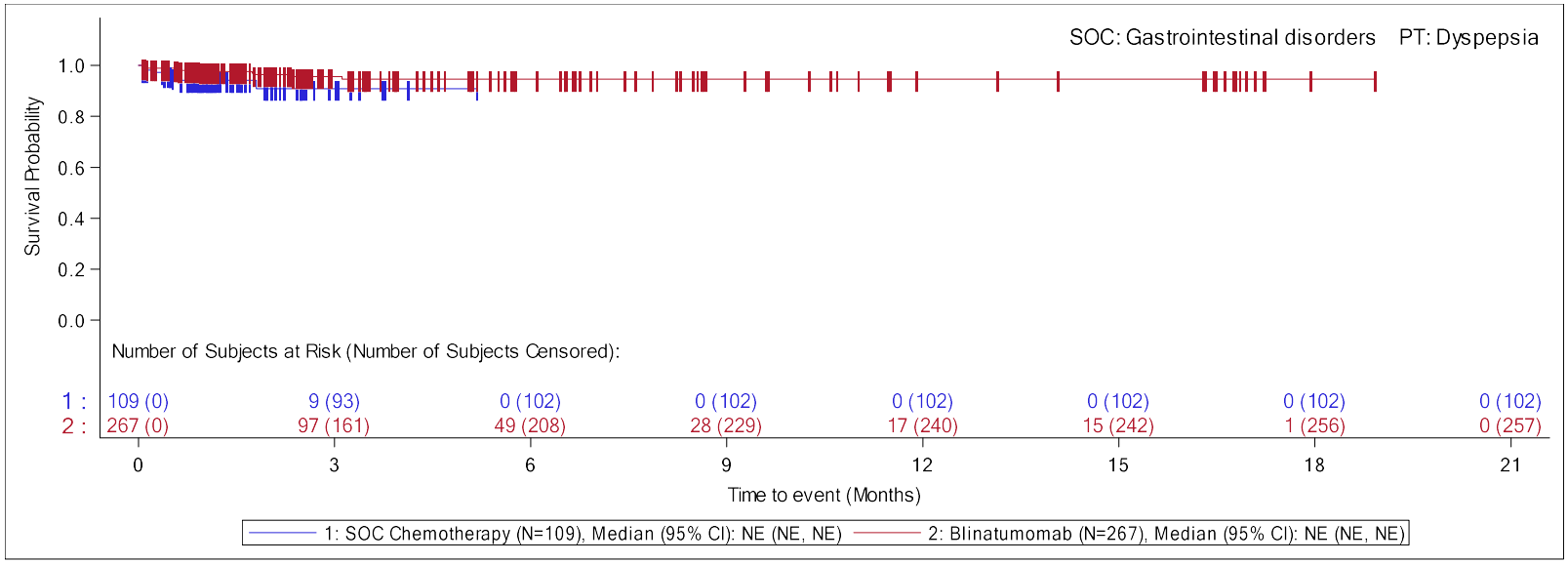
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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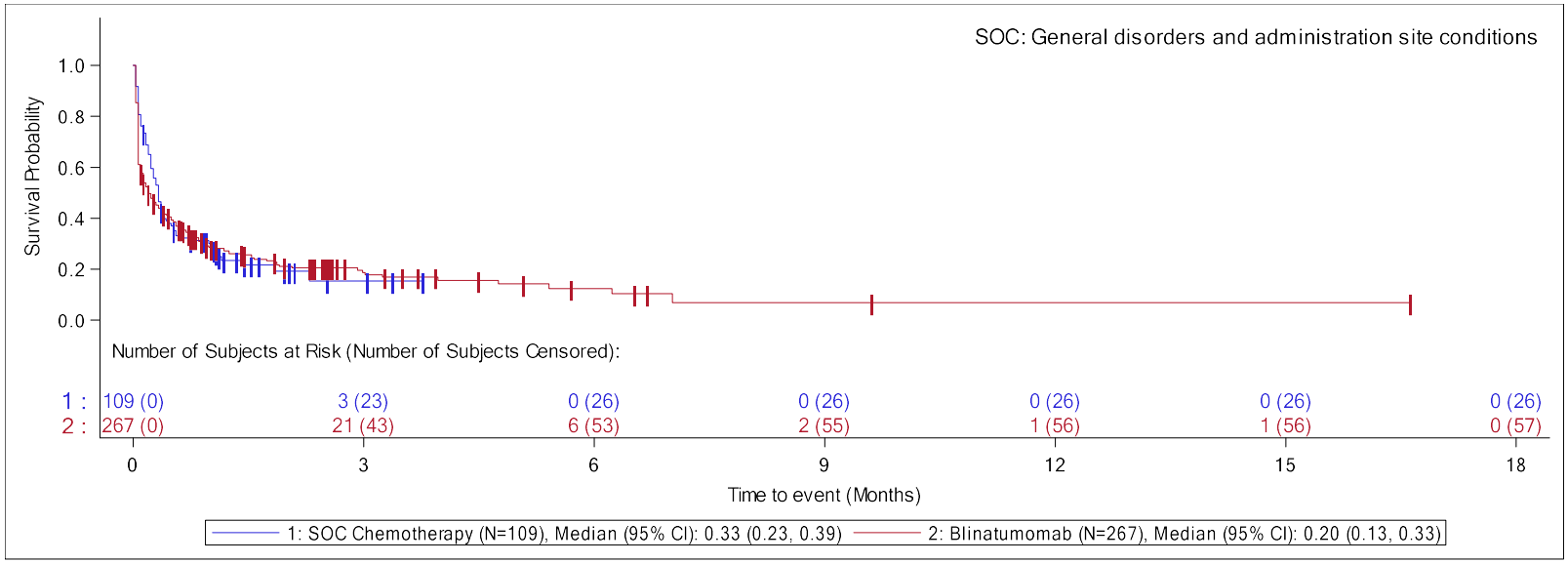
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)

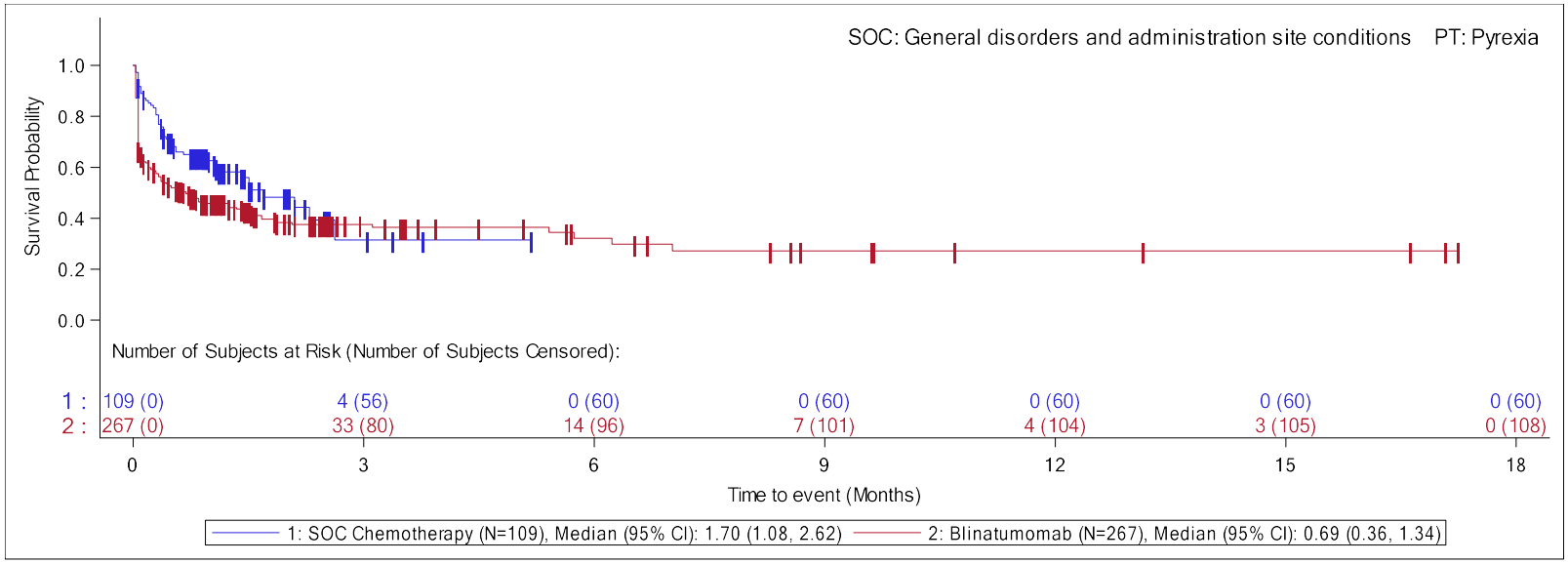

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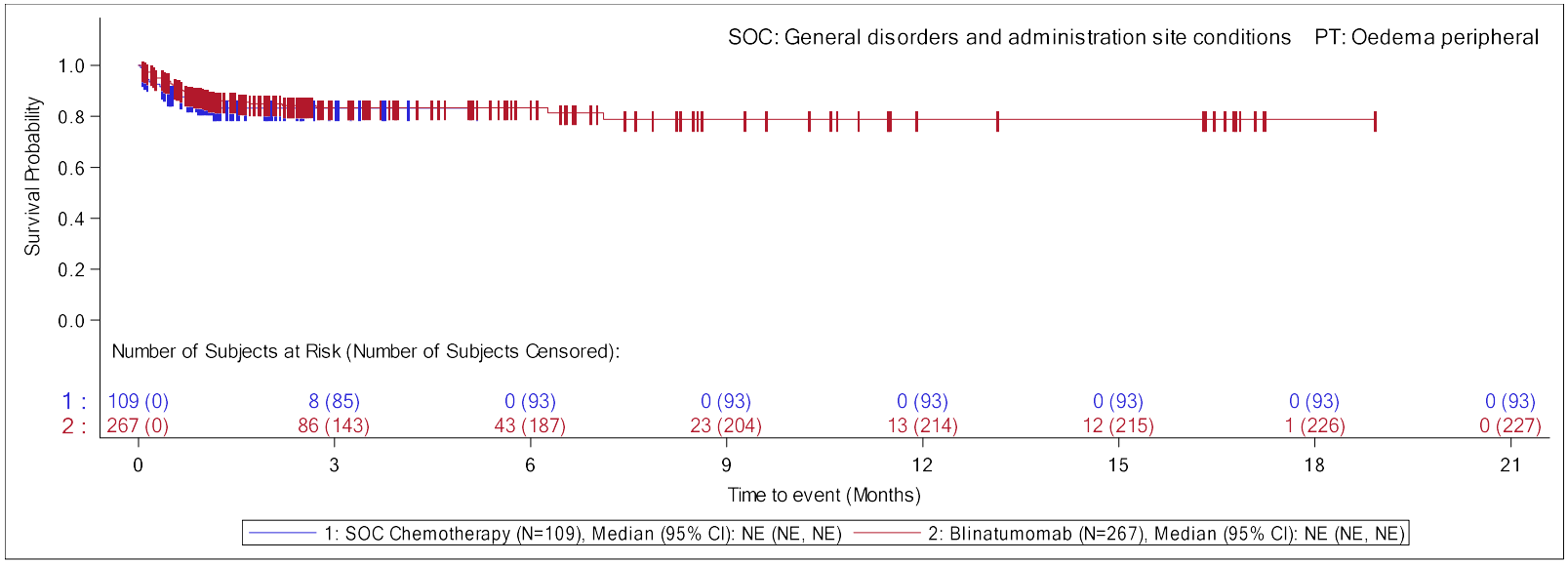
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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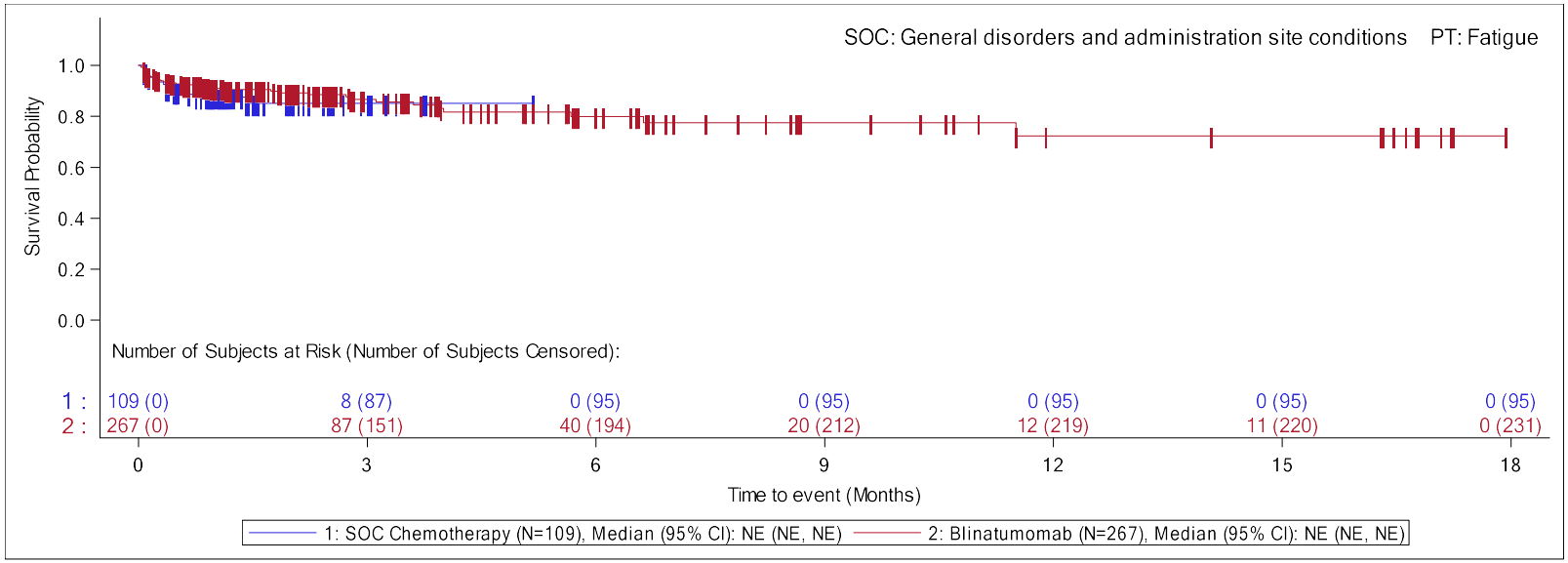

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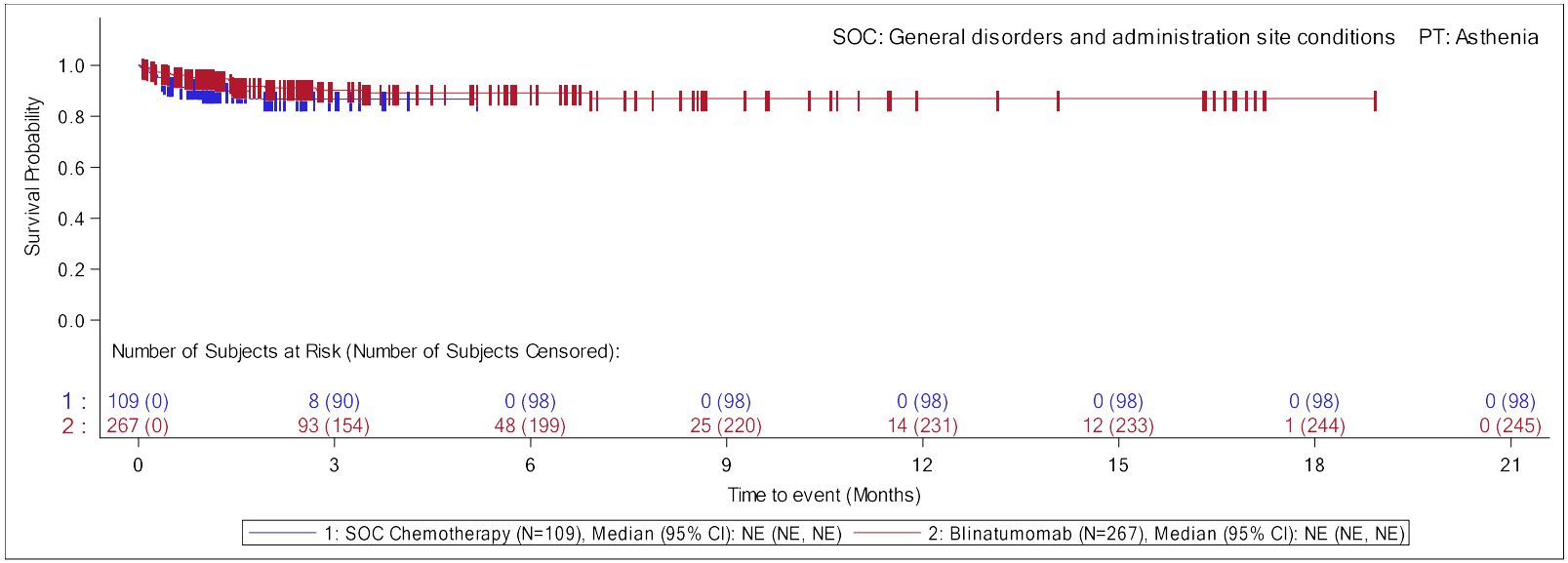

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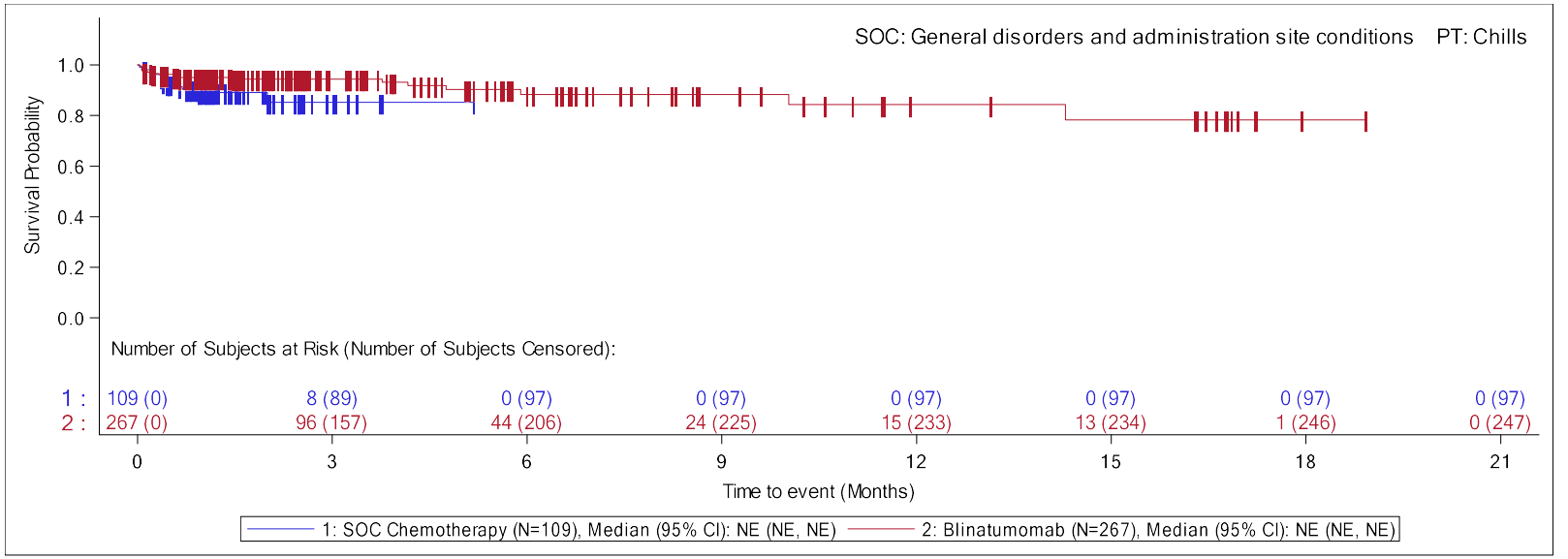

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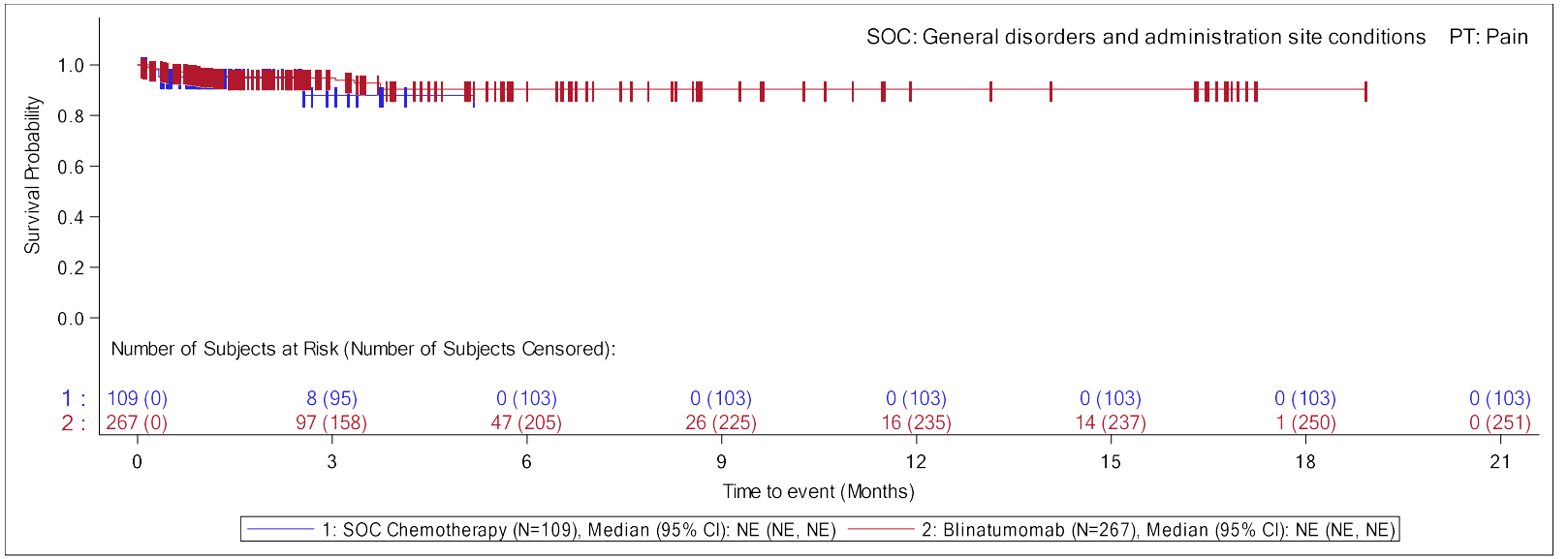

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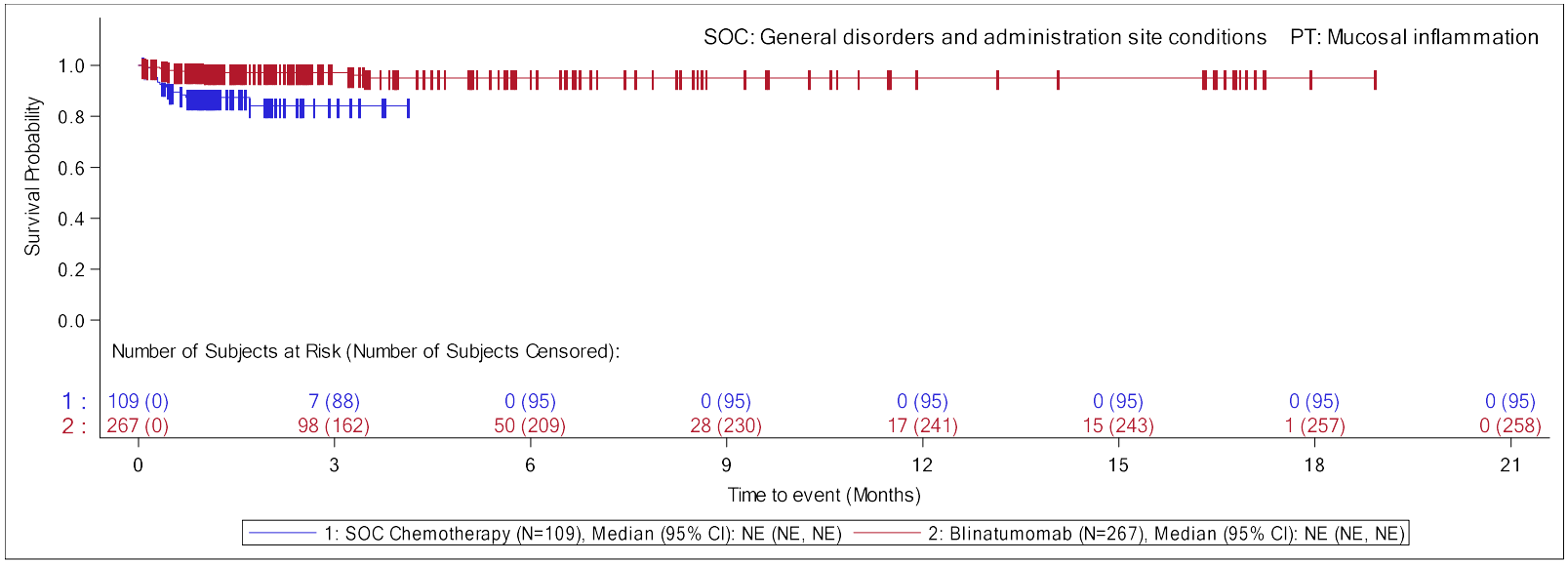

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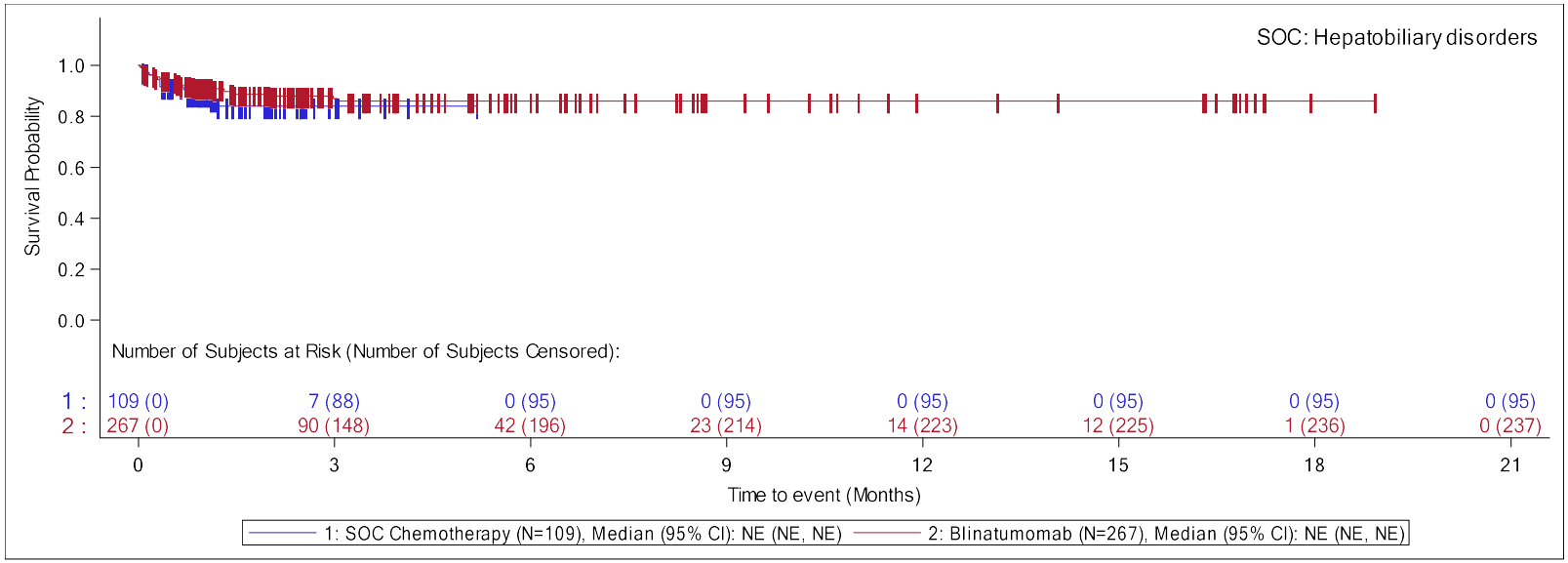

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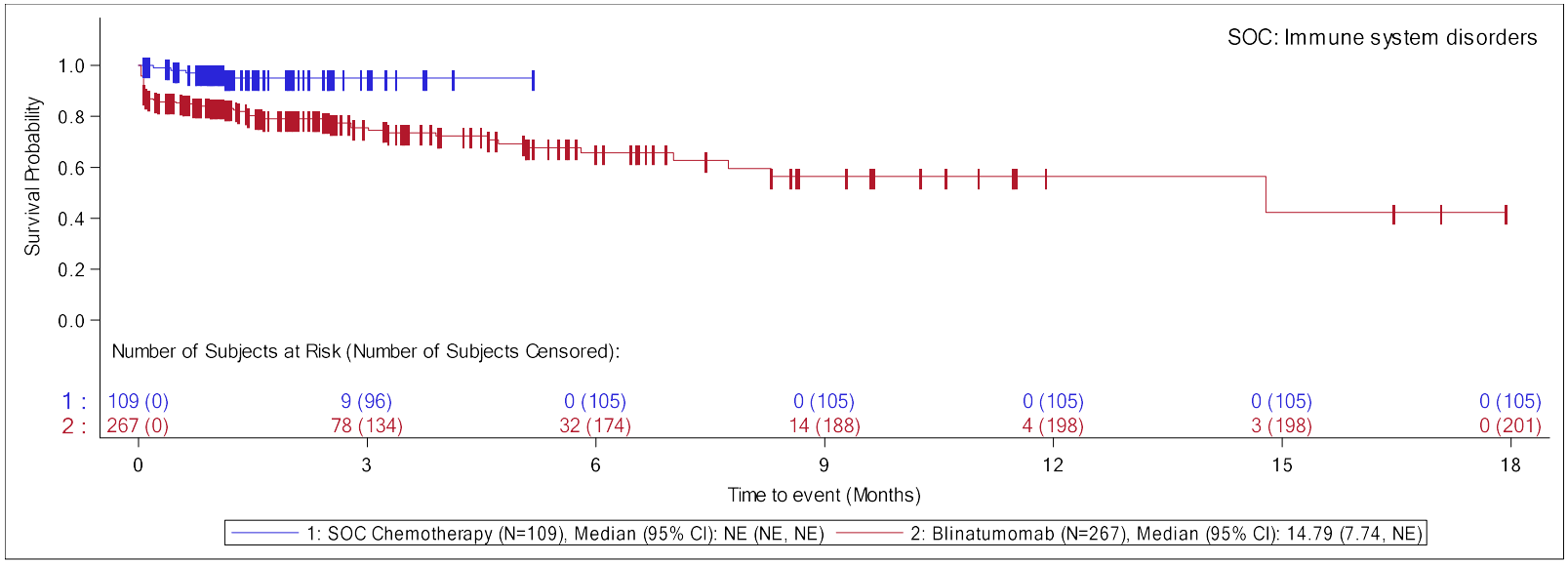

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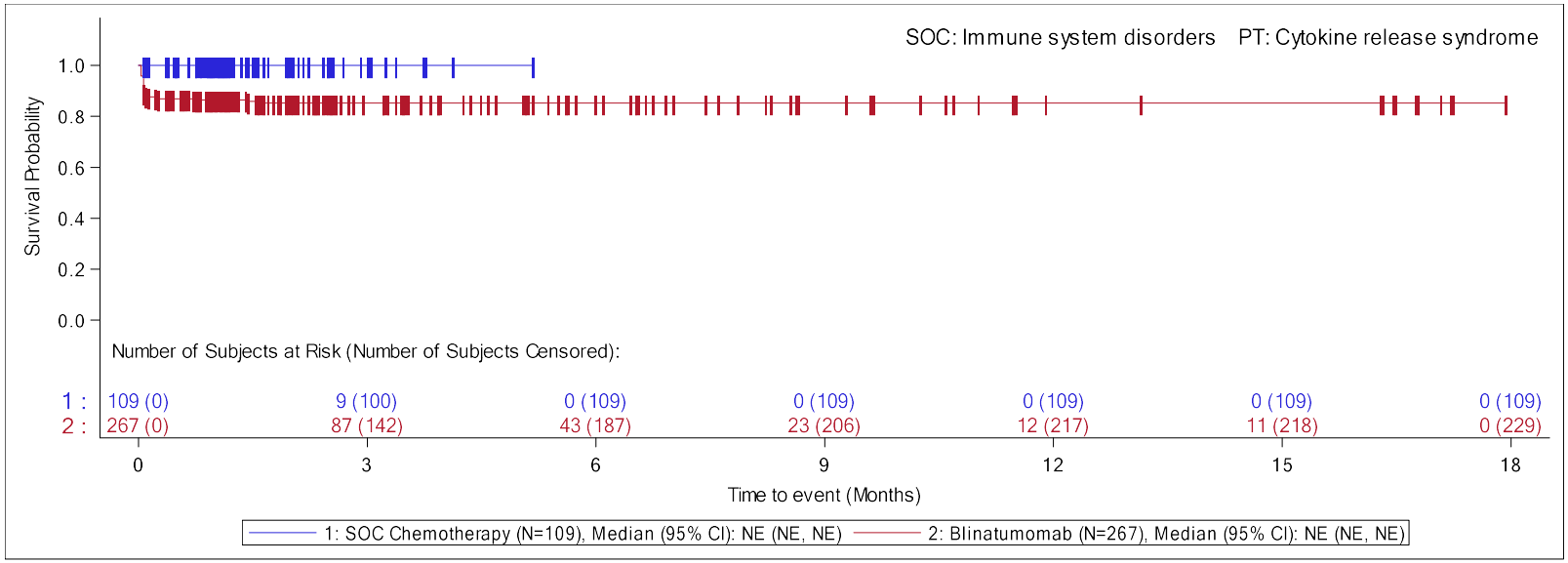

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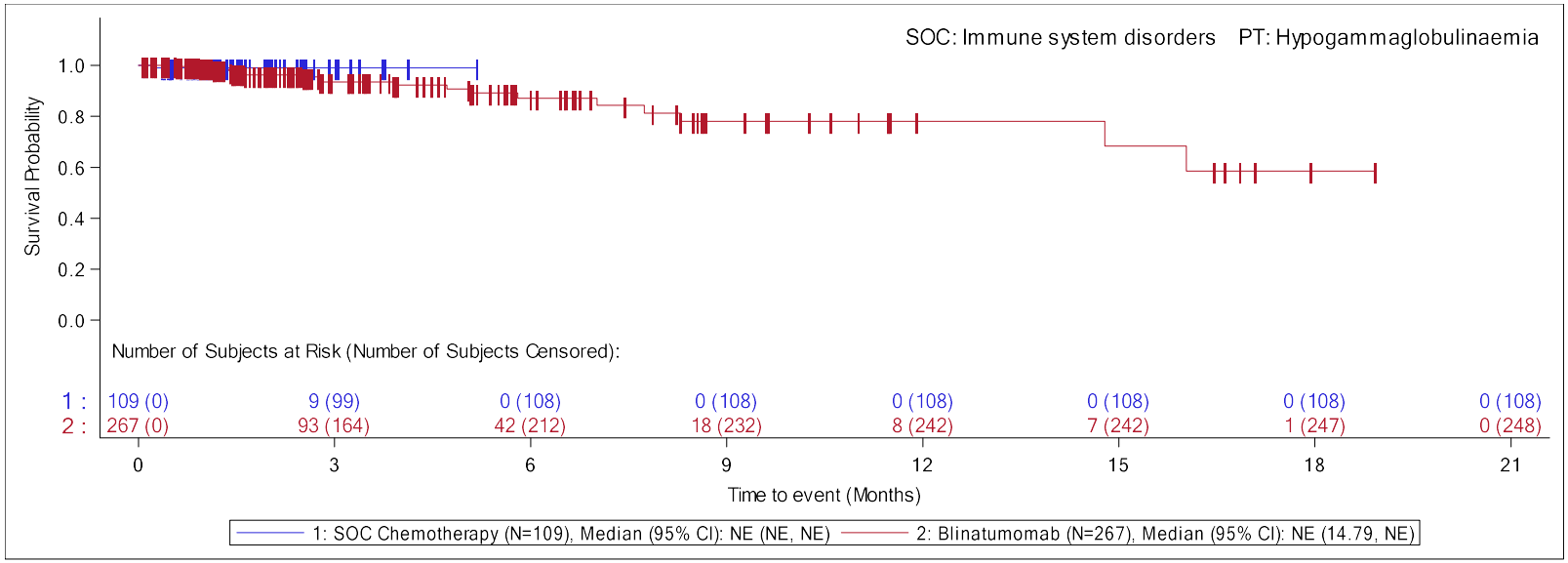

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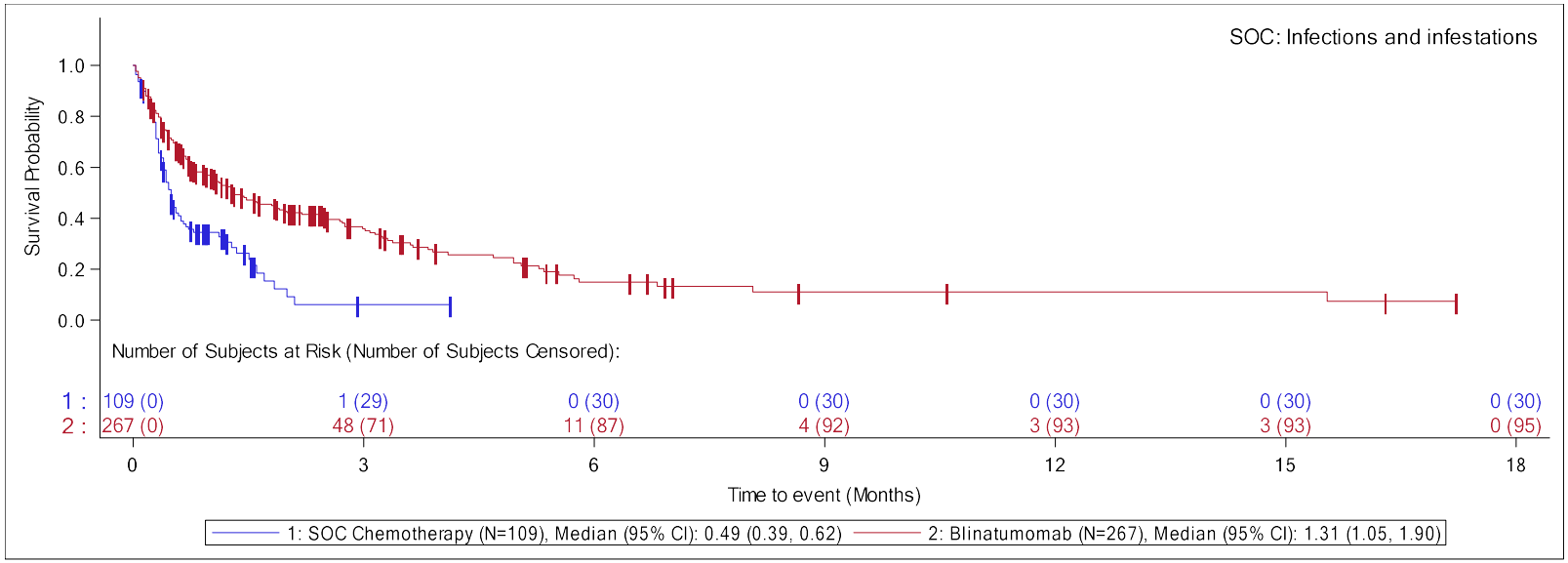

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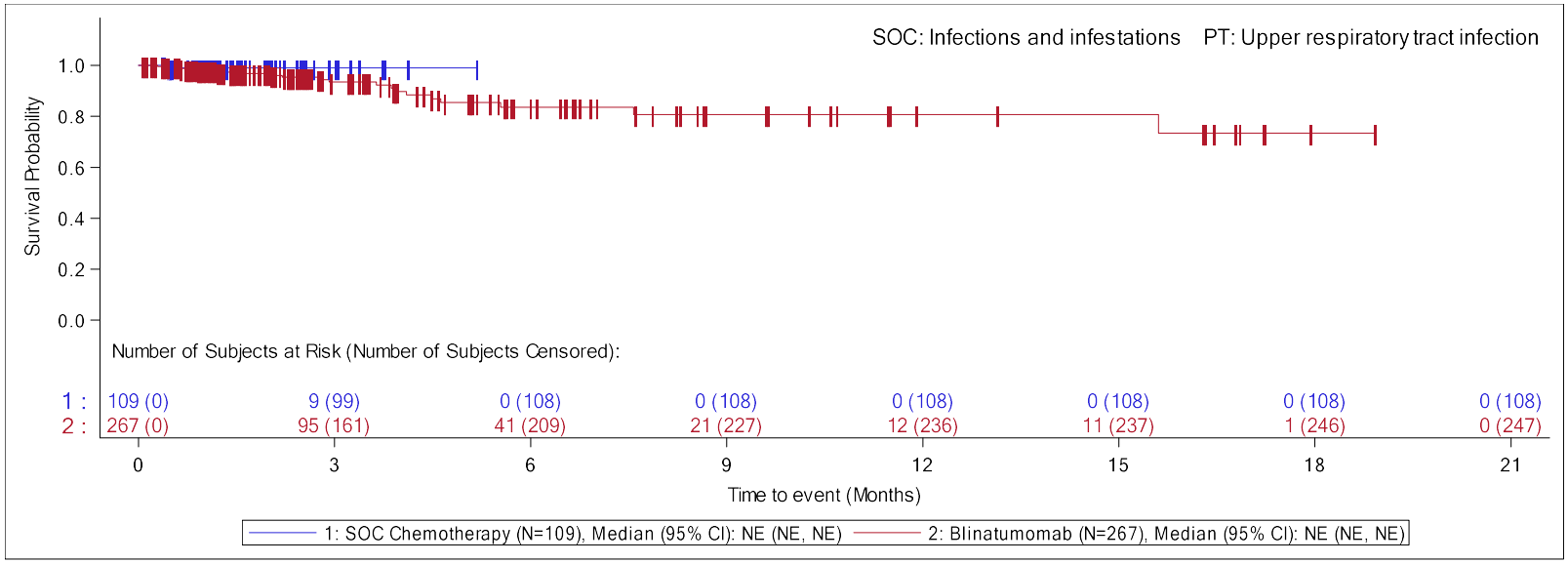

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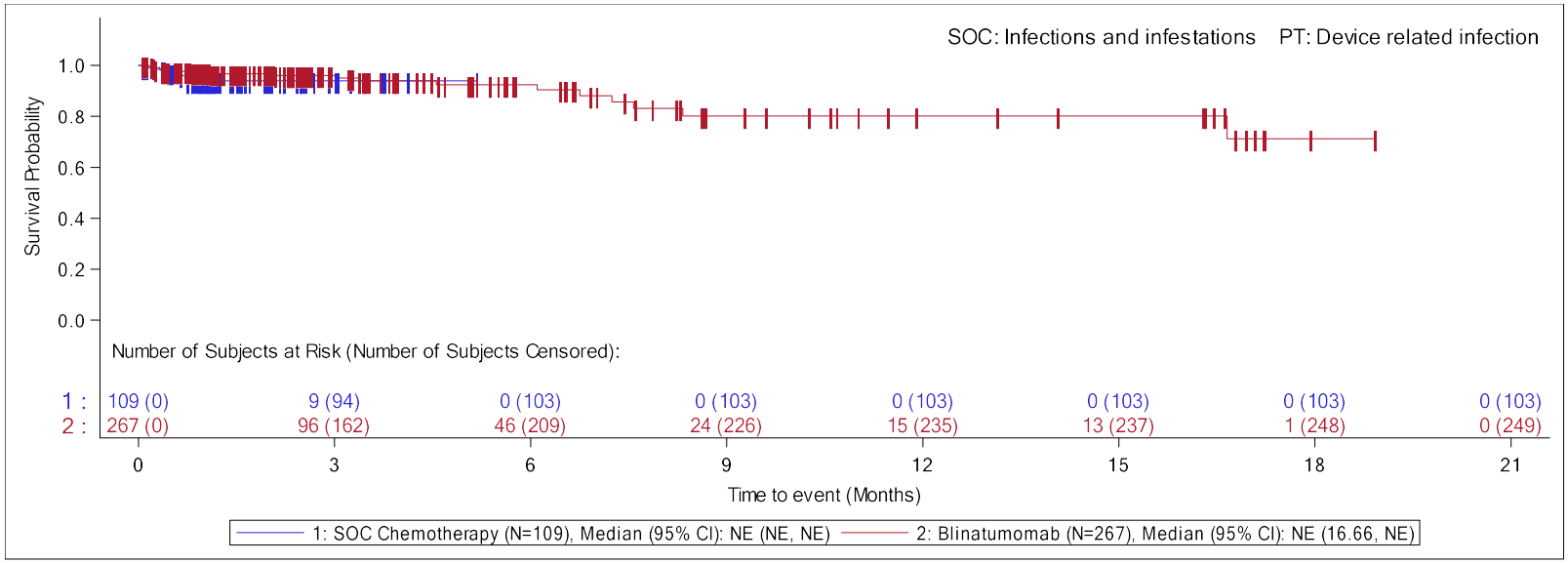

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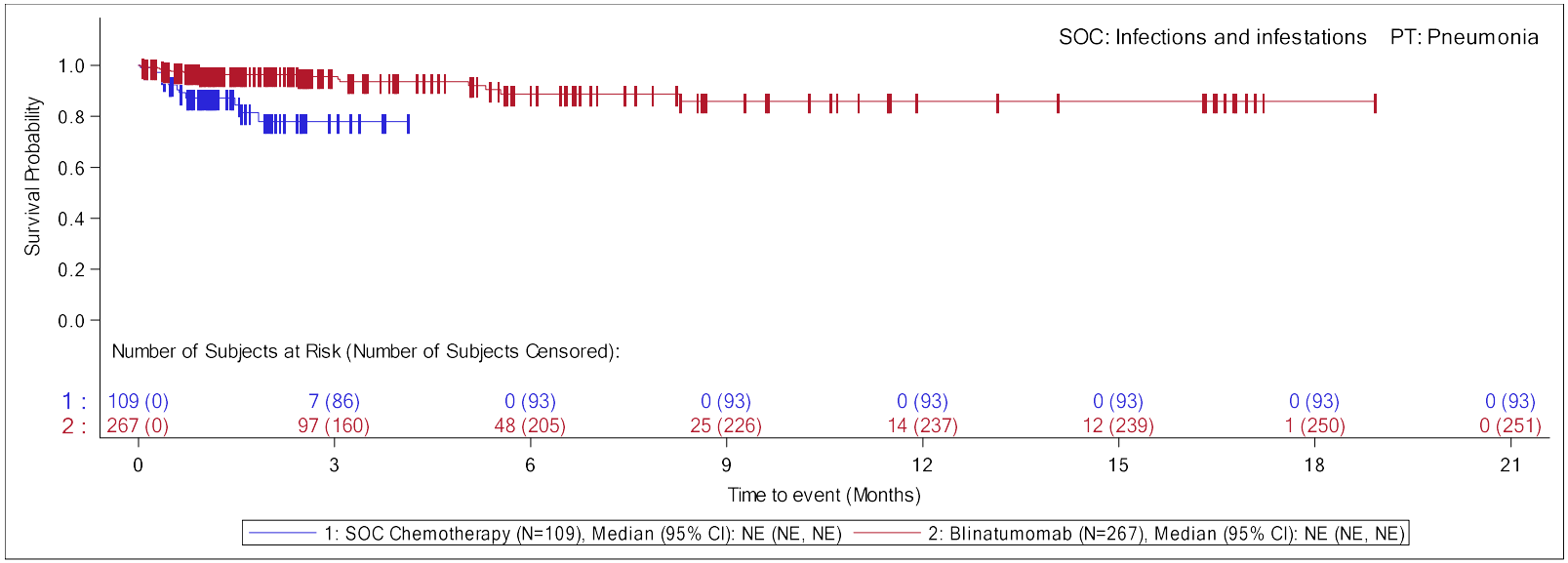

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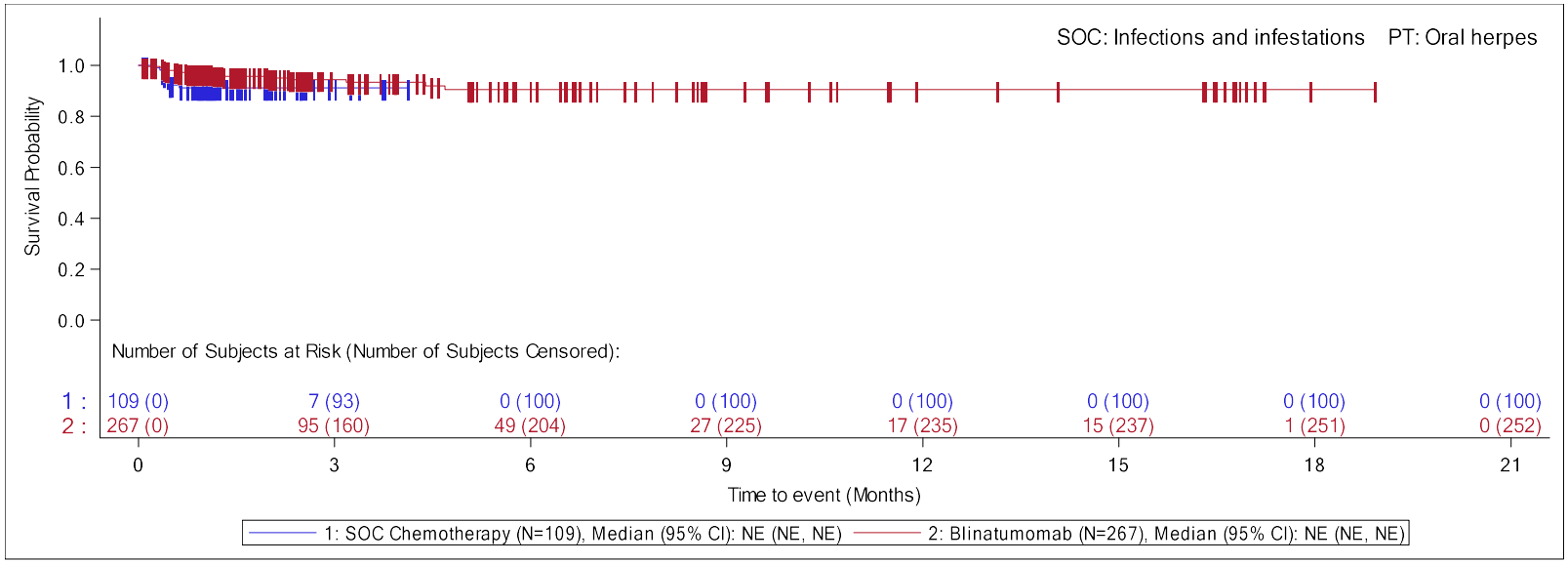

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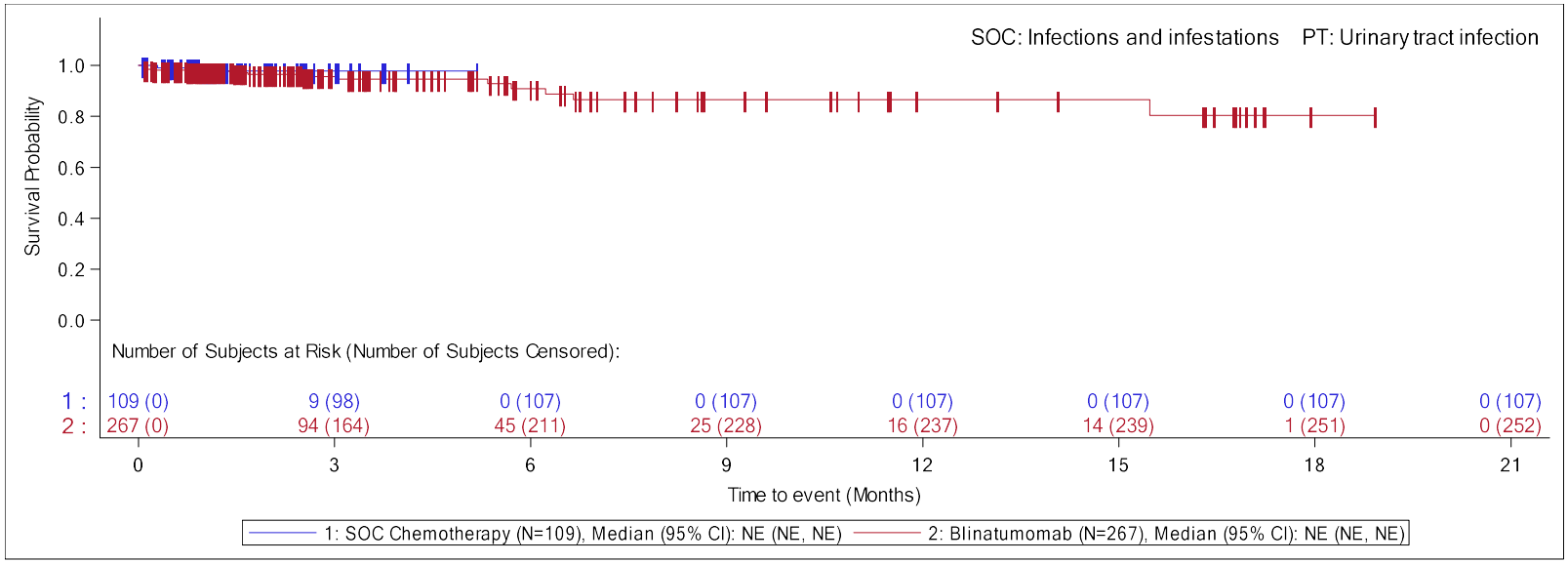

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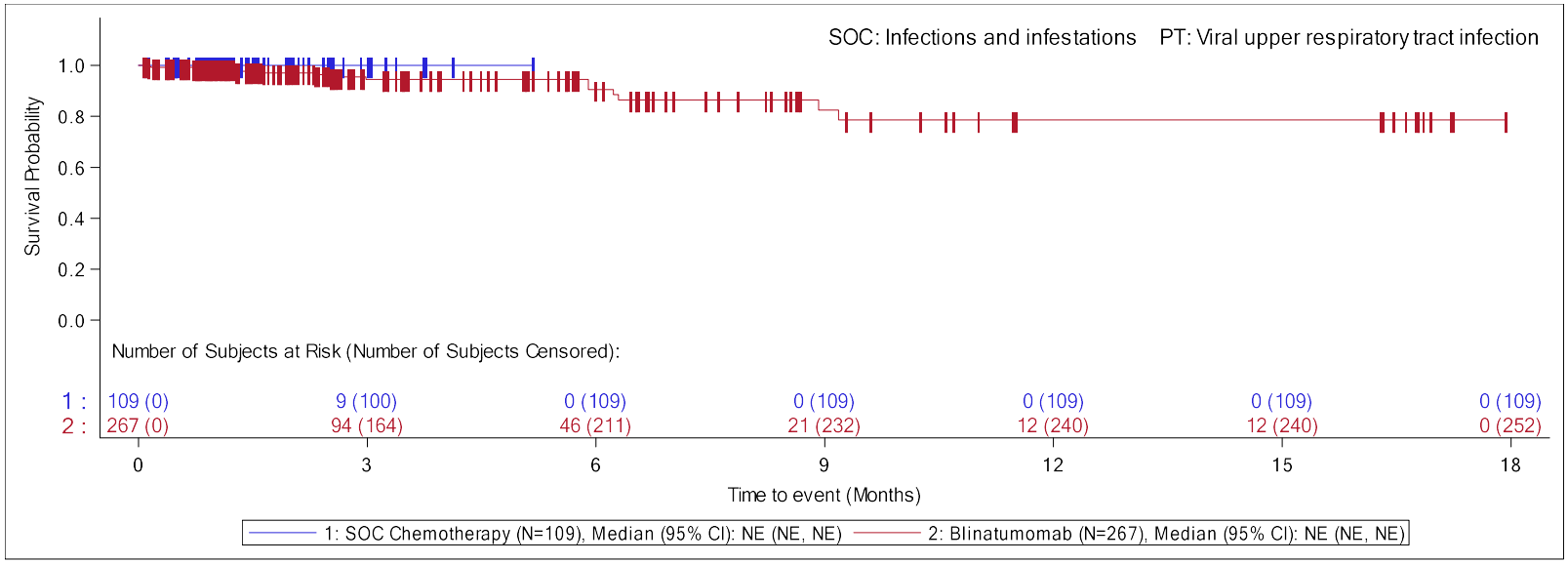

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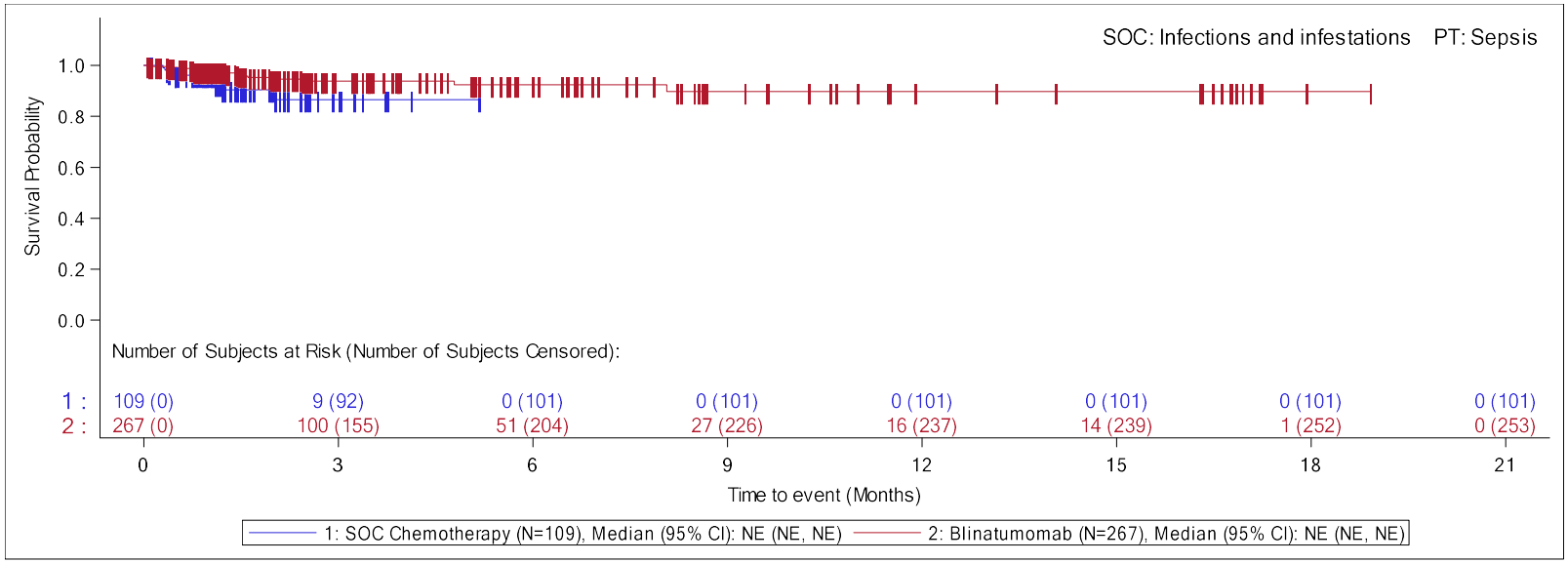

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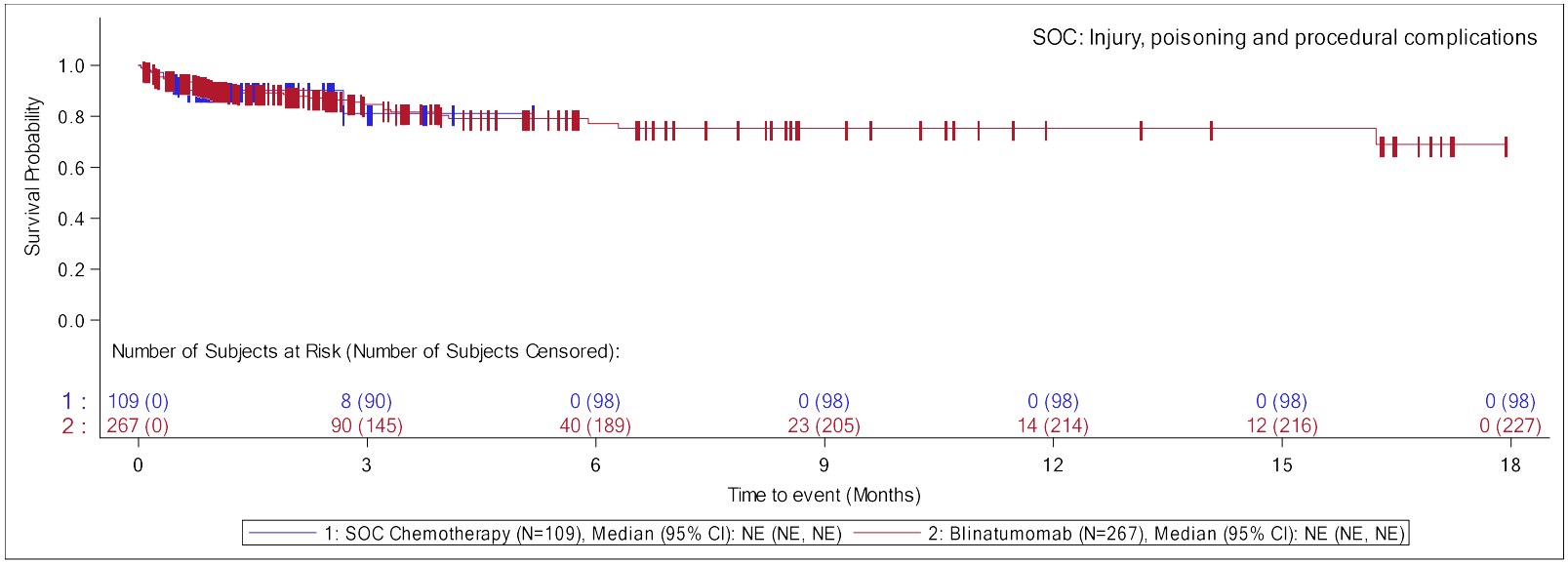

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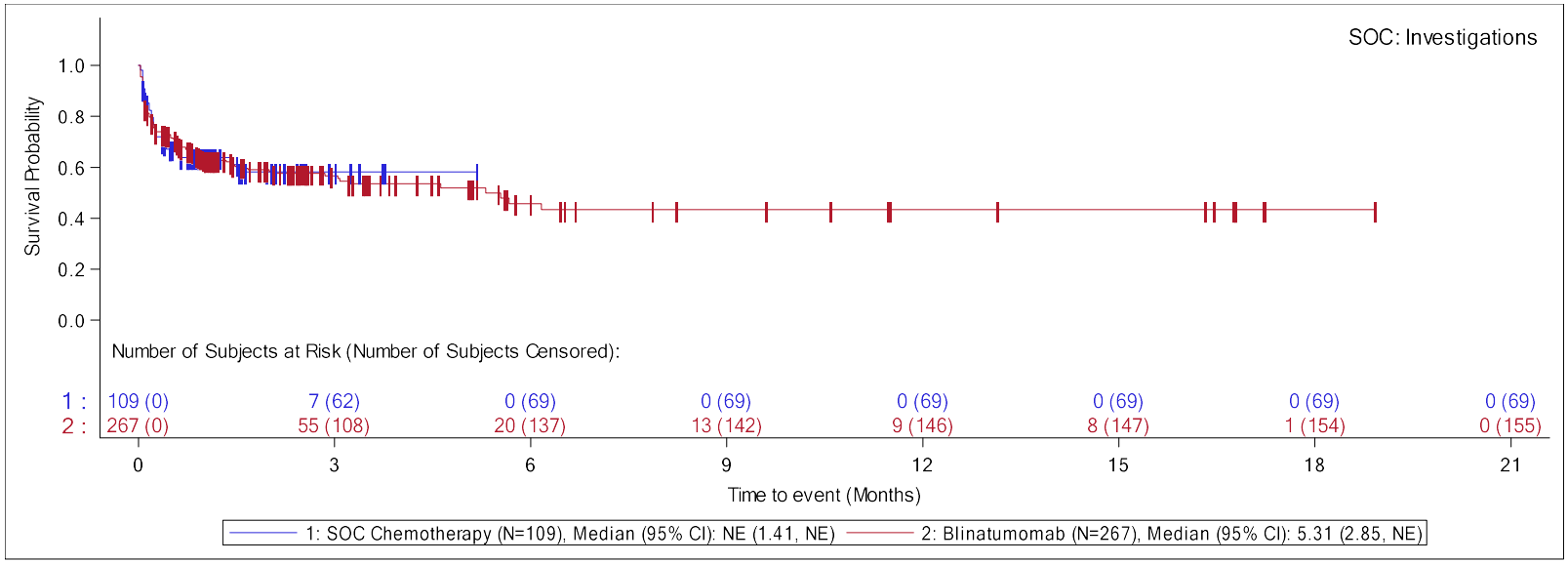

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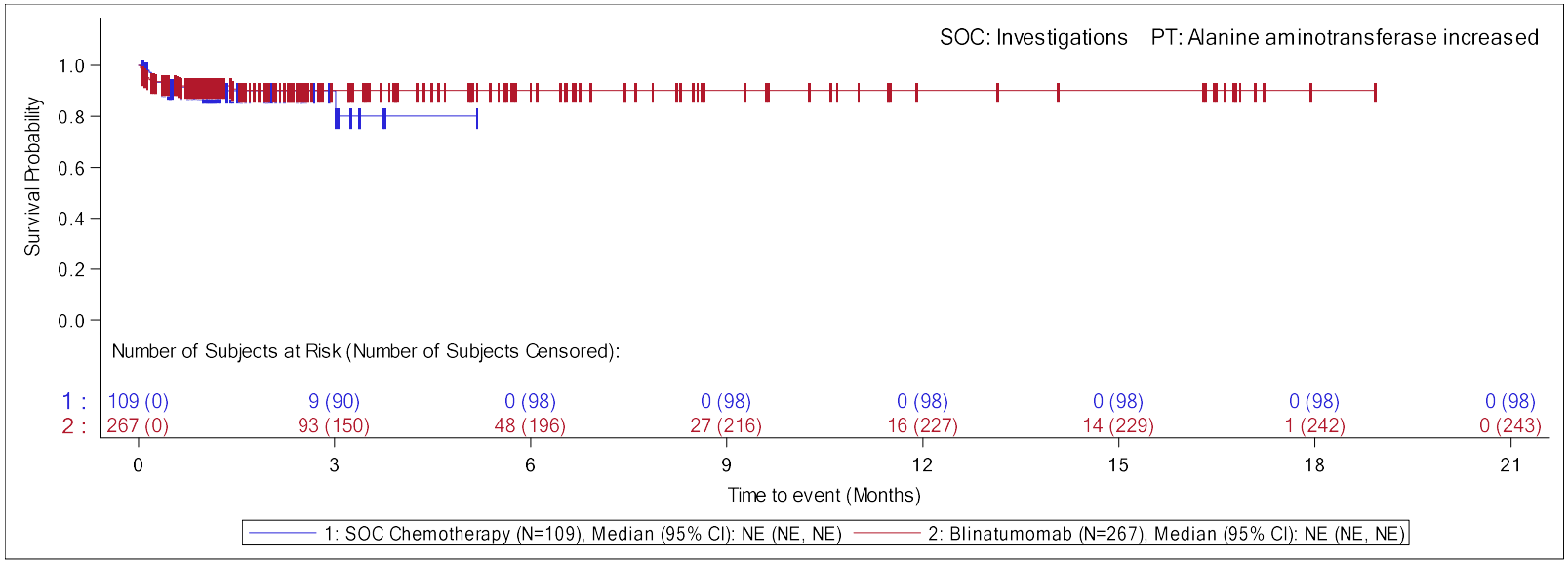

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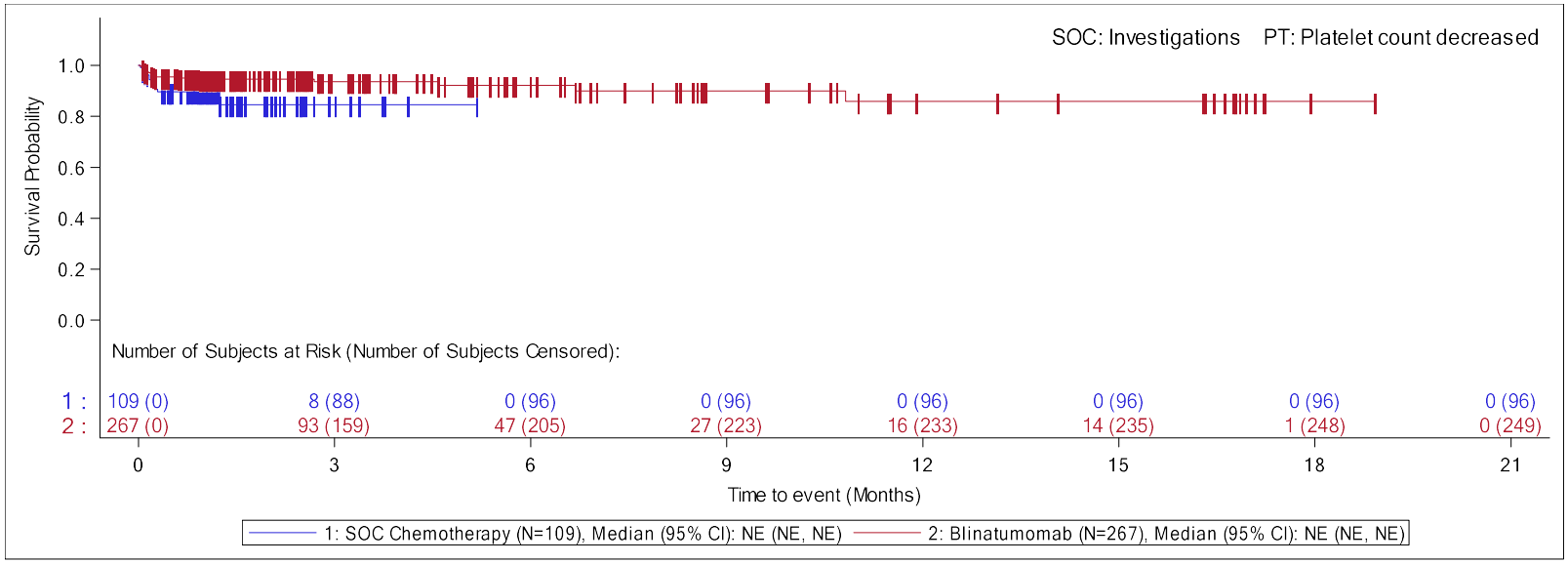

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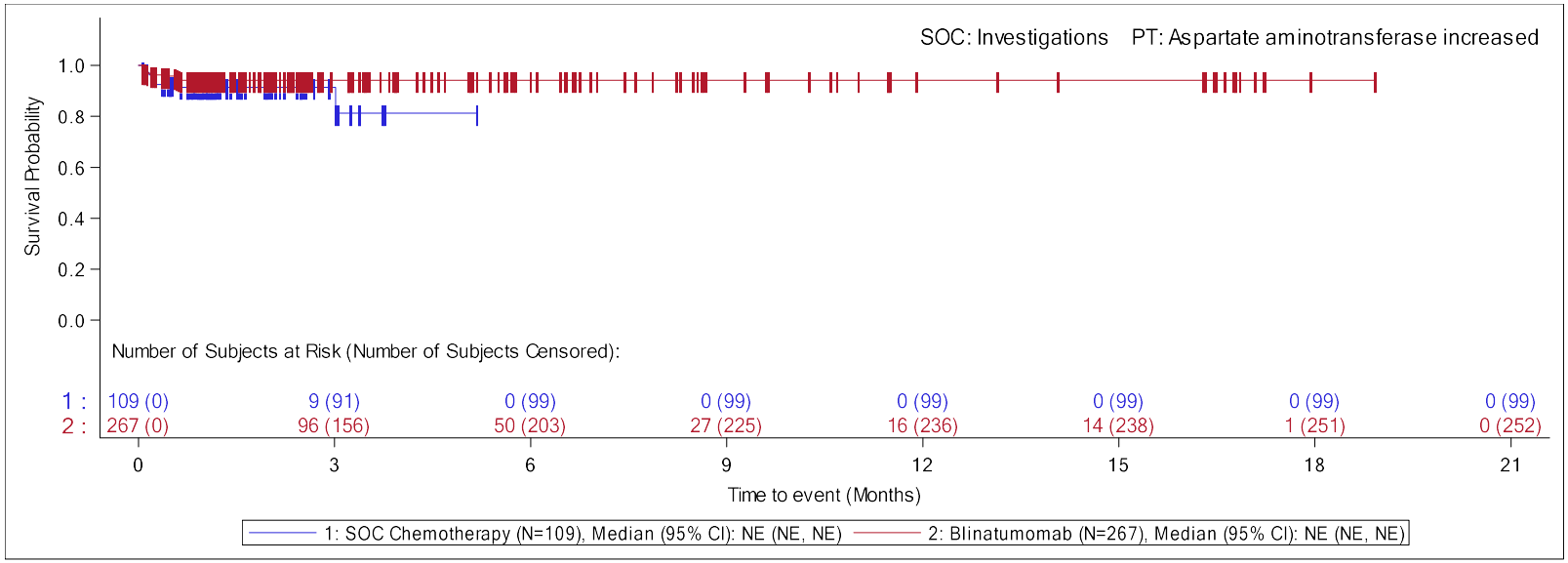

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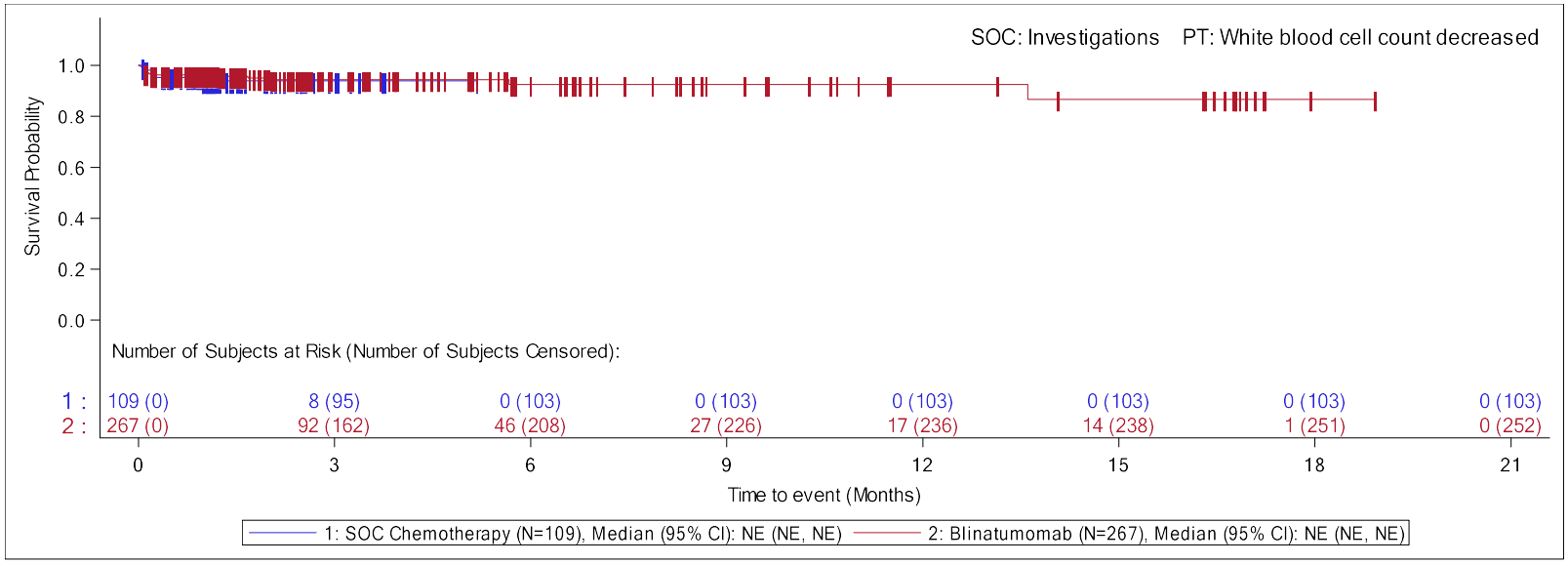

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Adverse events coded using MedDRA version 20.0.
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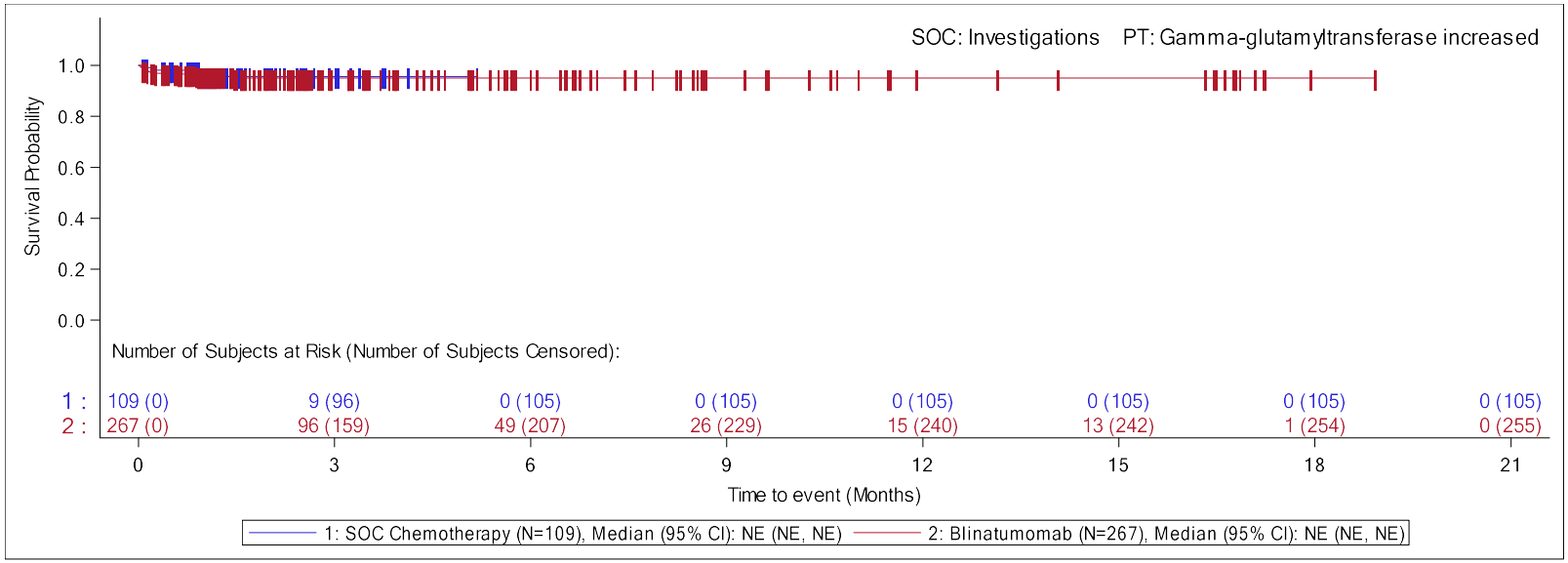
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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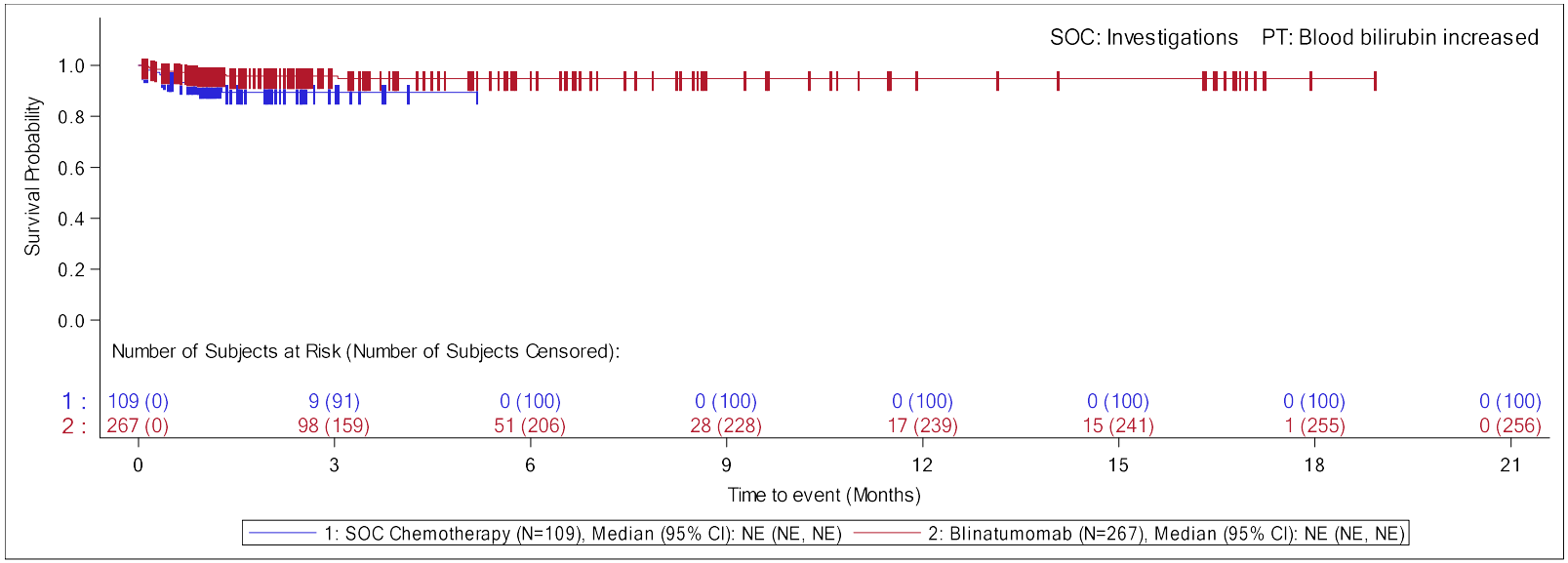

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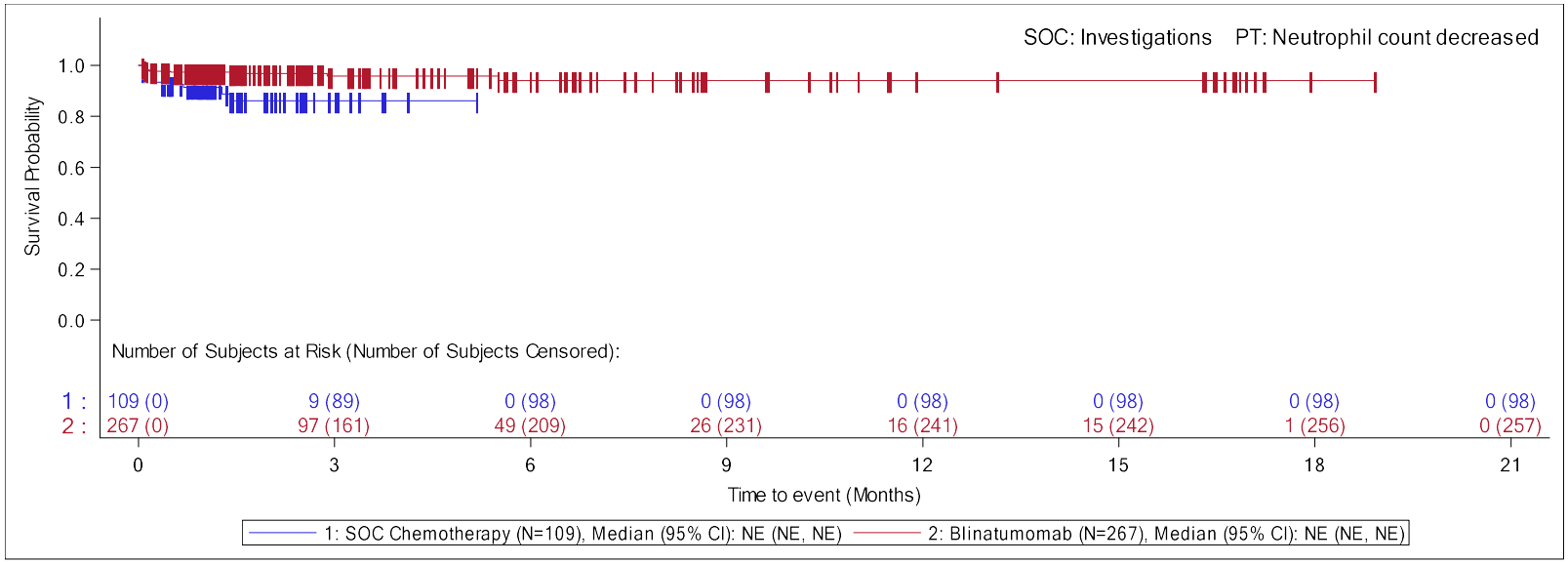

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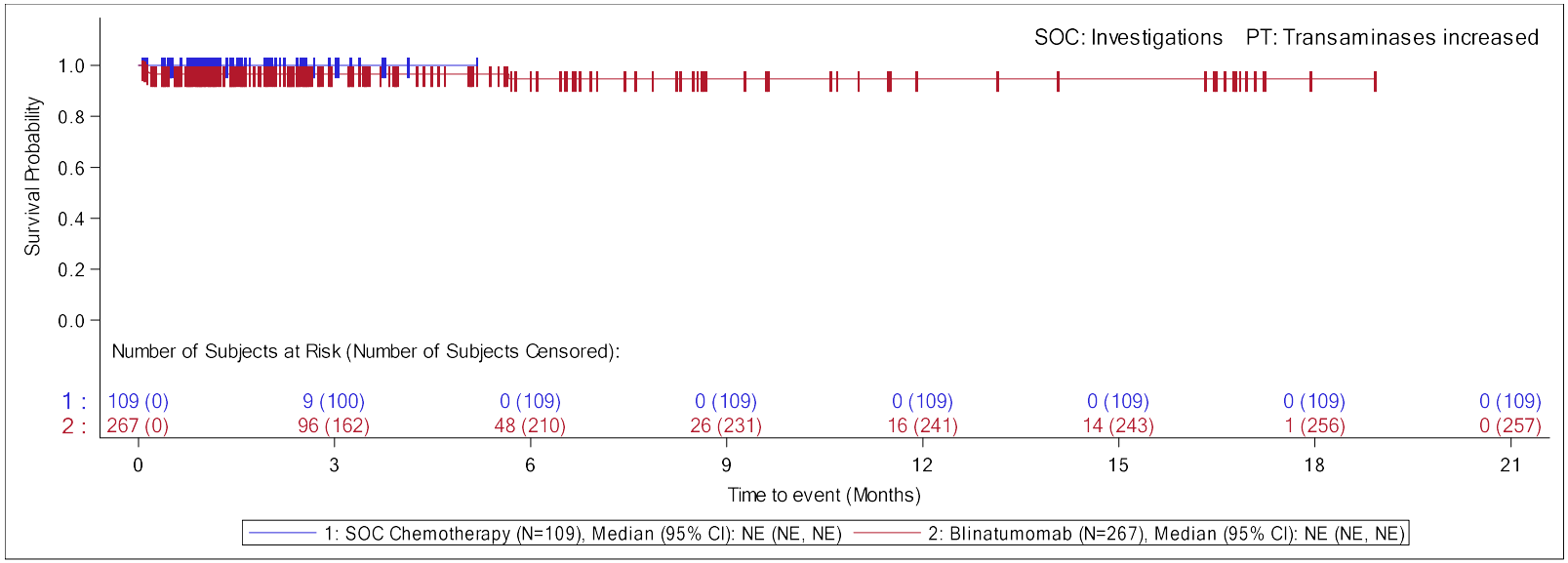

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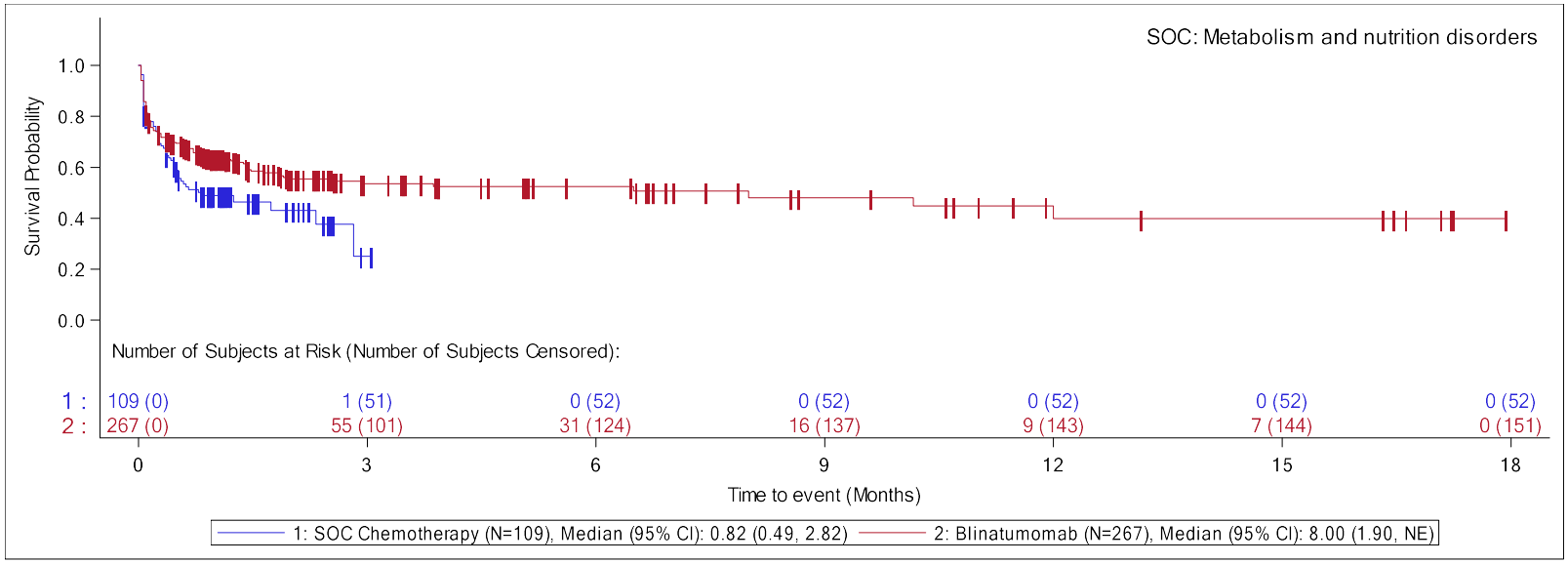

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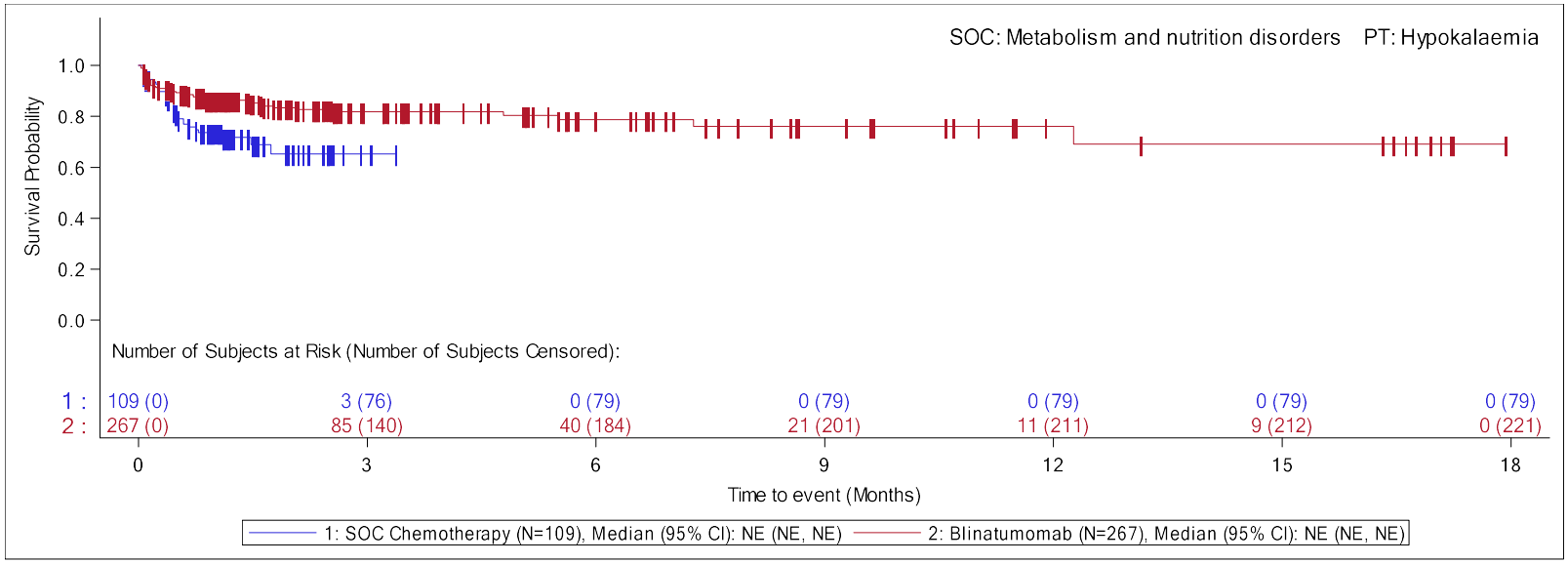

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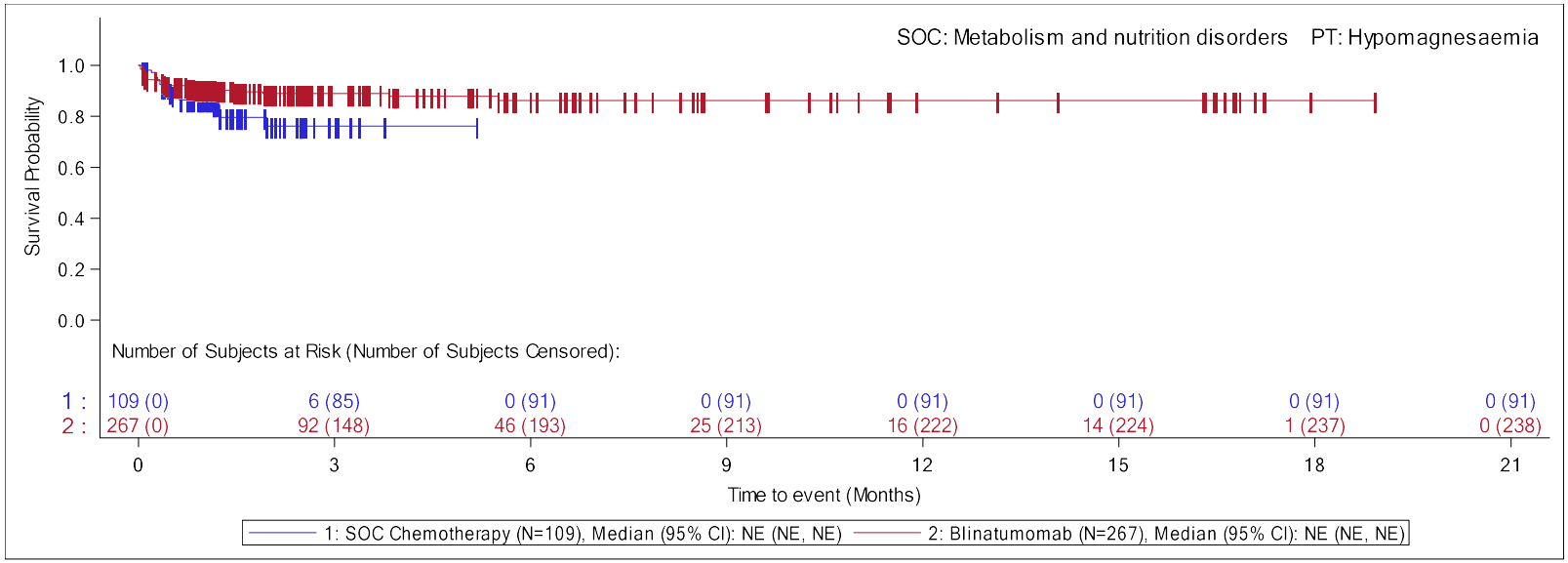

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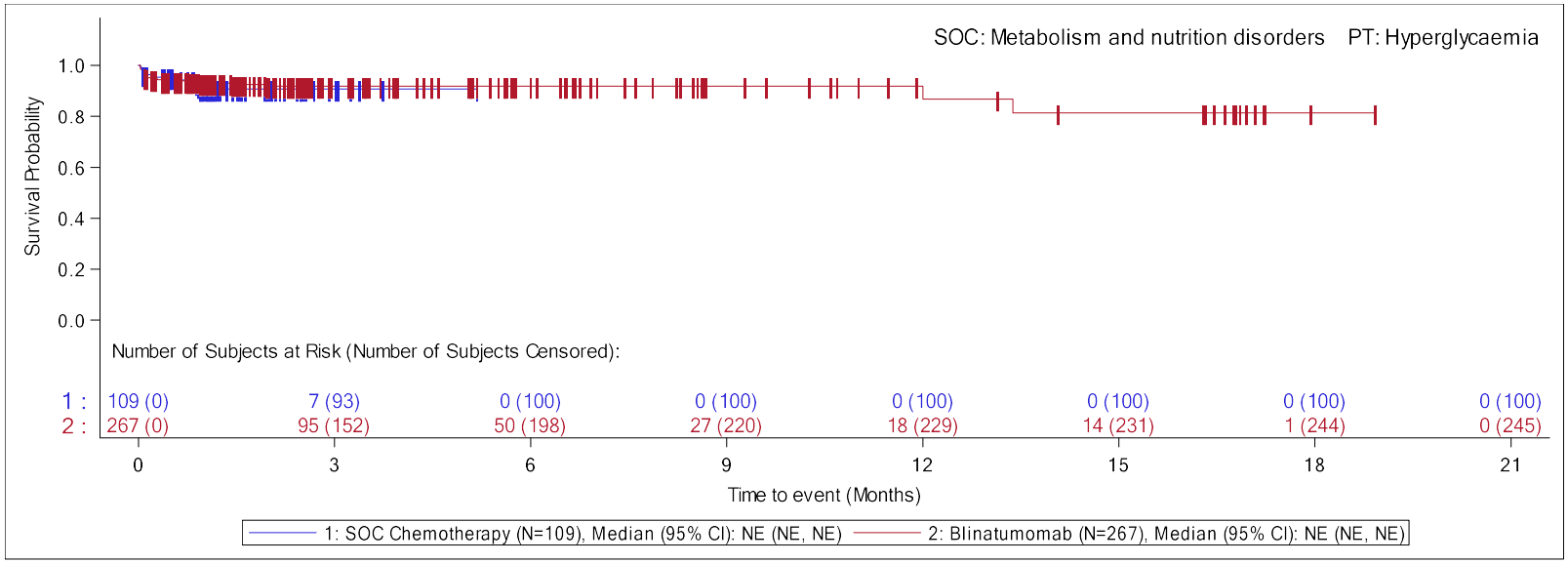

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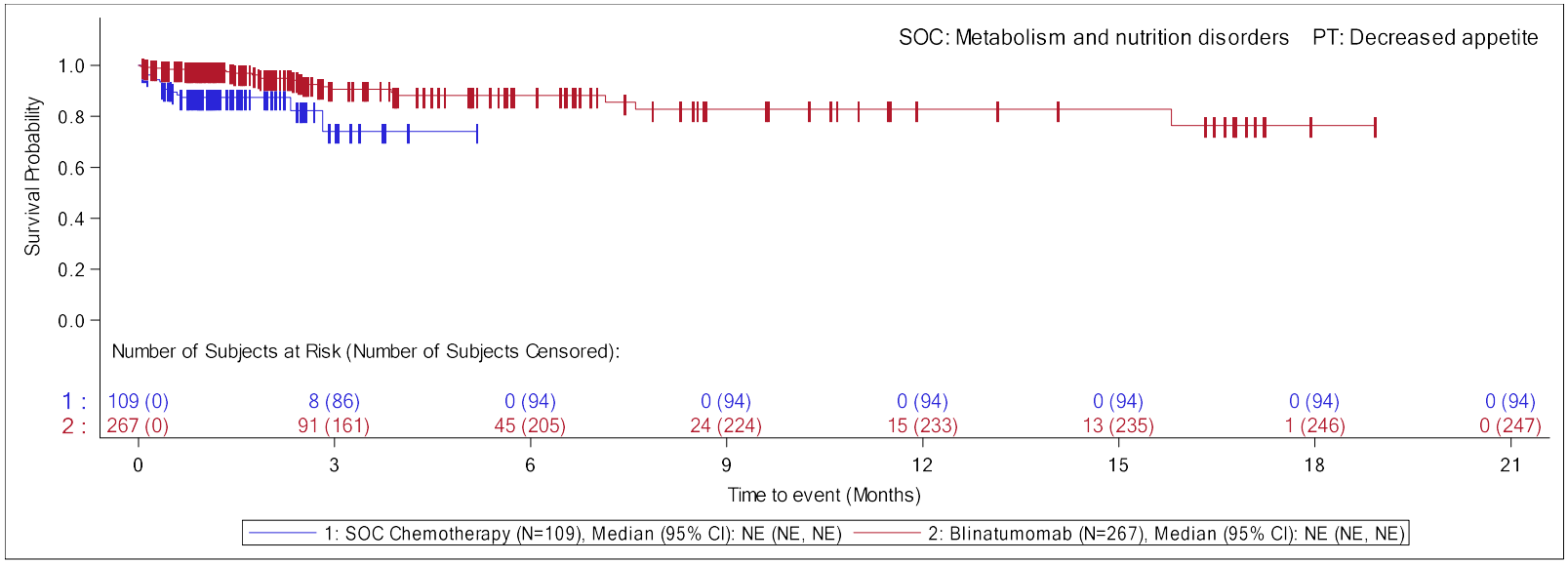

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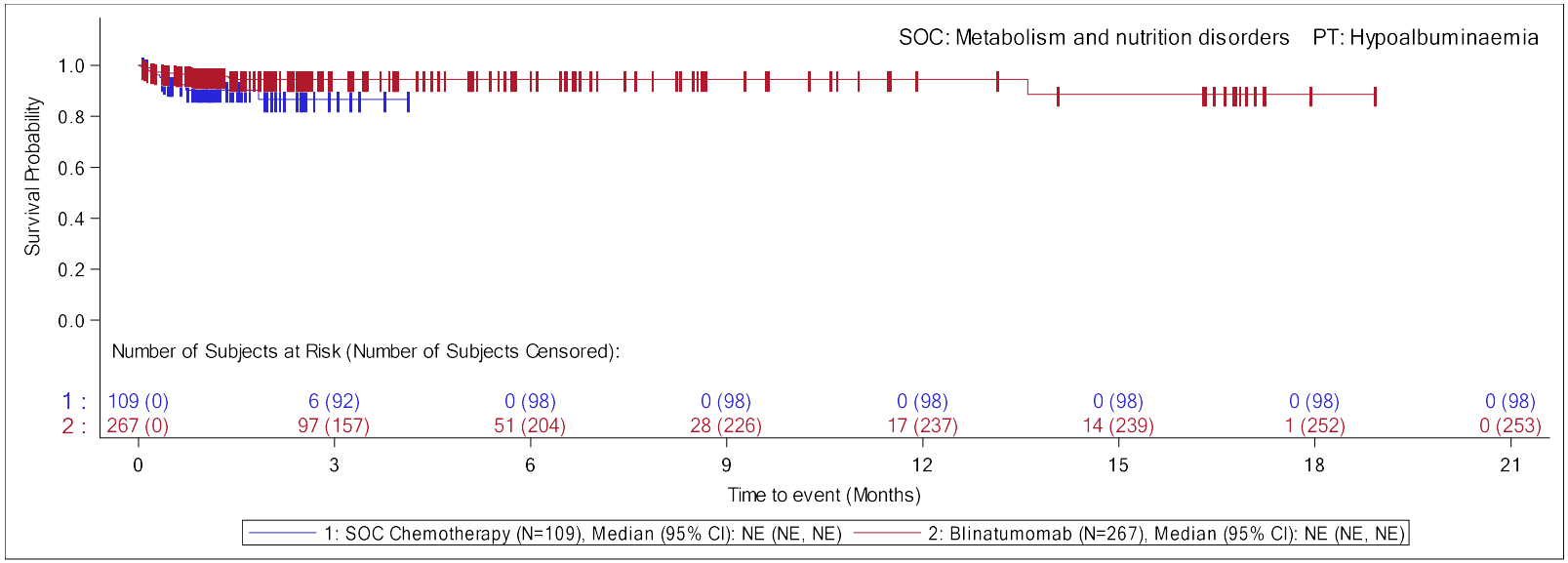

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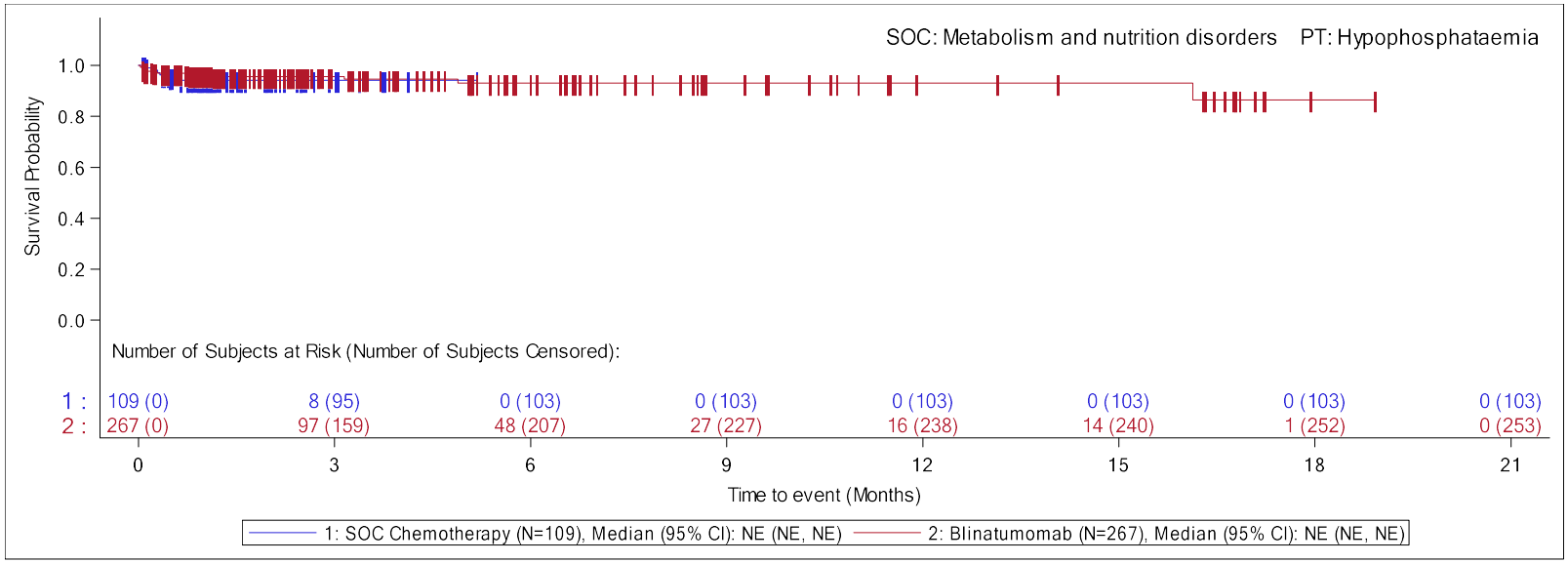

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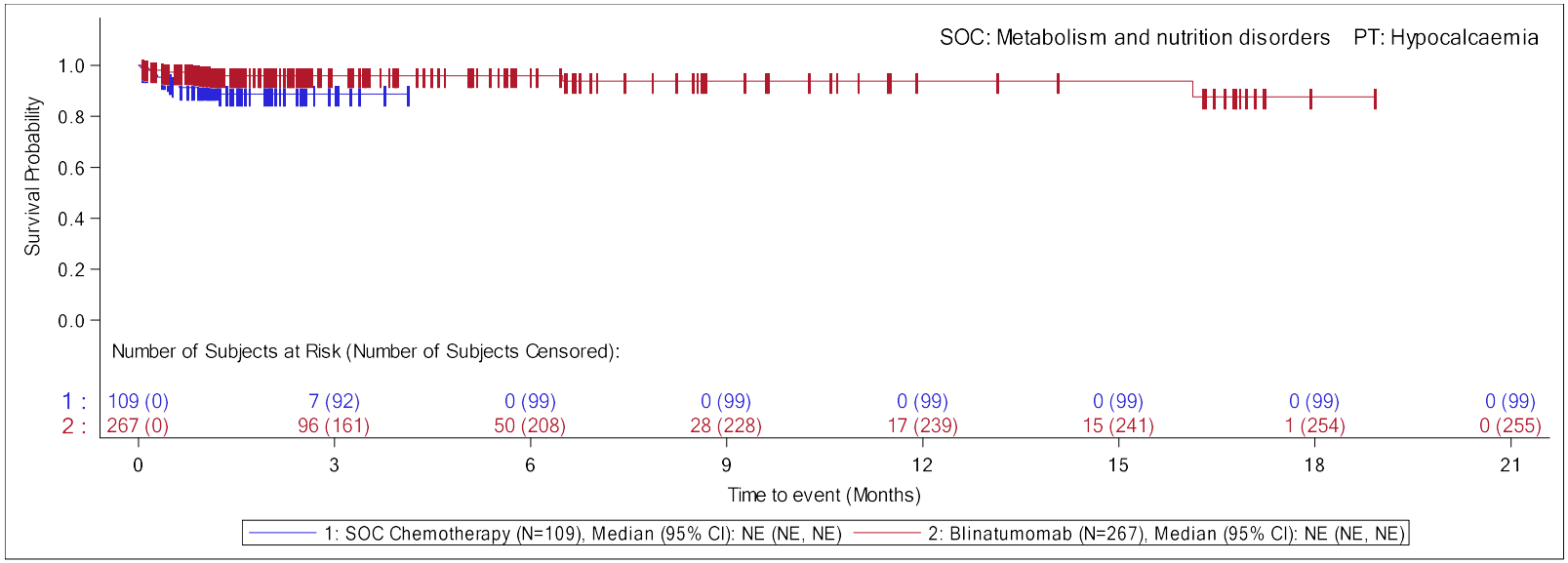

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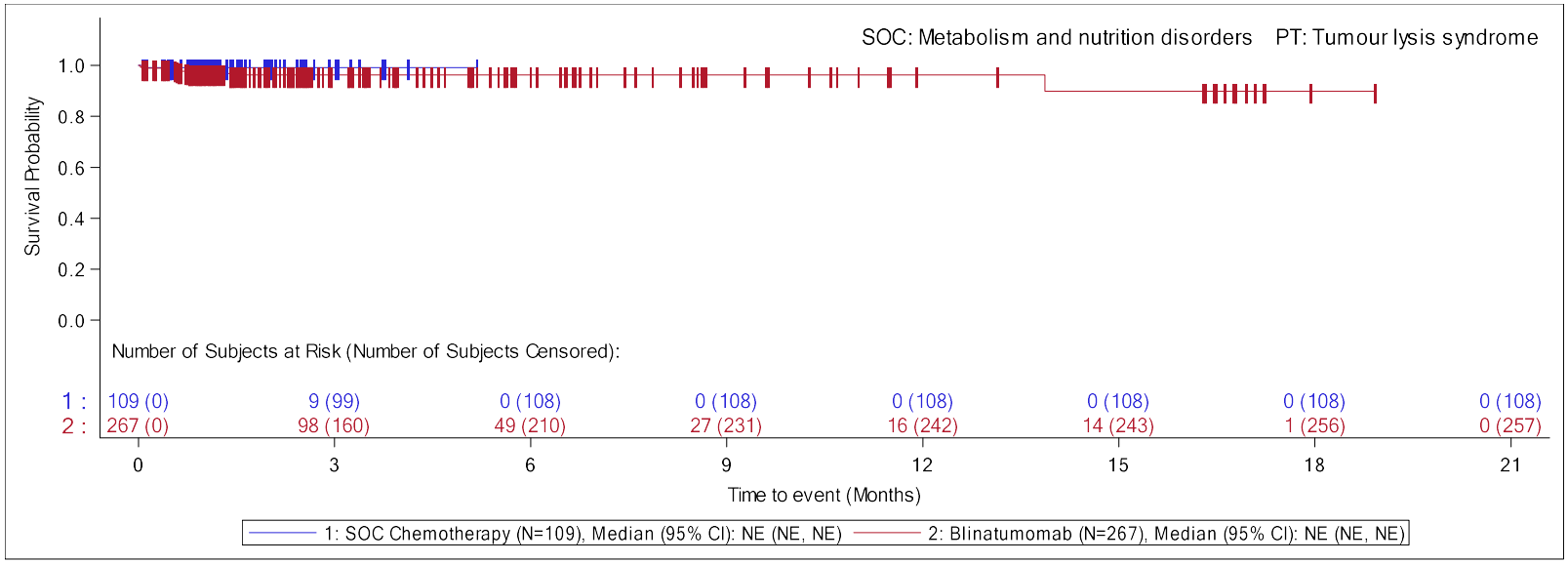

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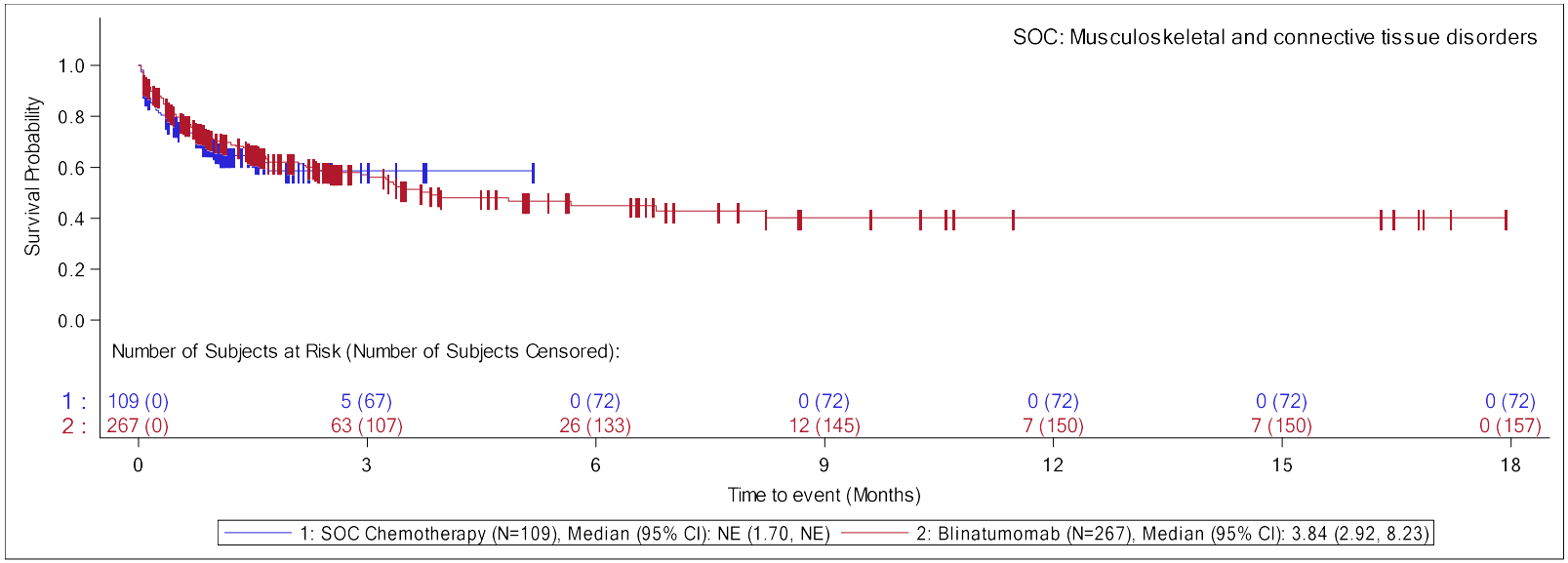

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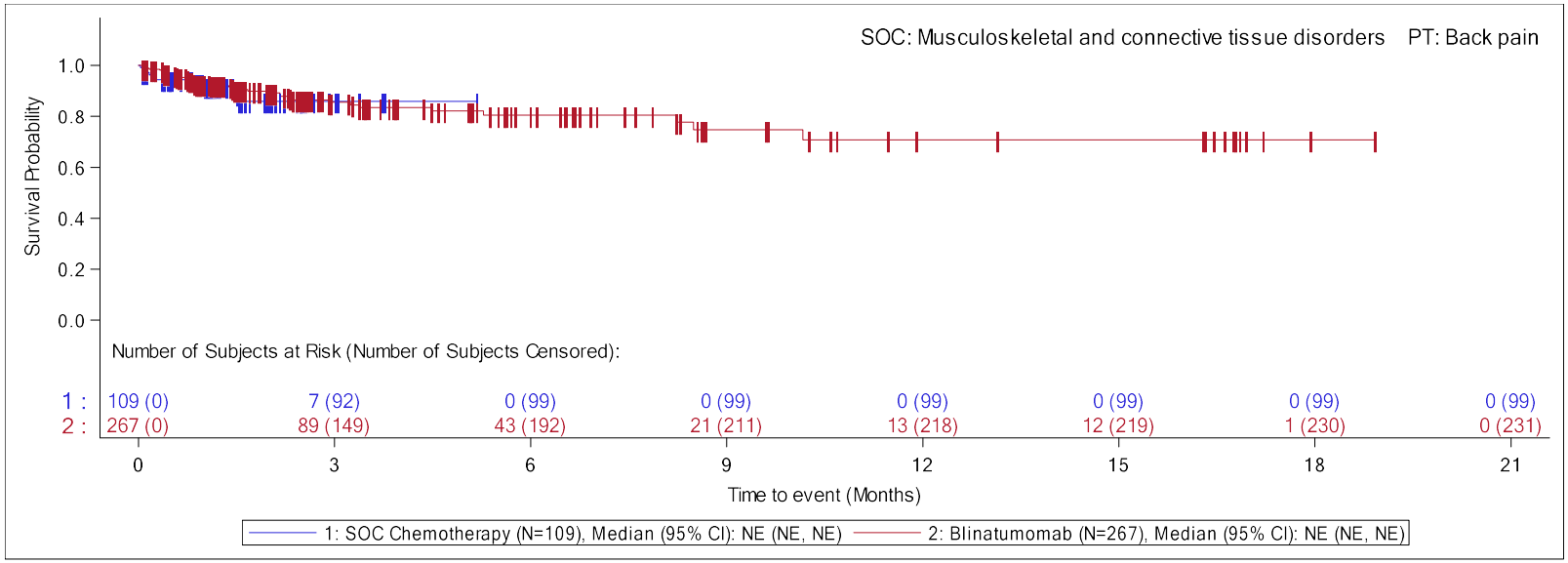

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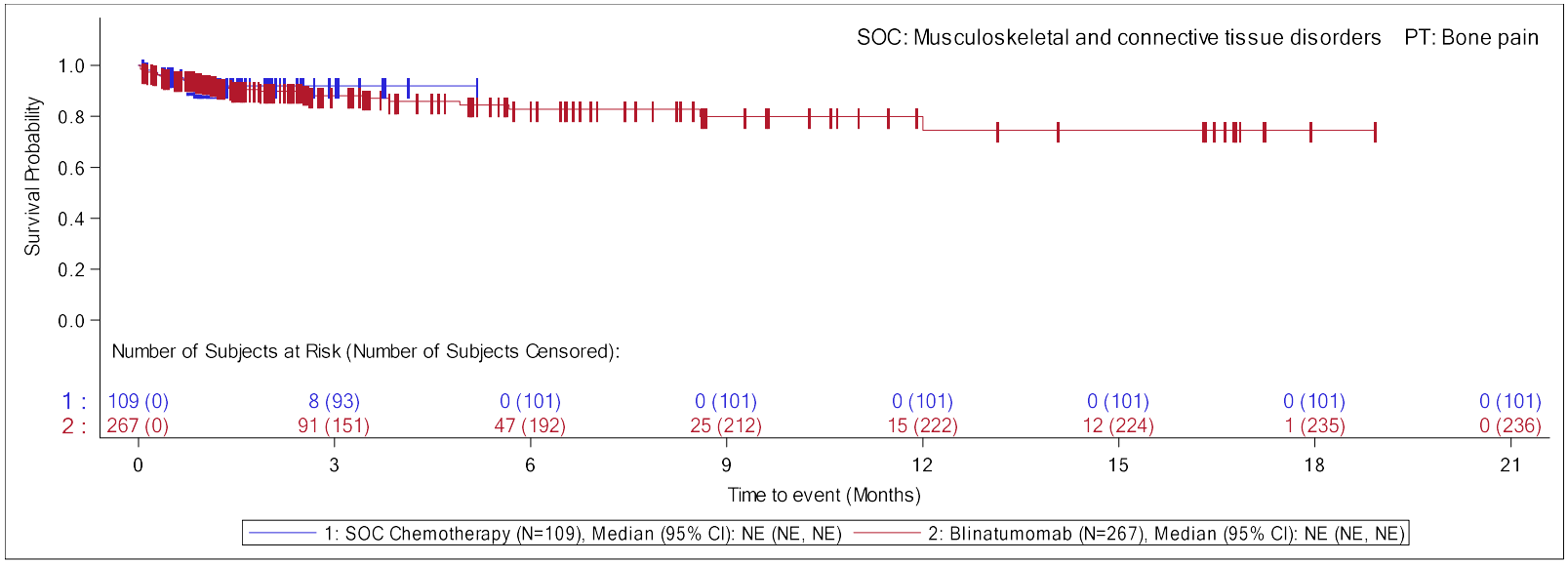

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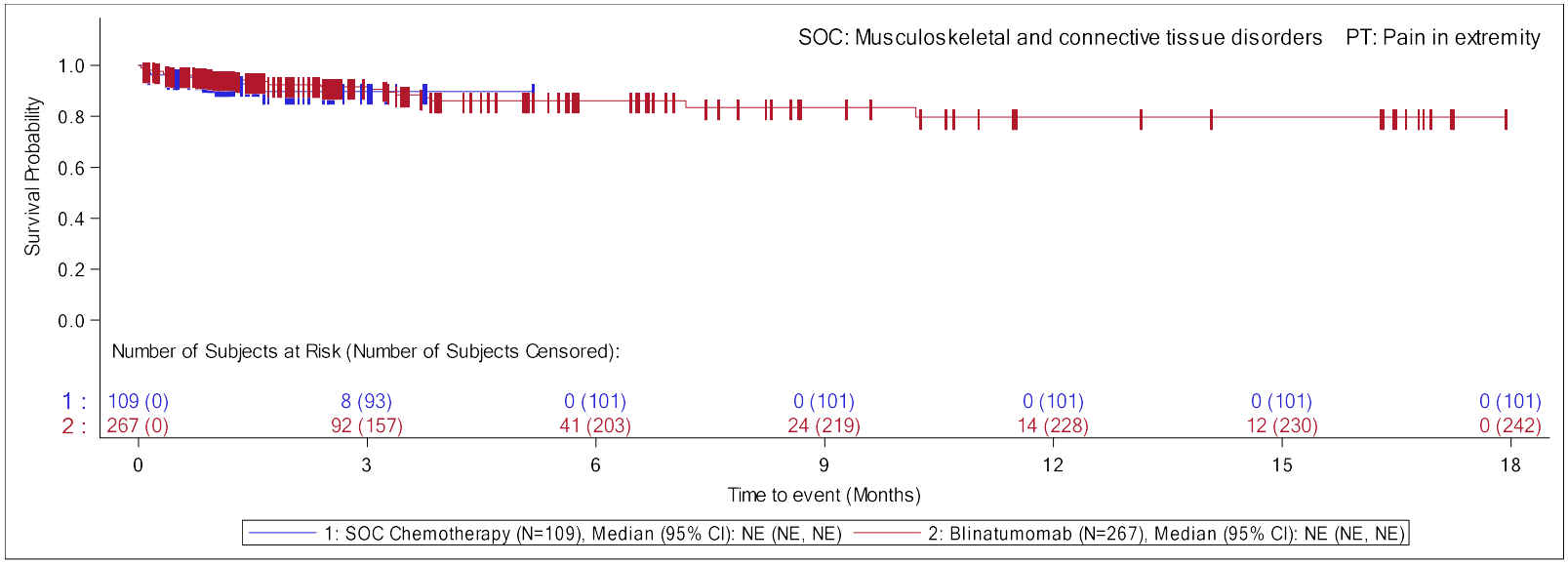

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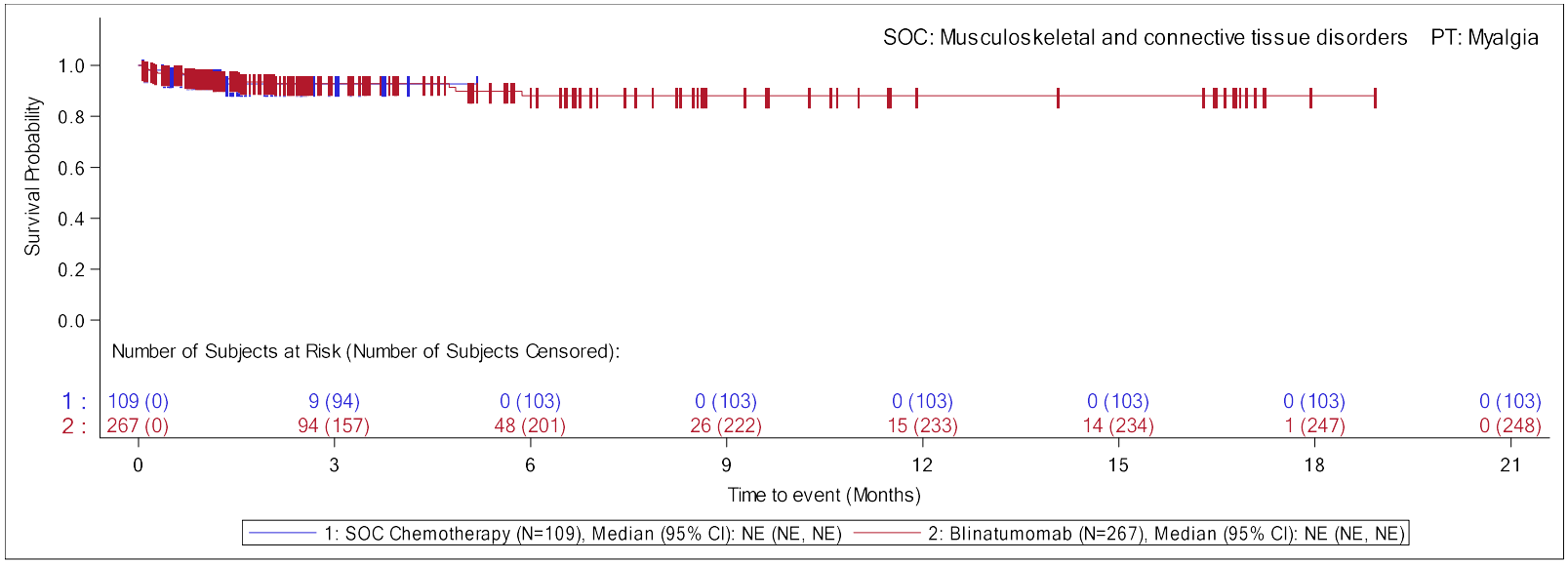

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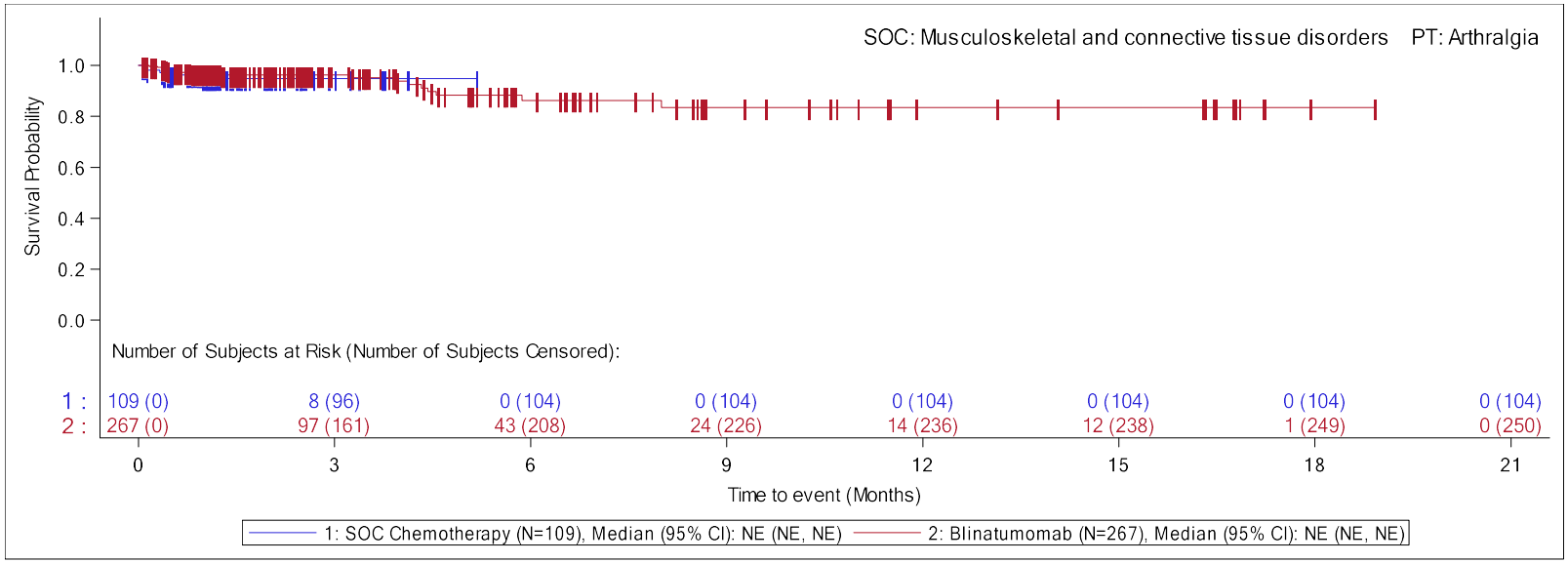

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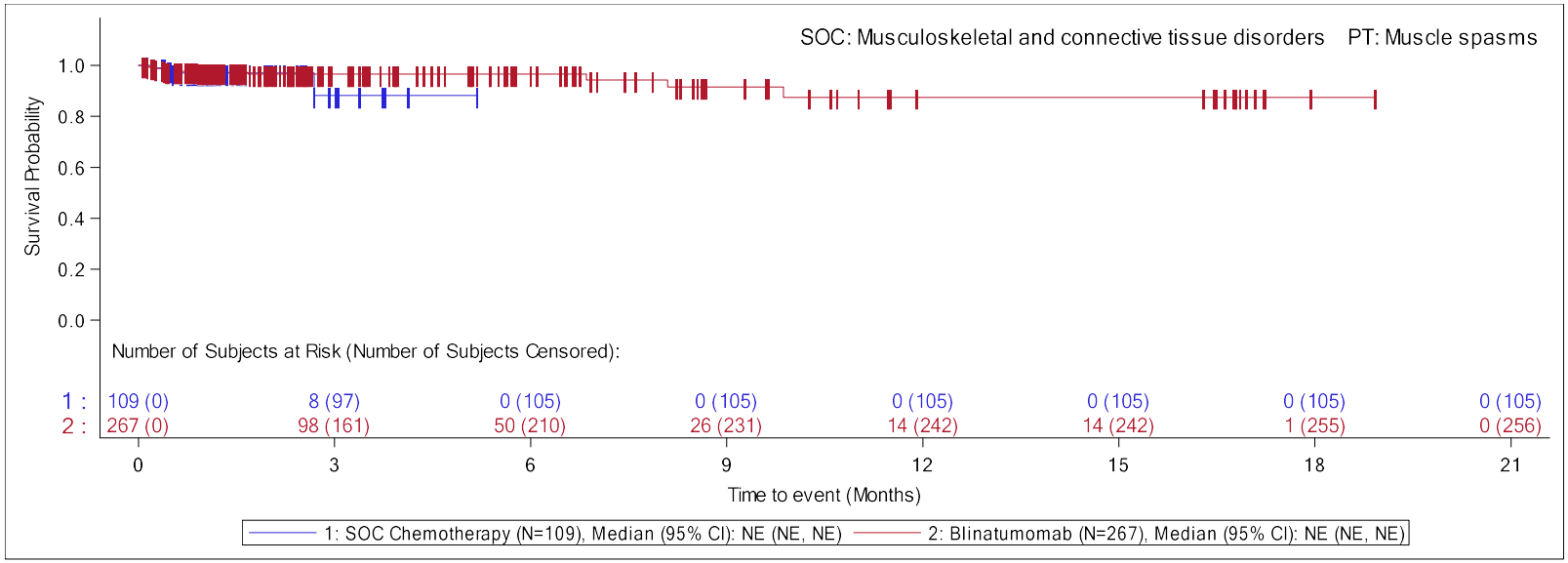

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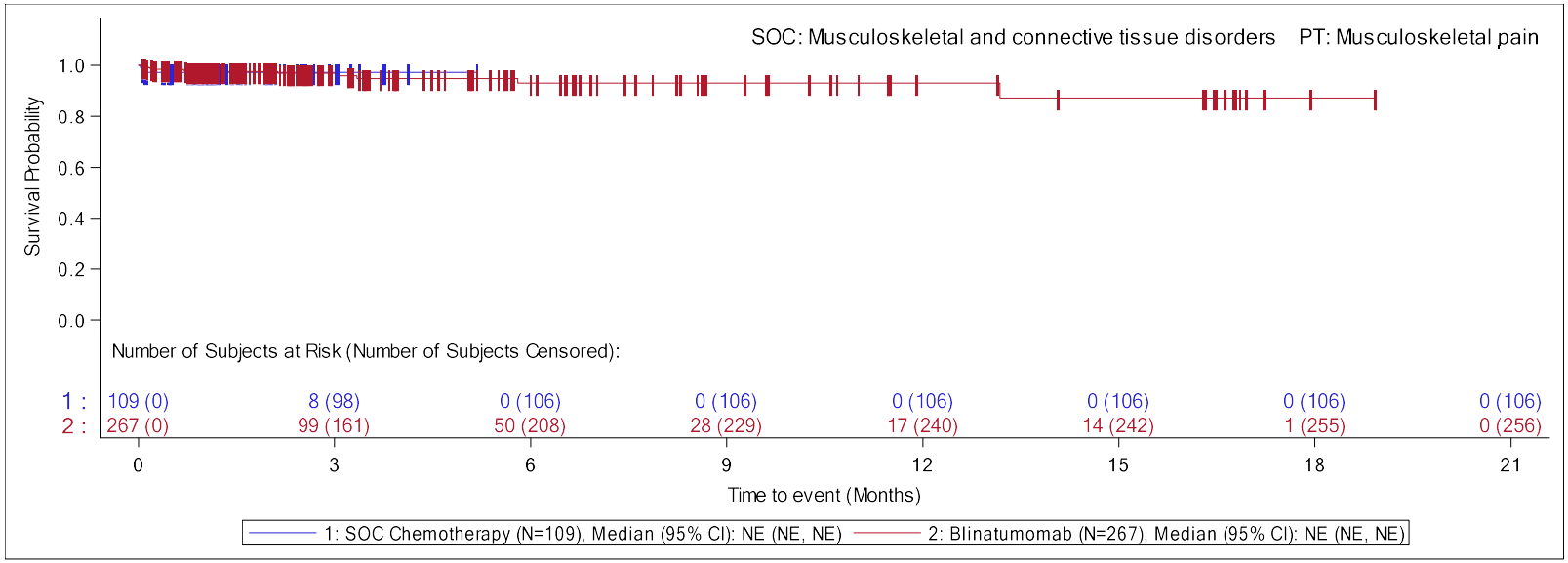

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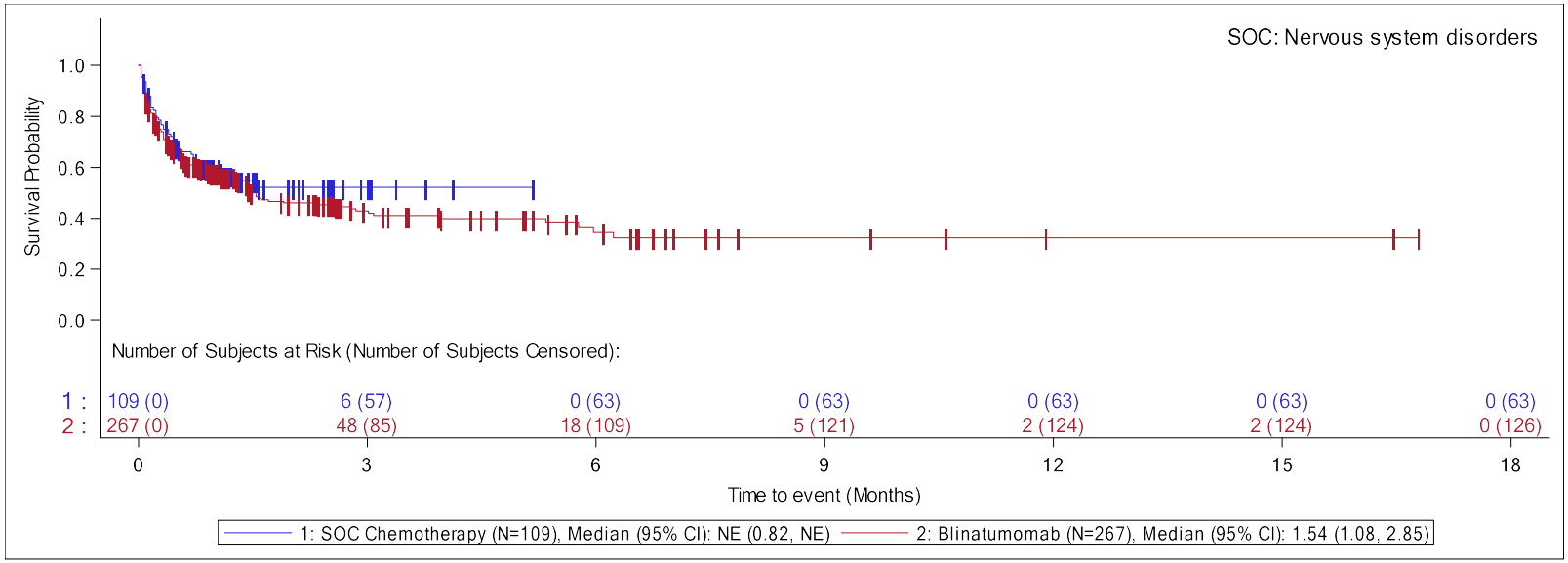

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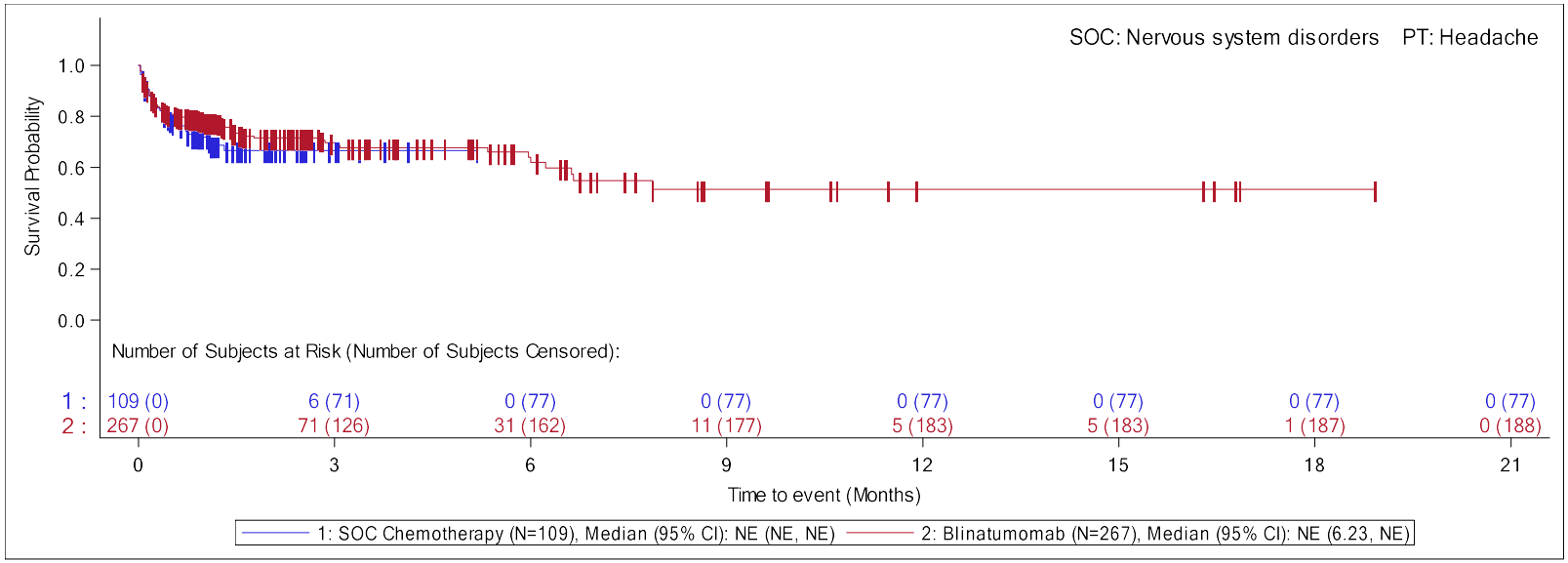

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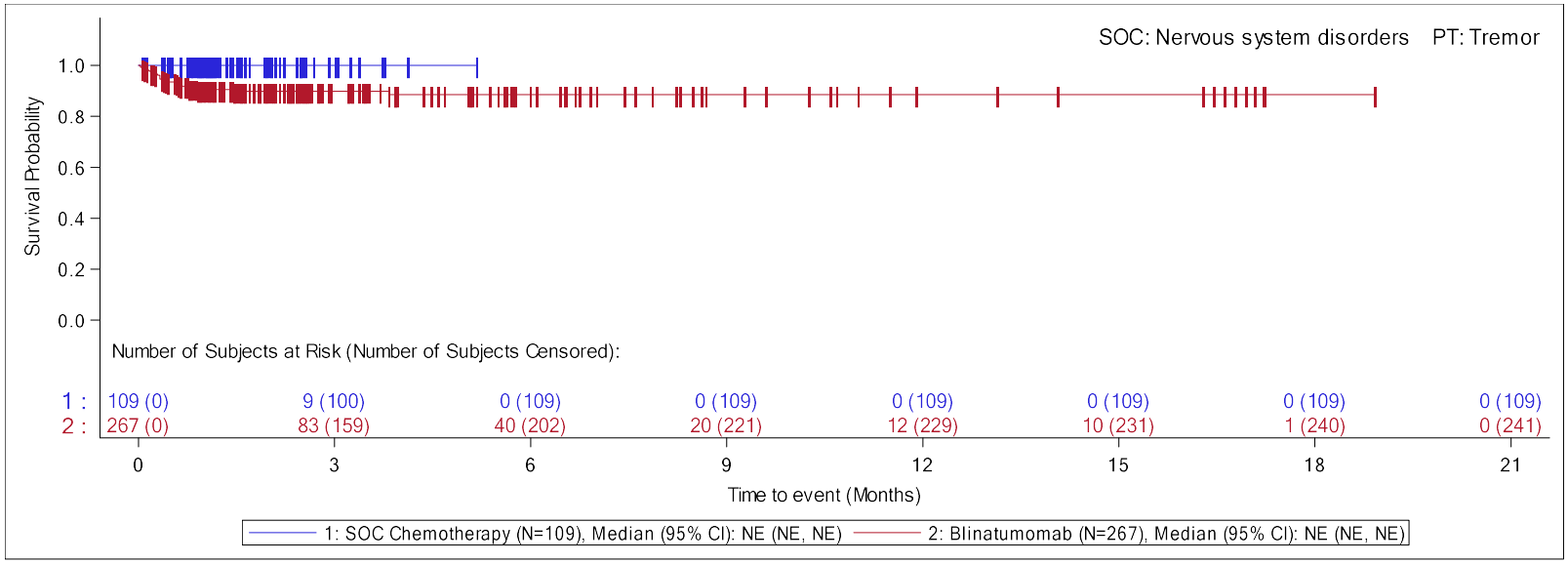
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event by System Organ Class and Preferred Term
(Safety Analysis Set)



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Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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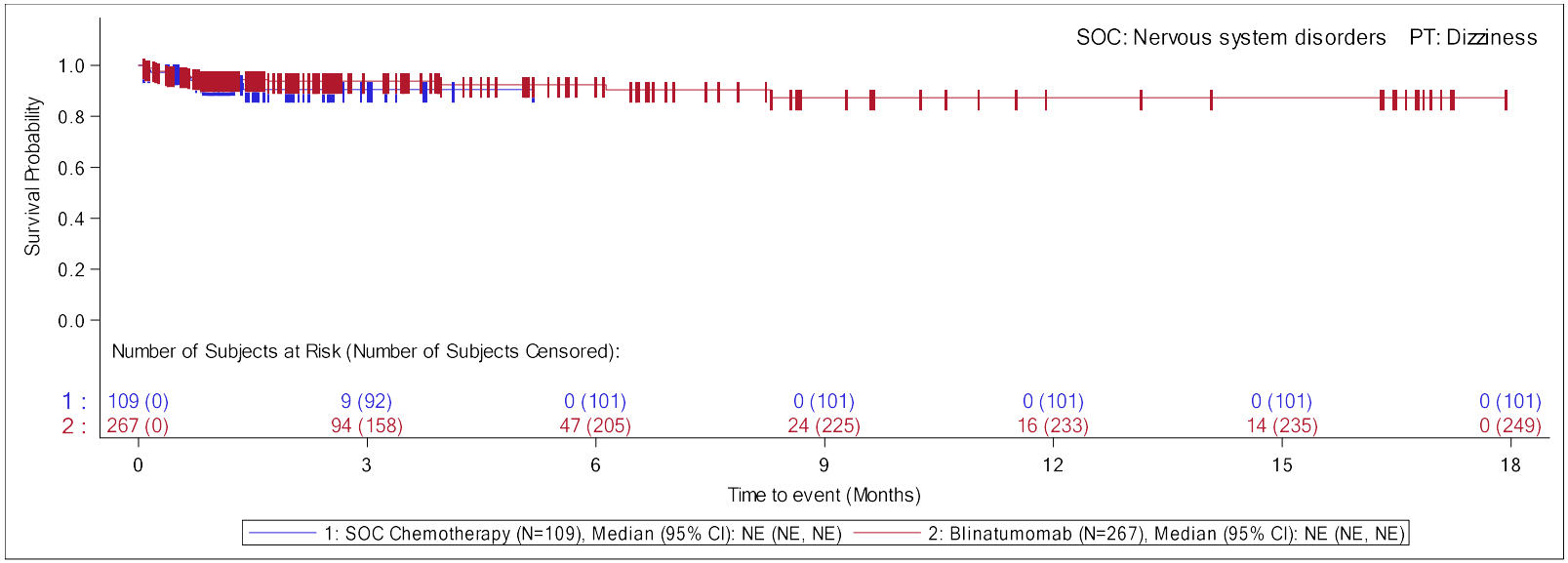

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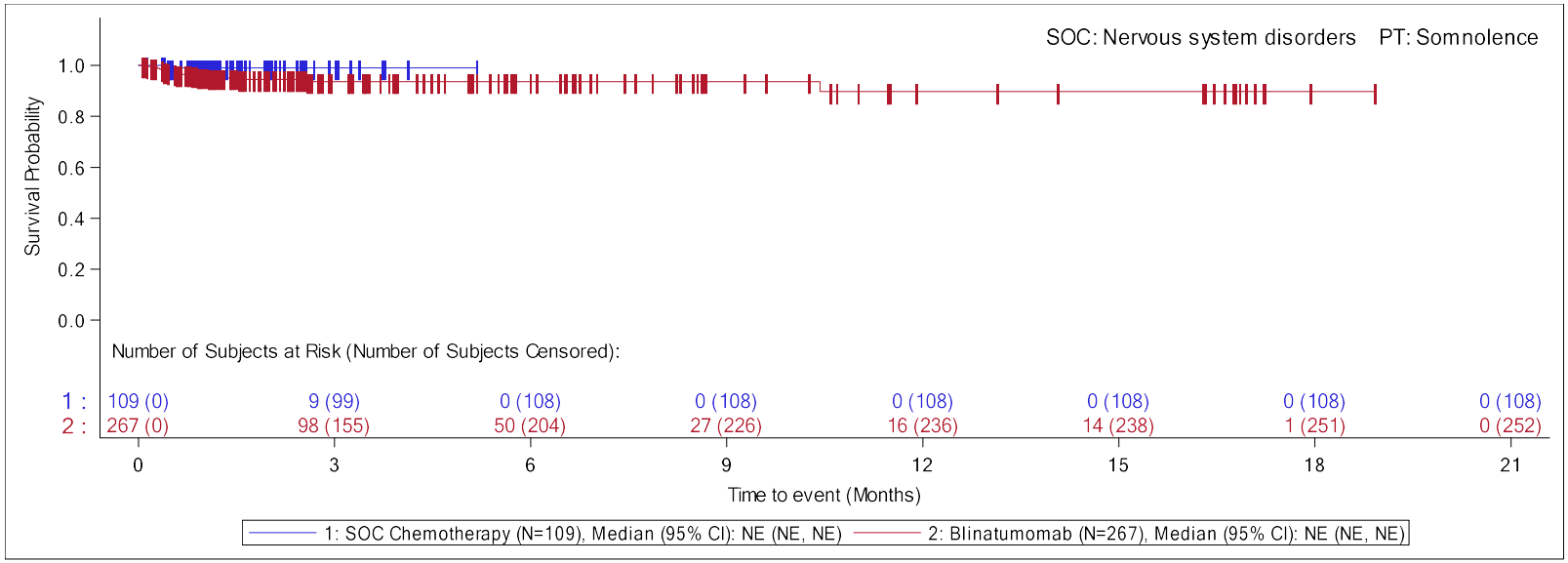

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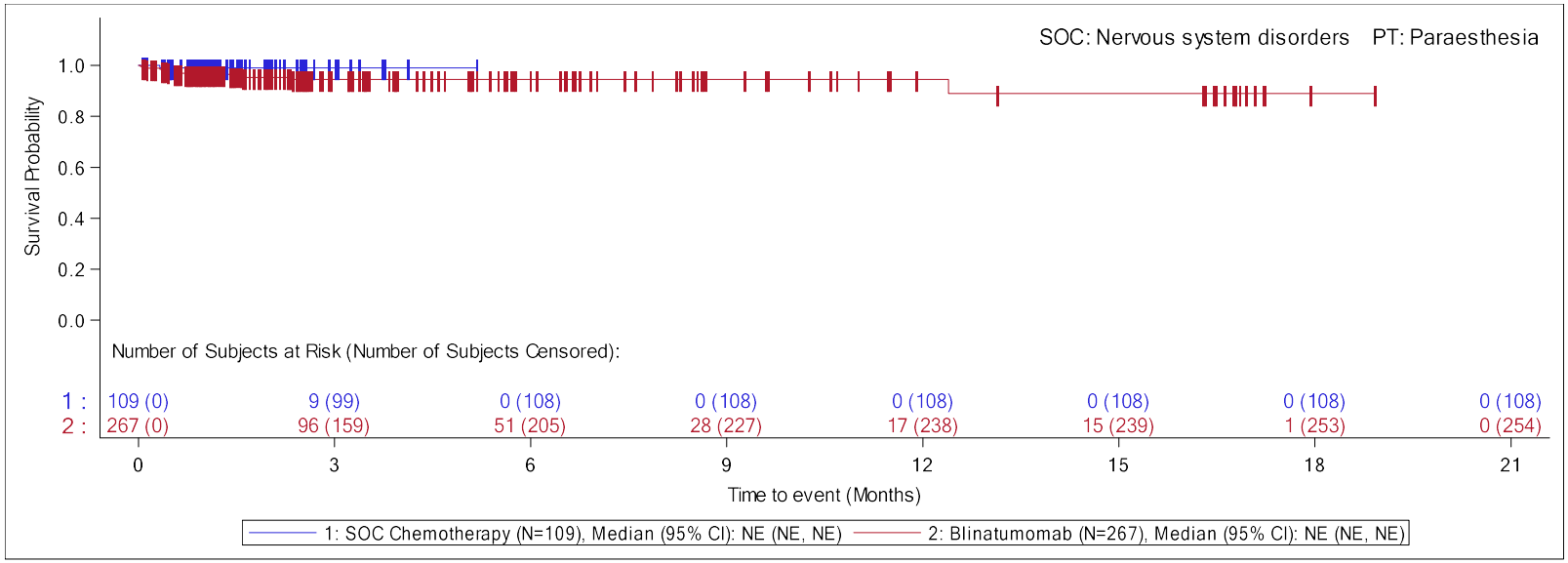

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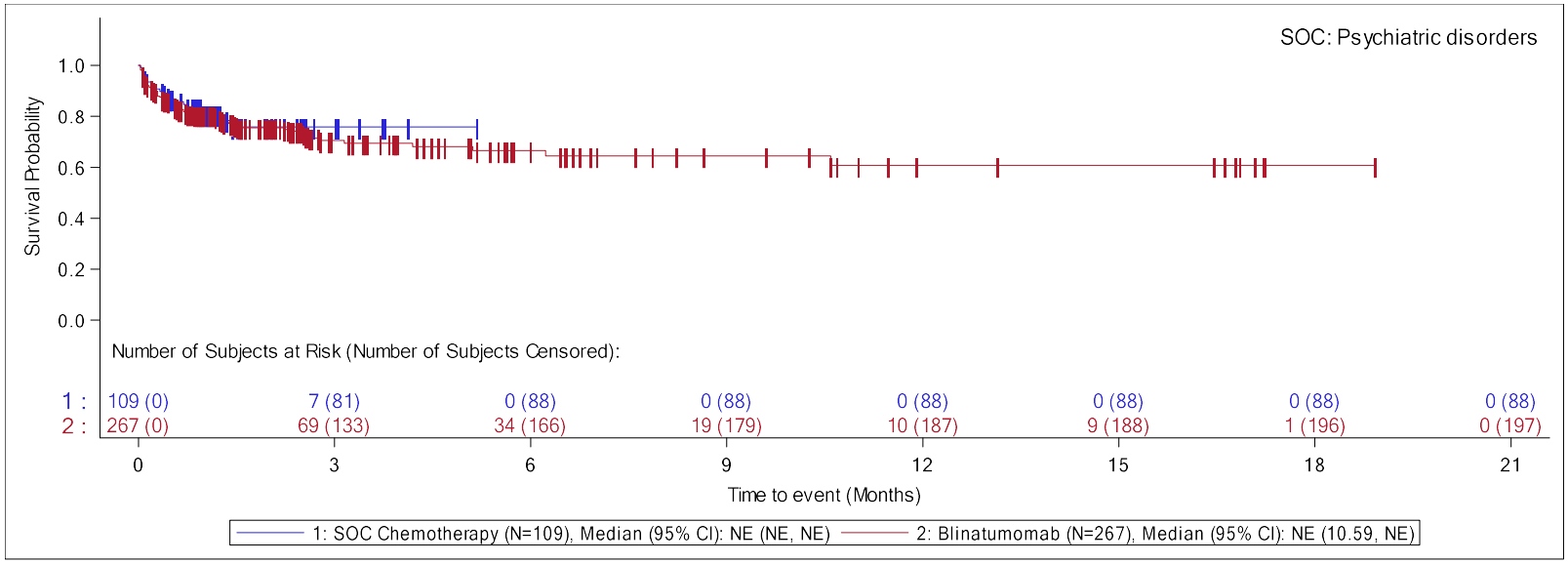

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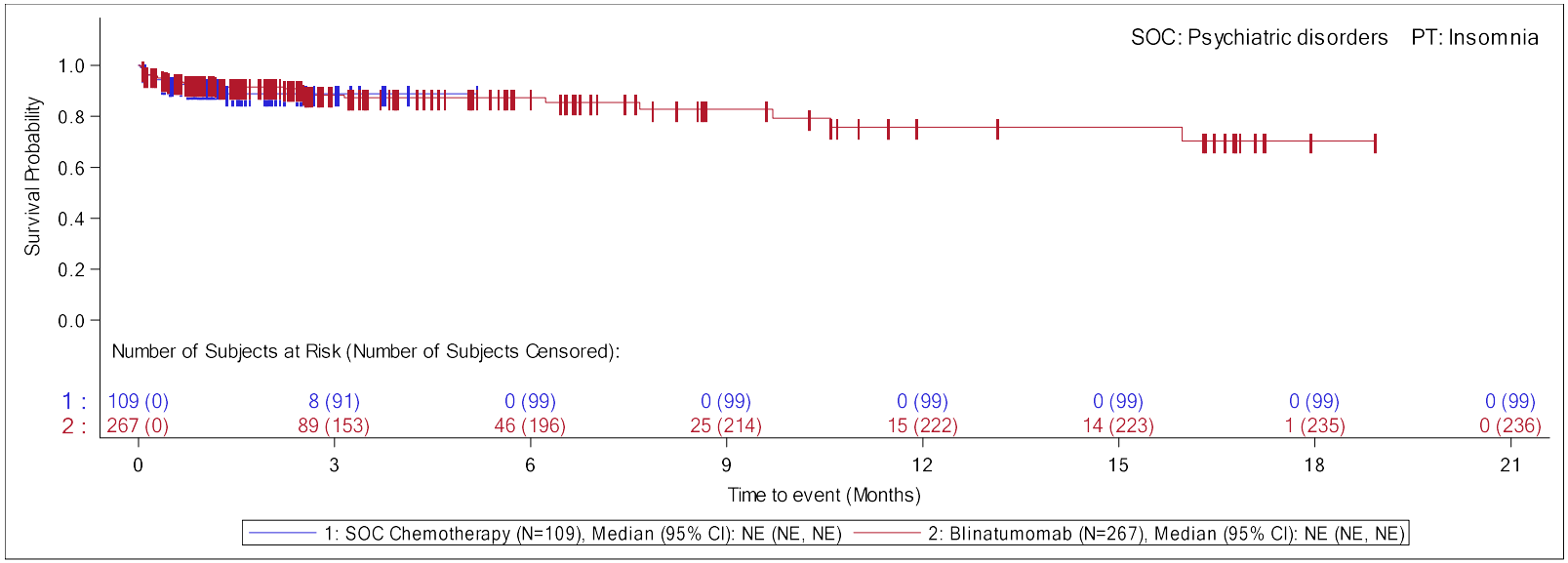

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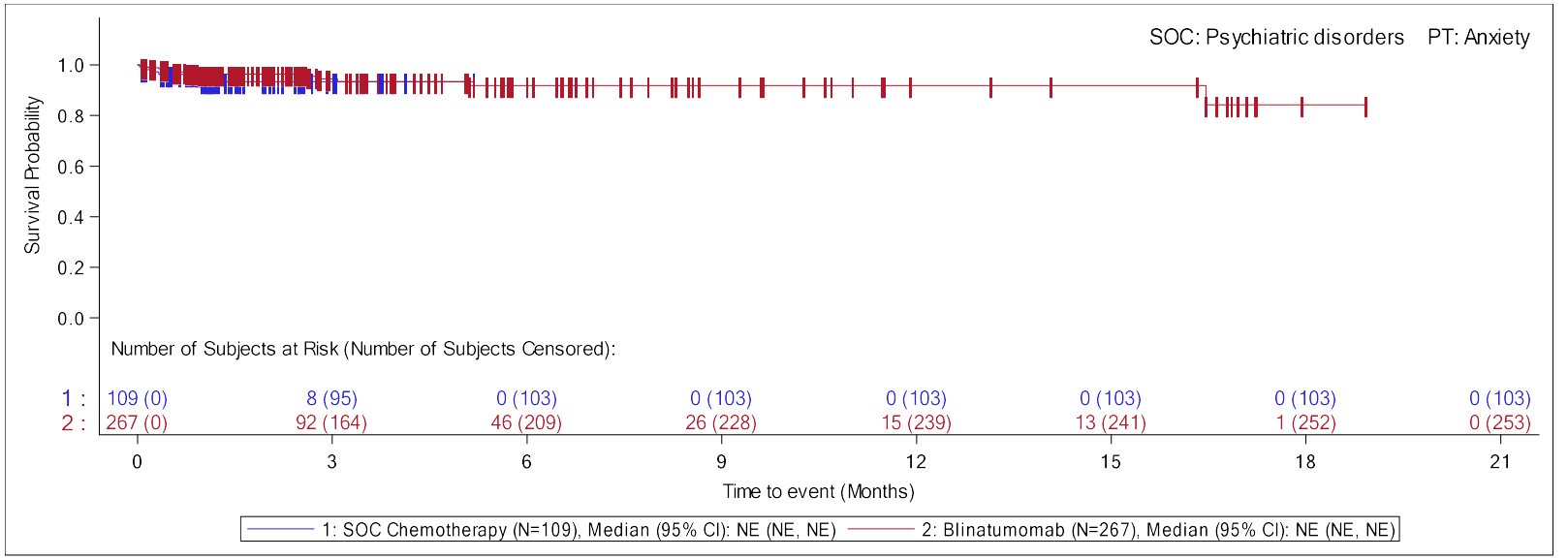

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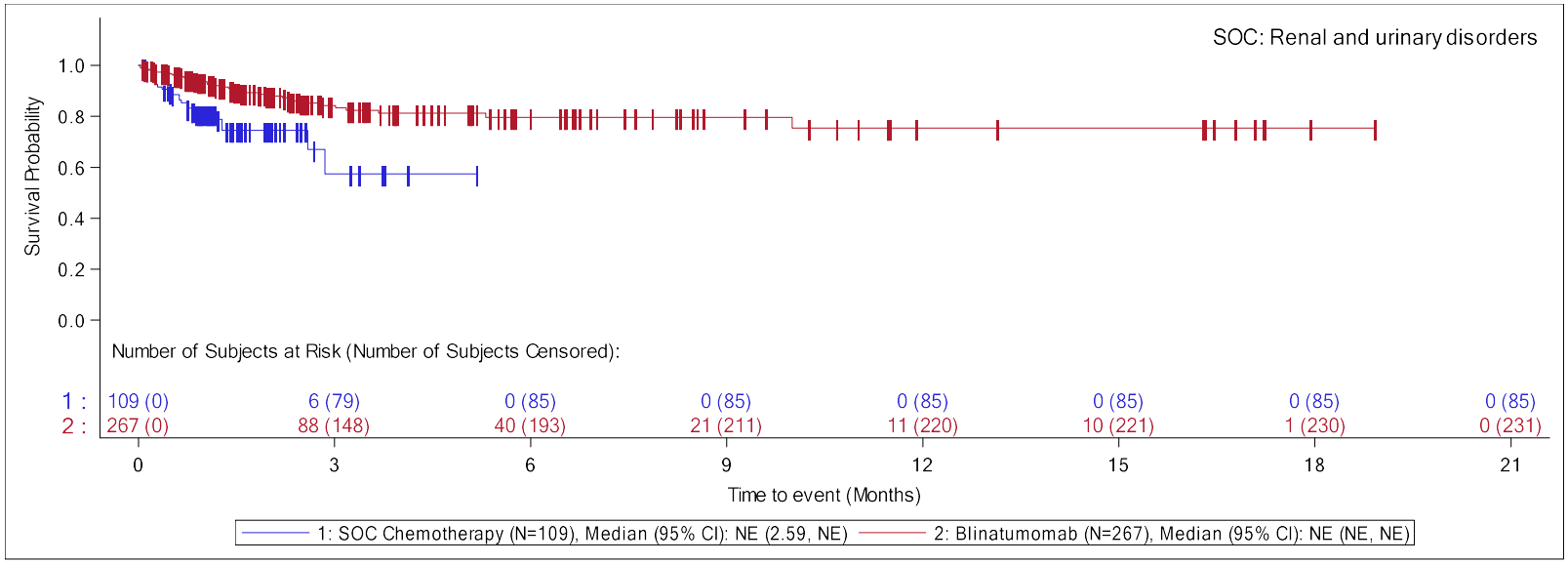

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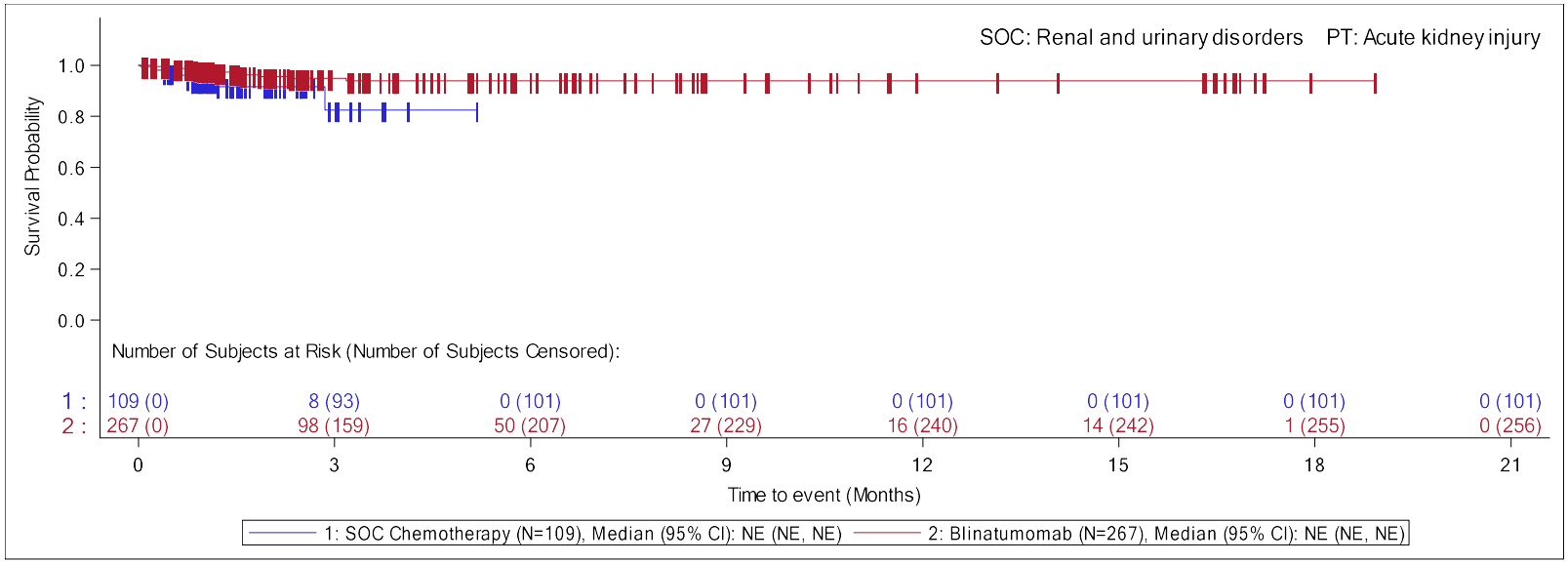

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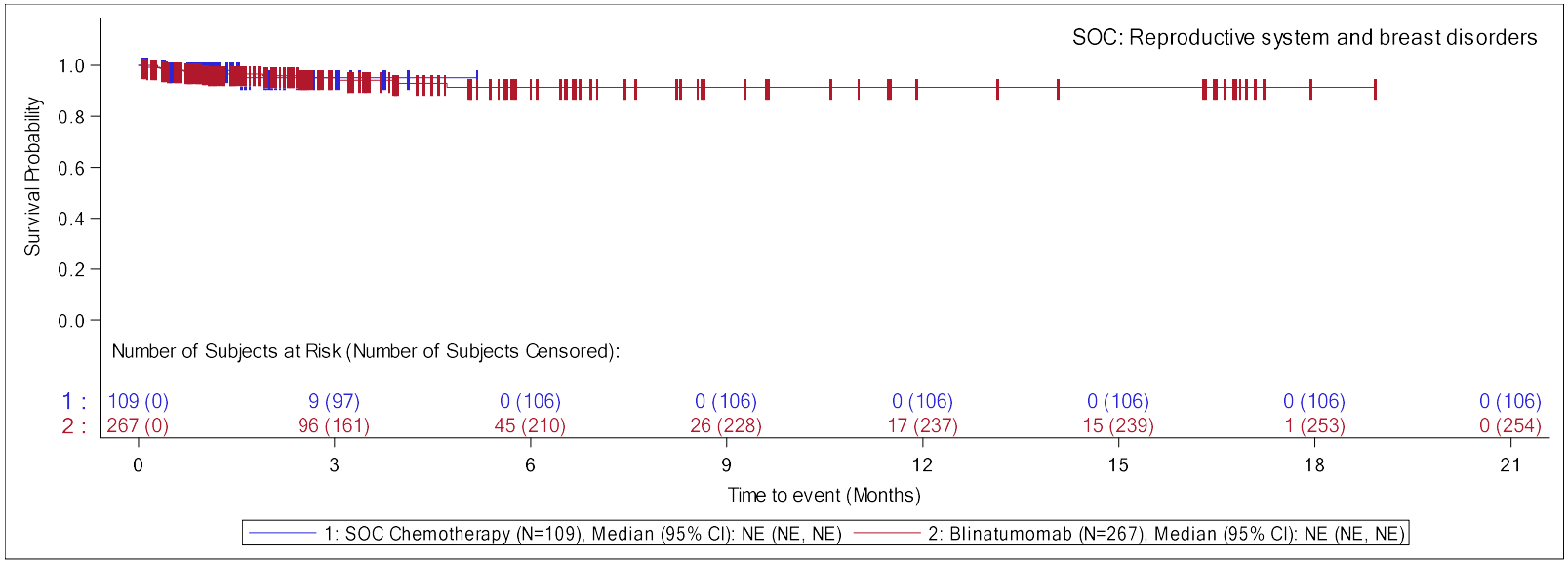

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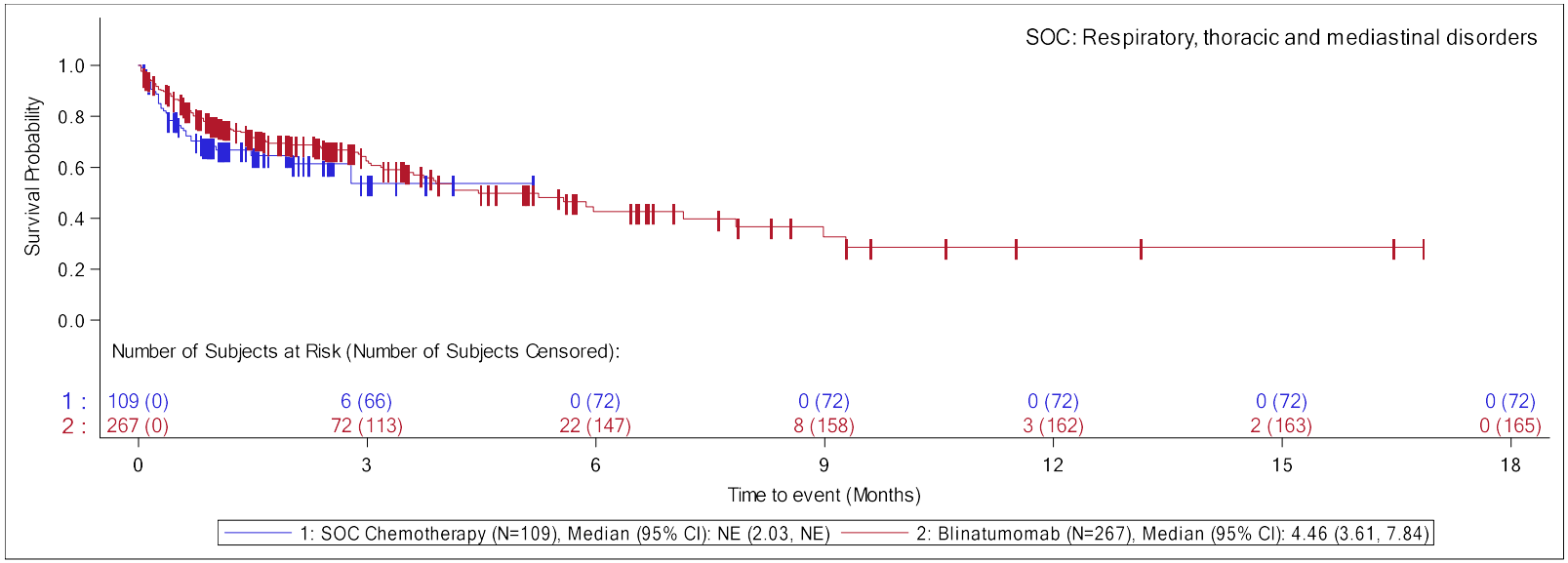

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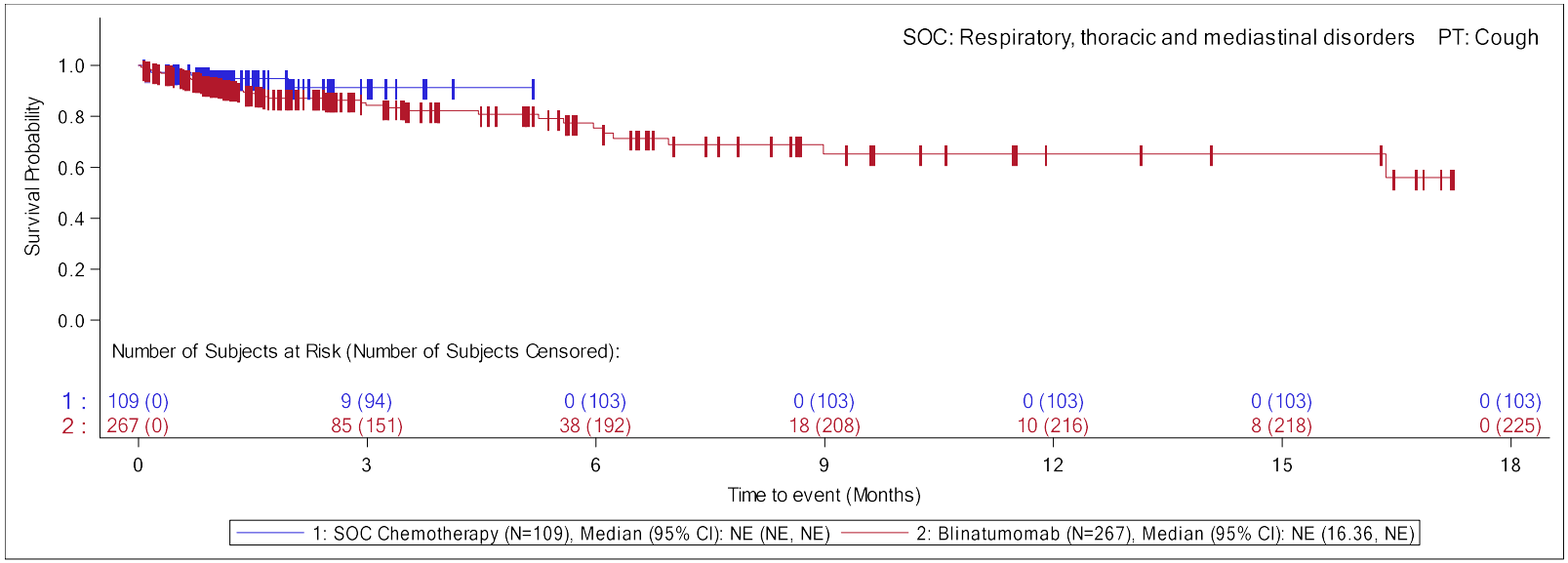

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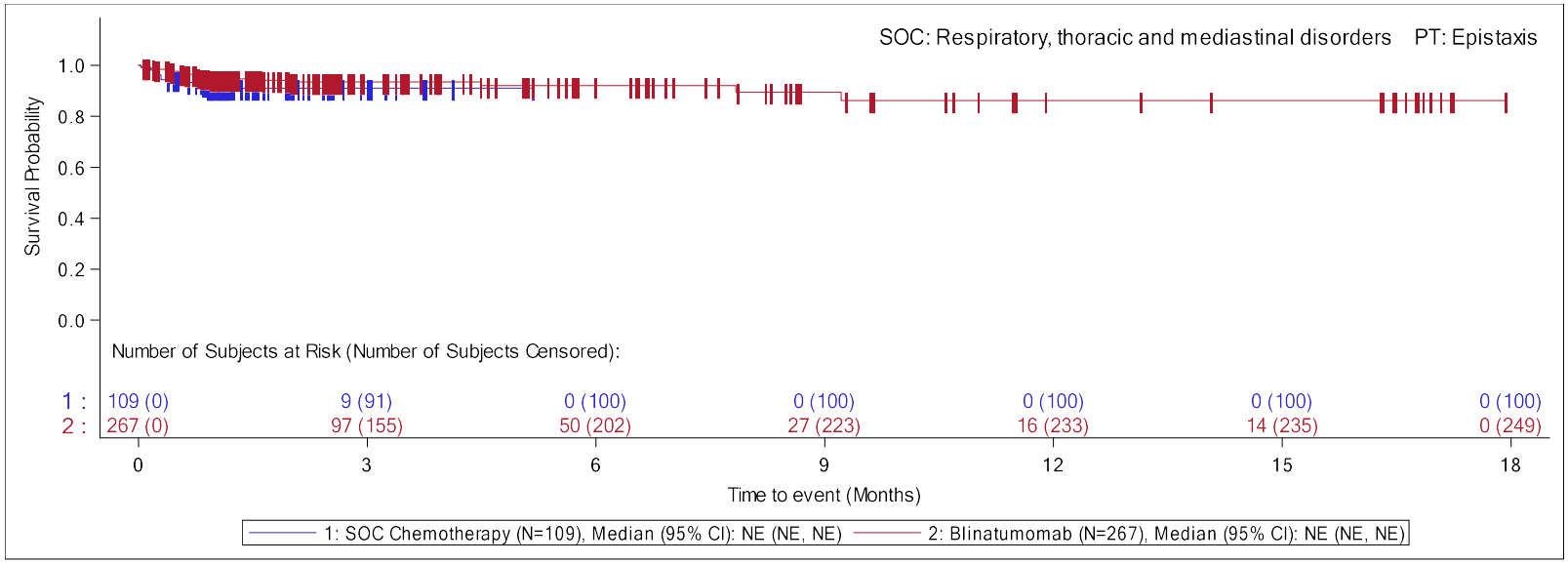

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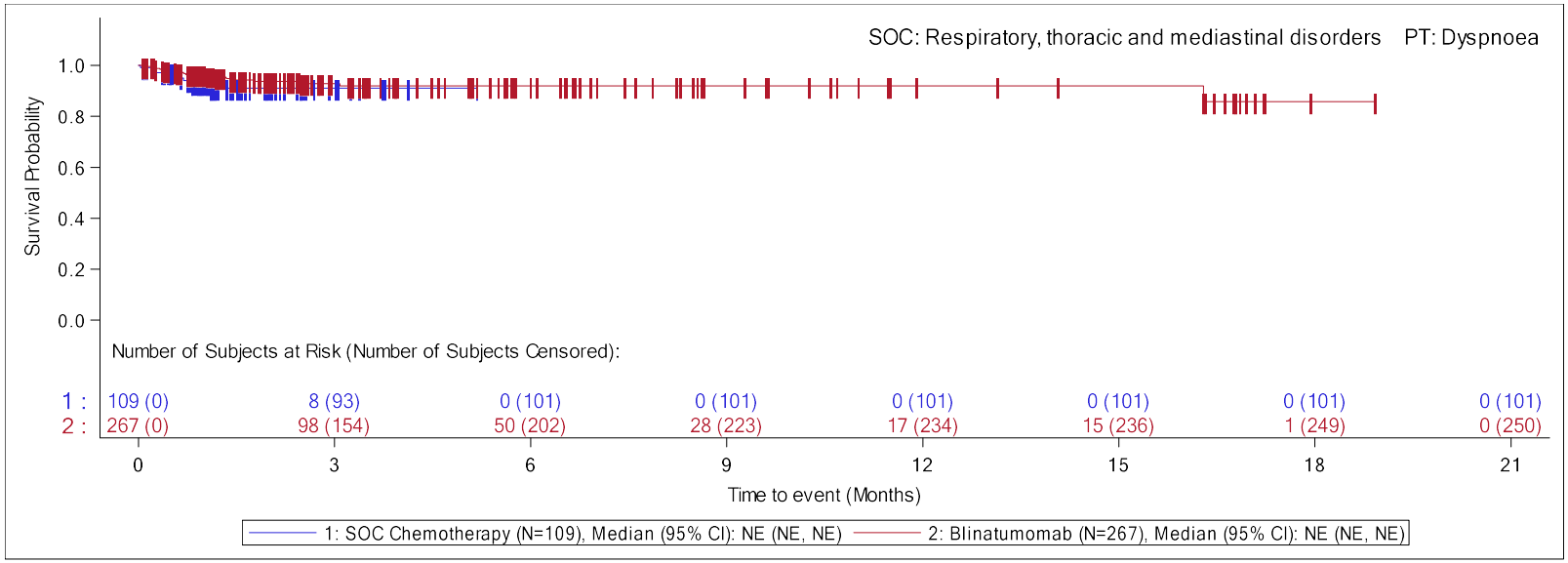

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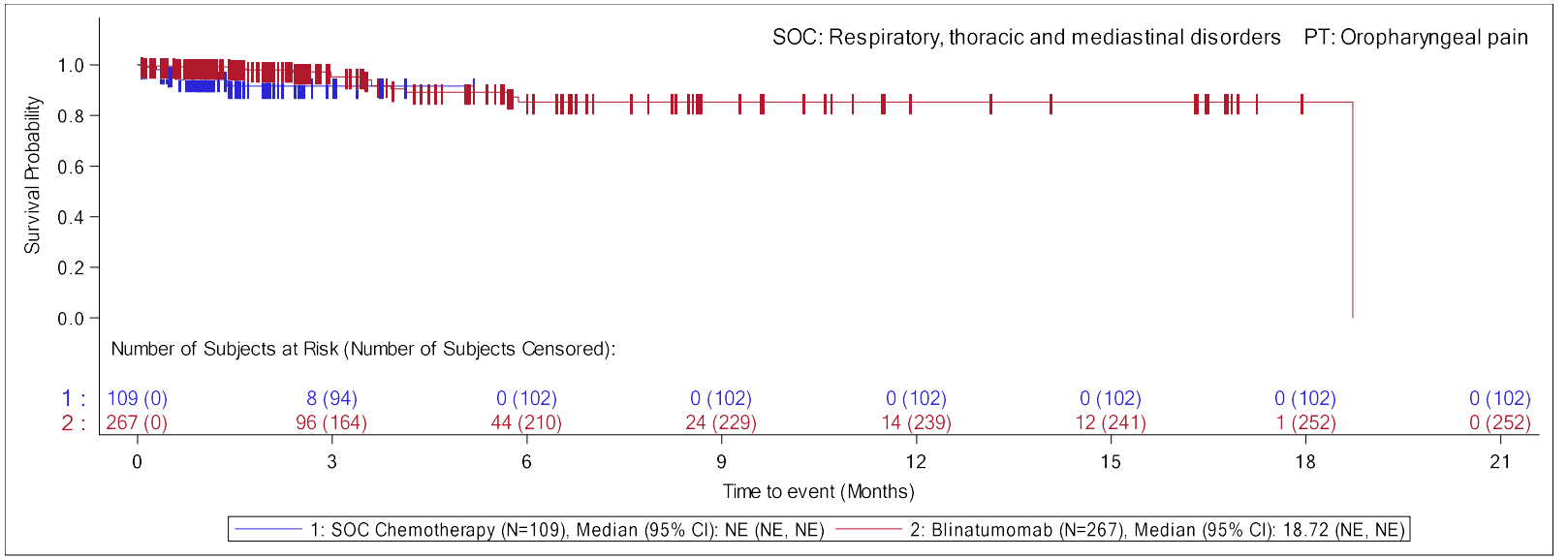

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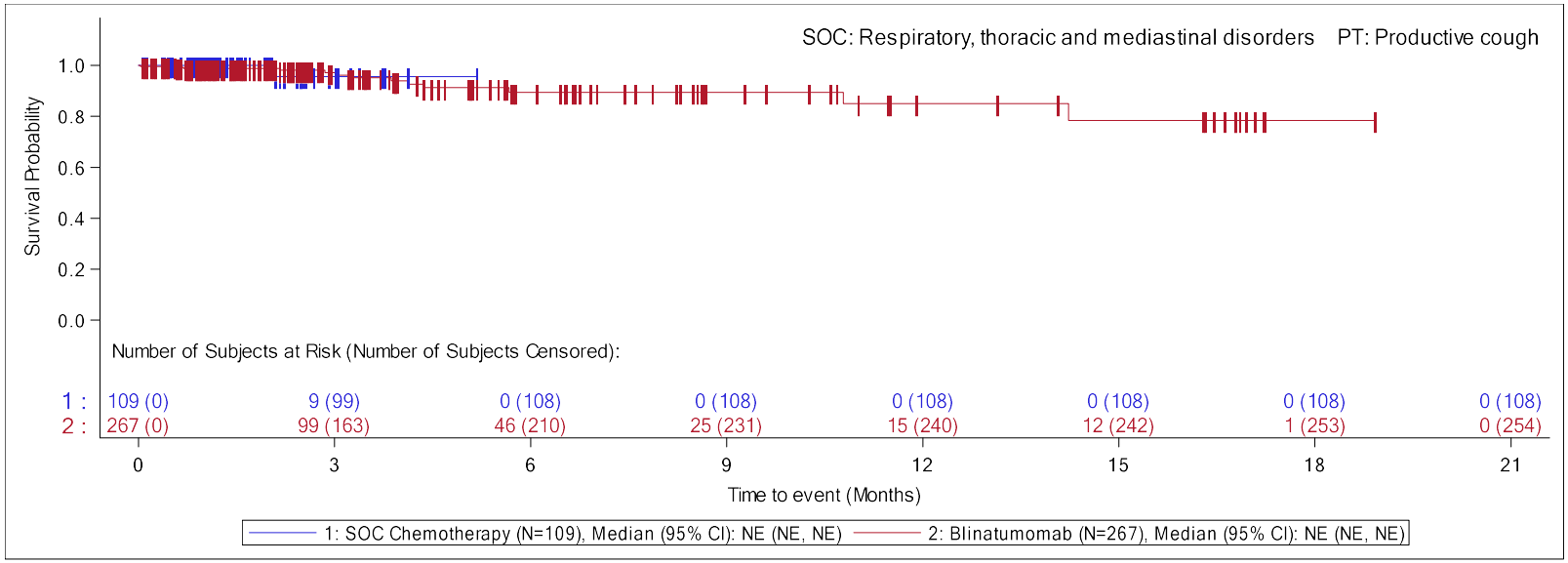

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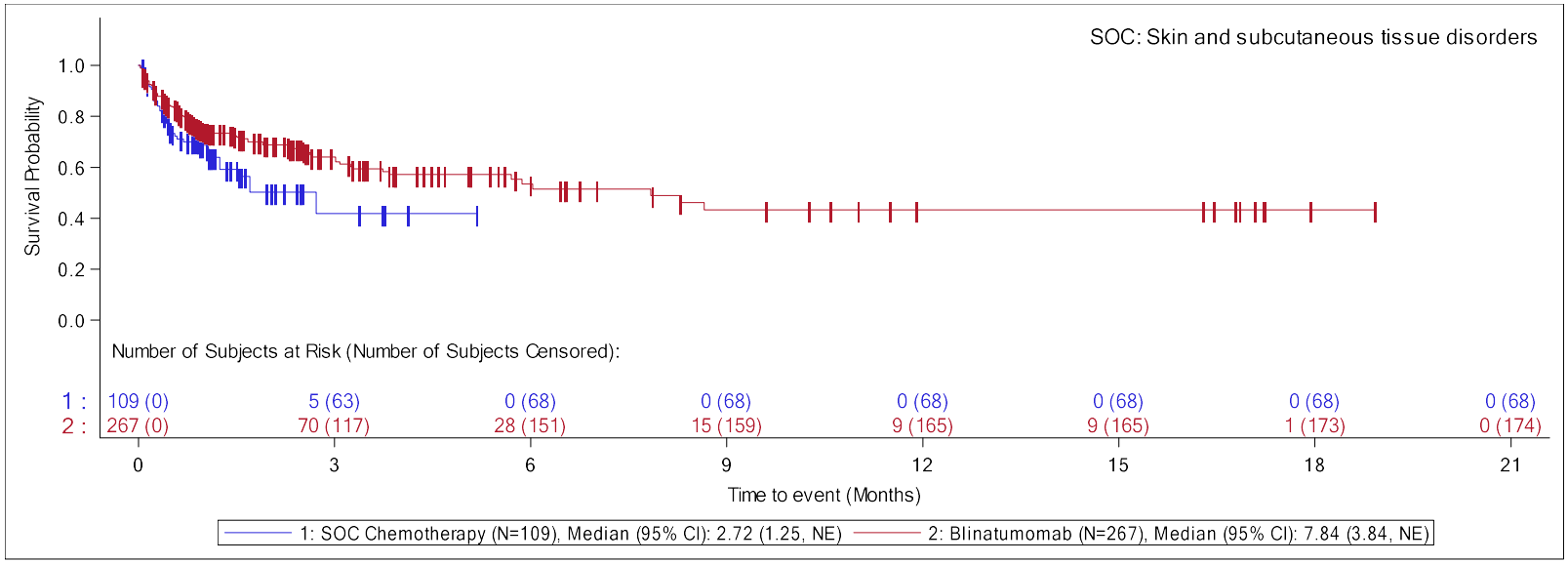

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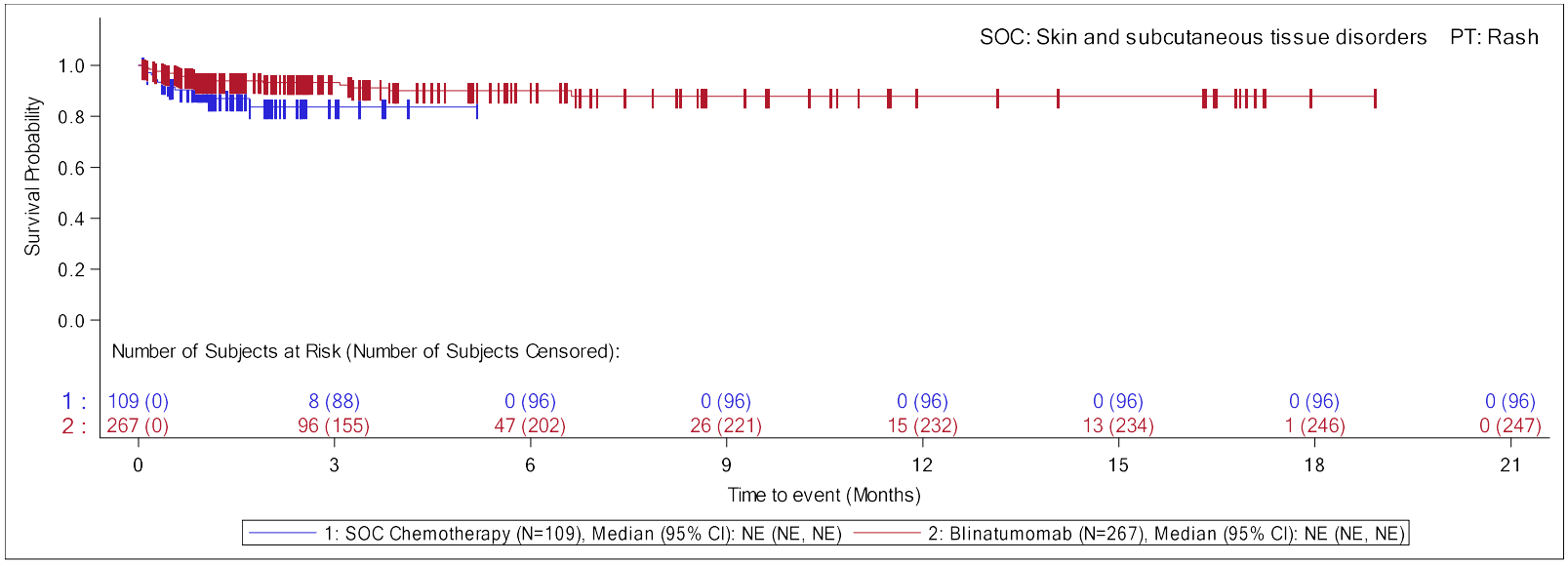

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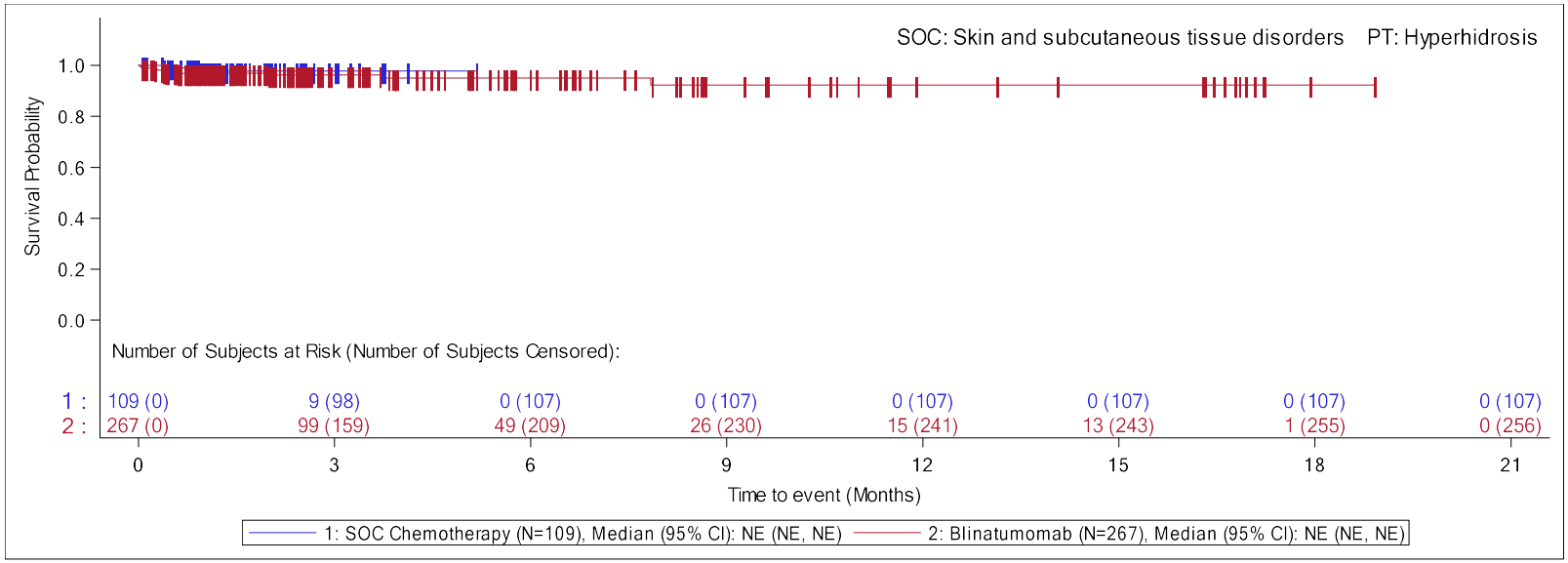

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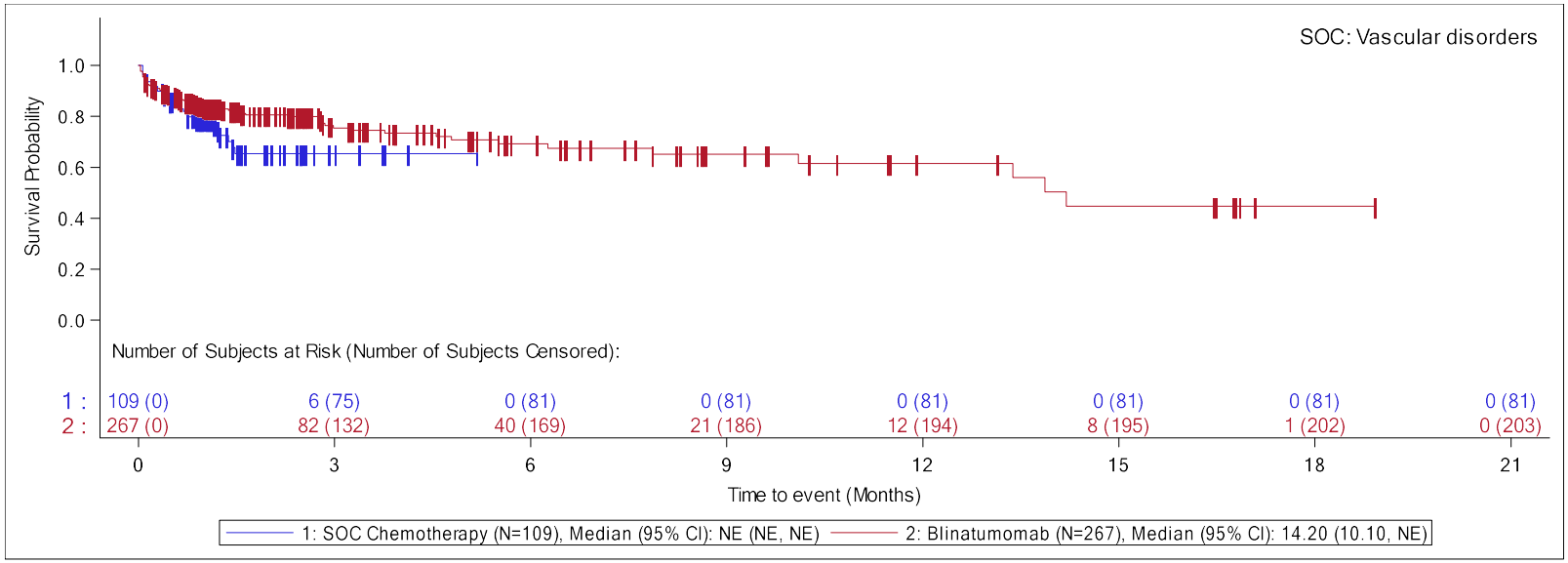

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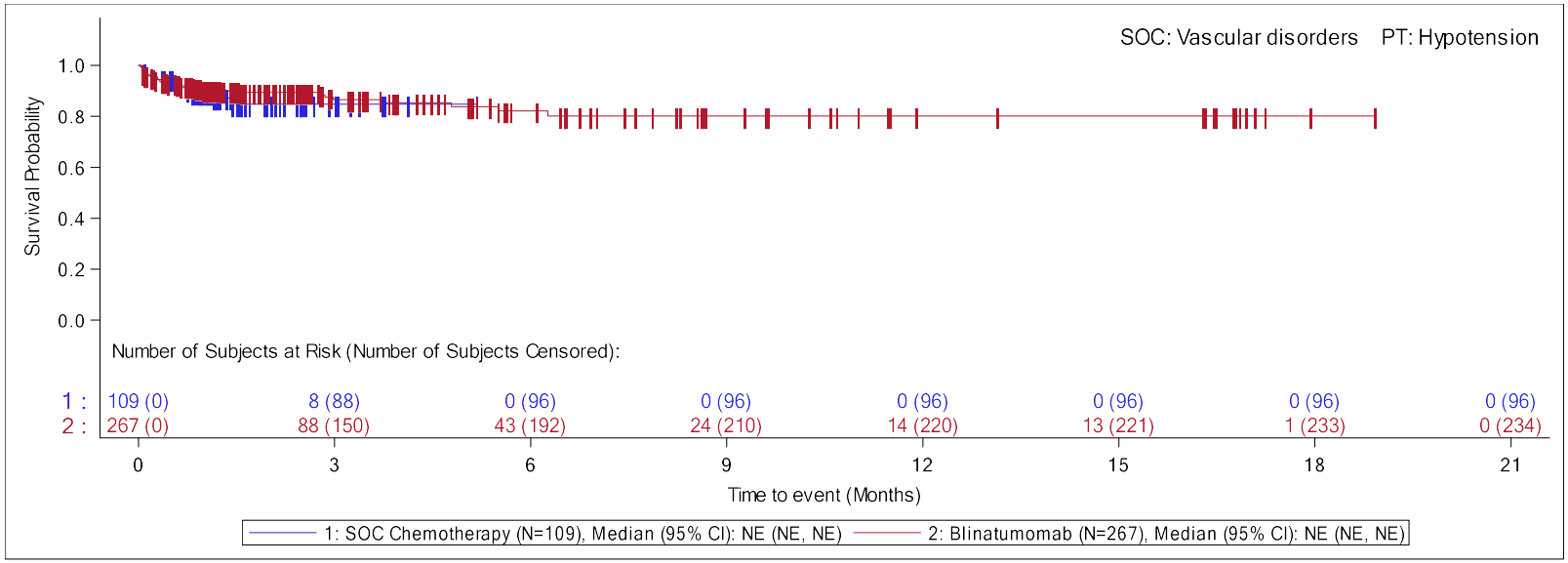

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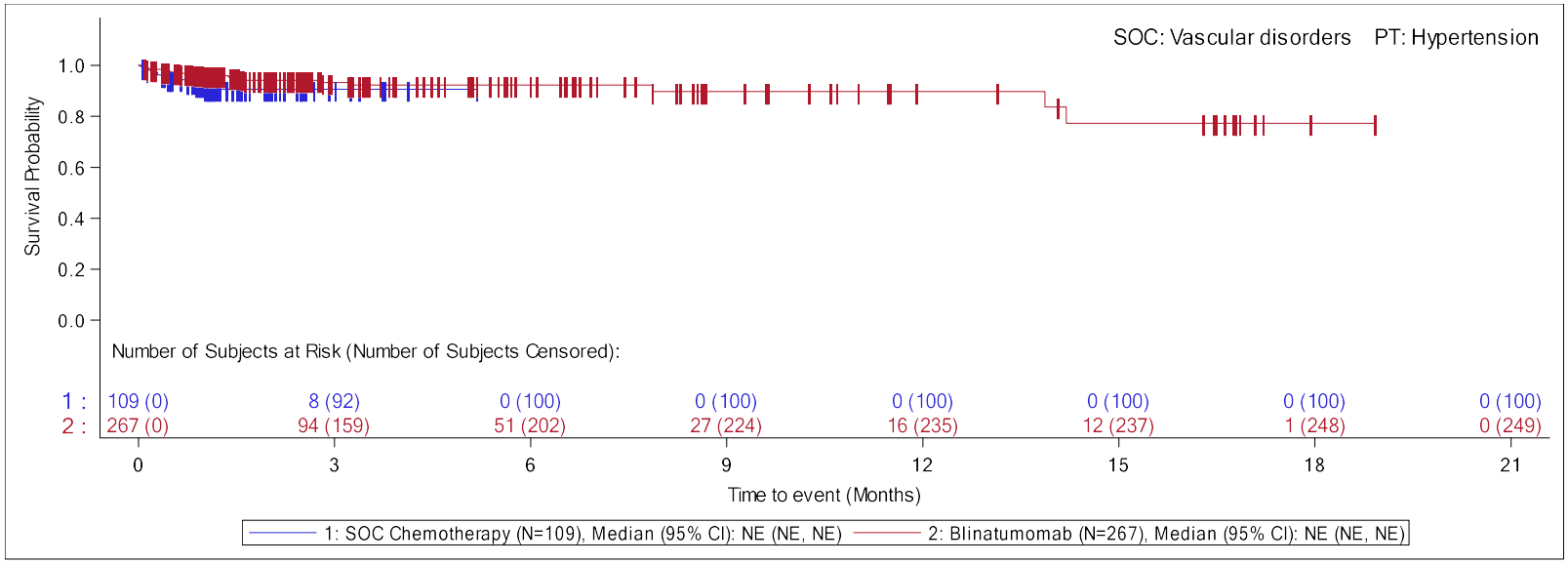

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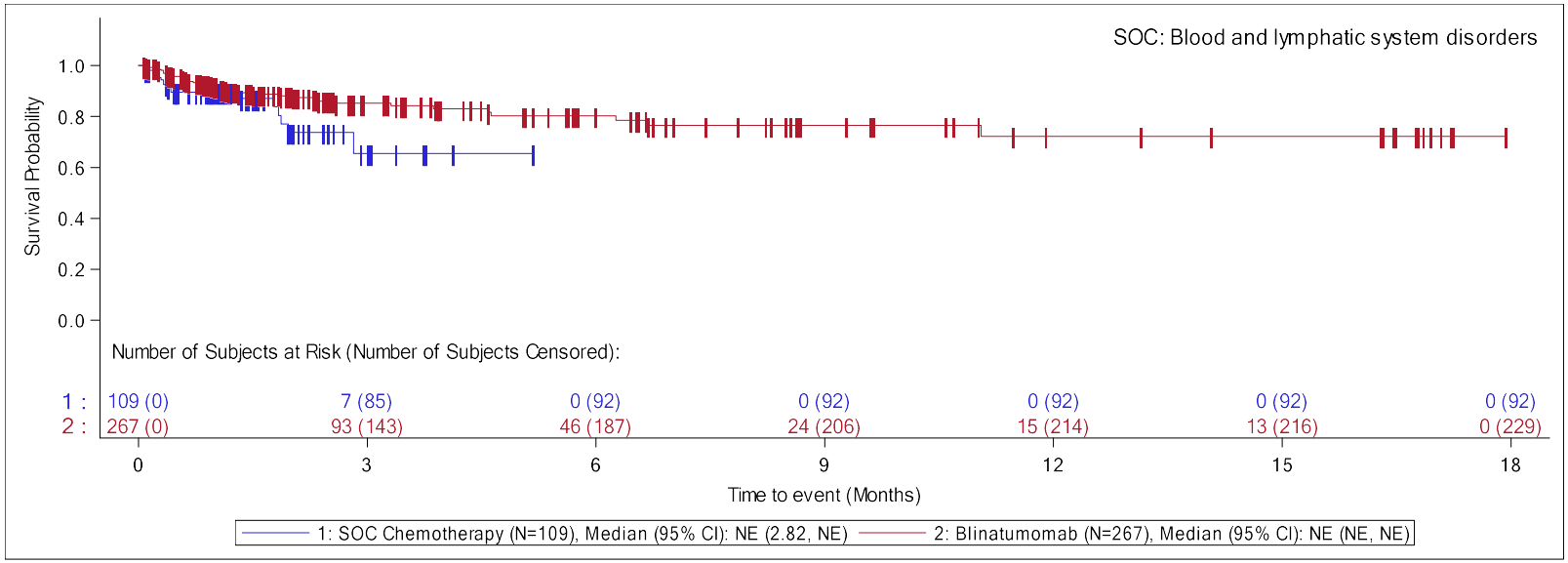
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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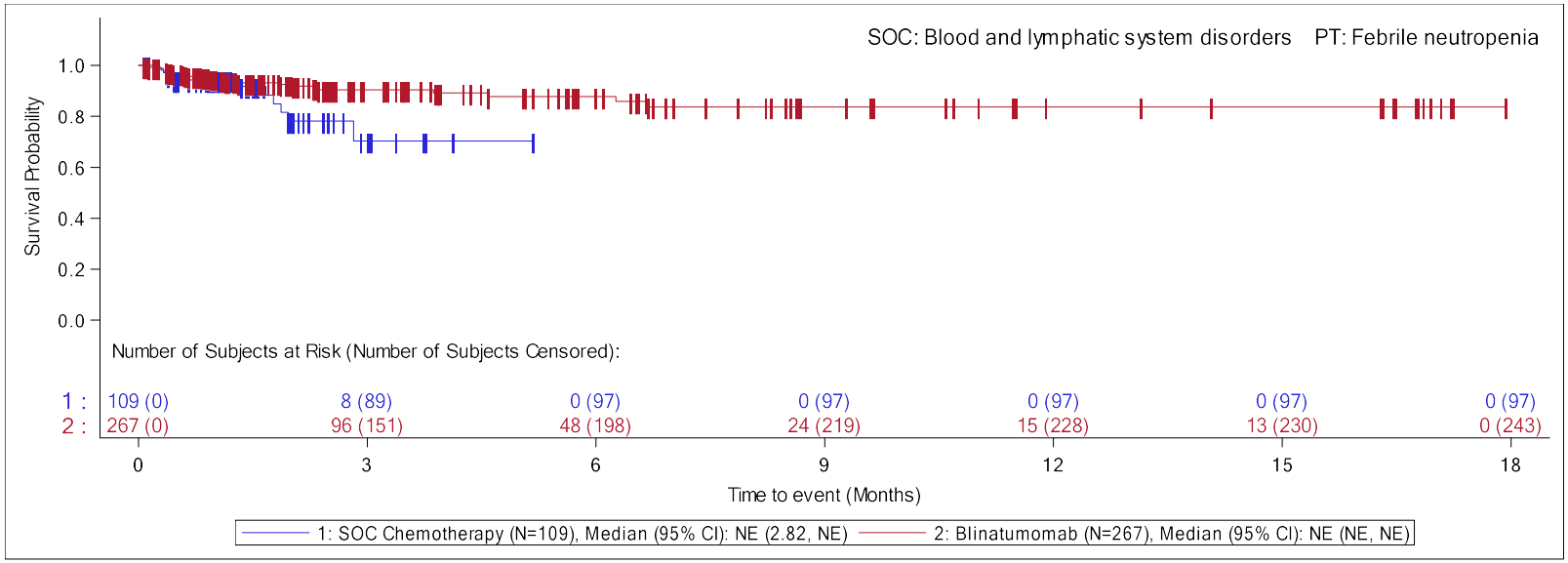

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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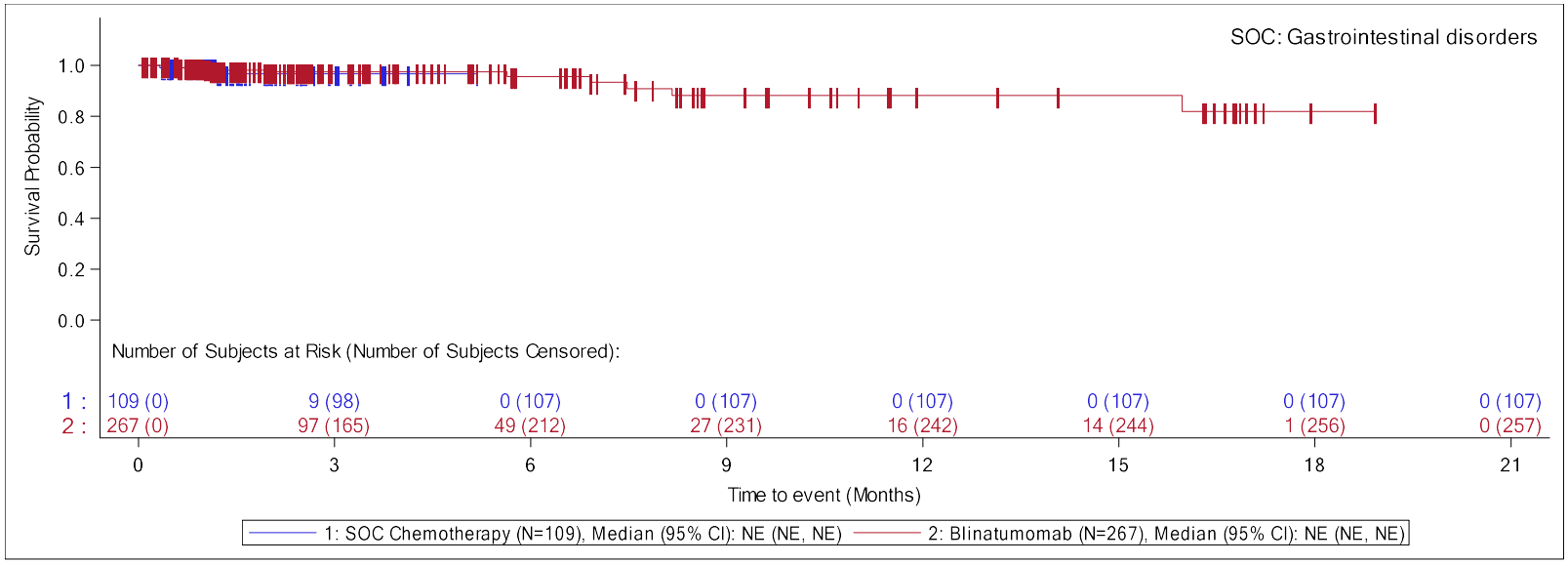

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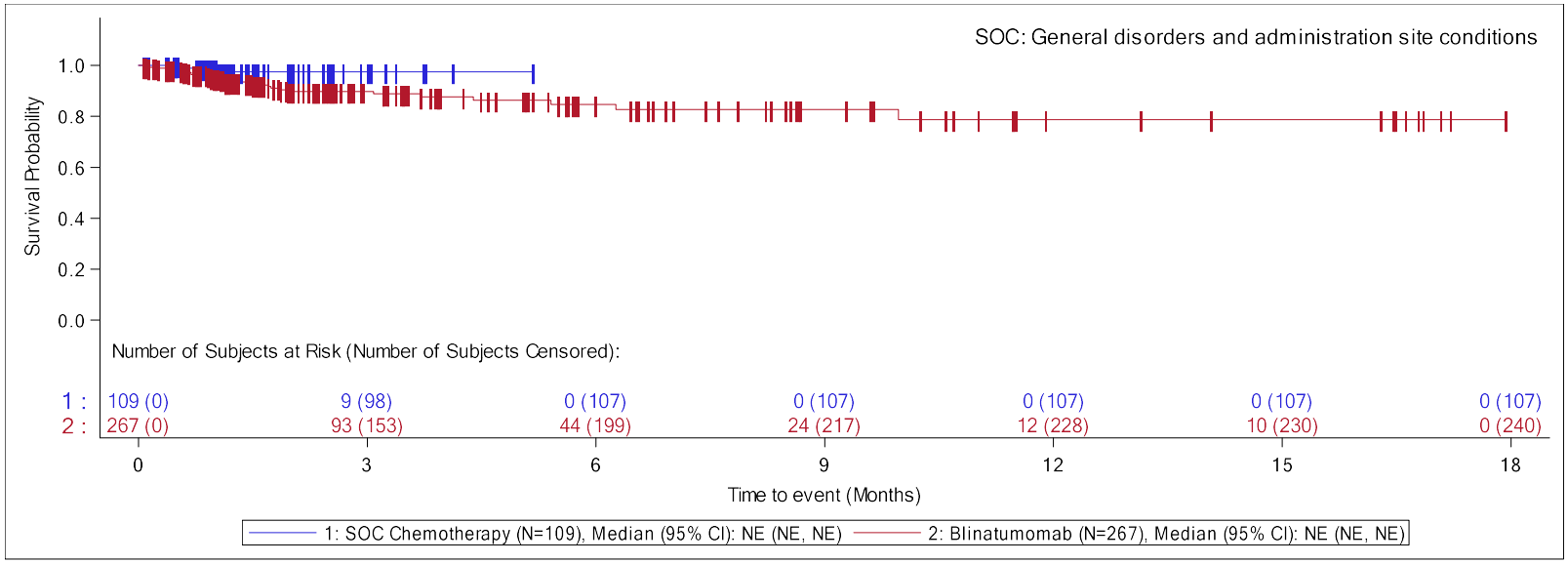

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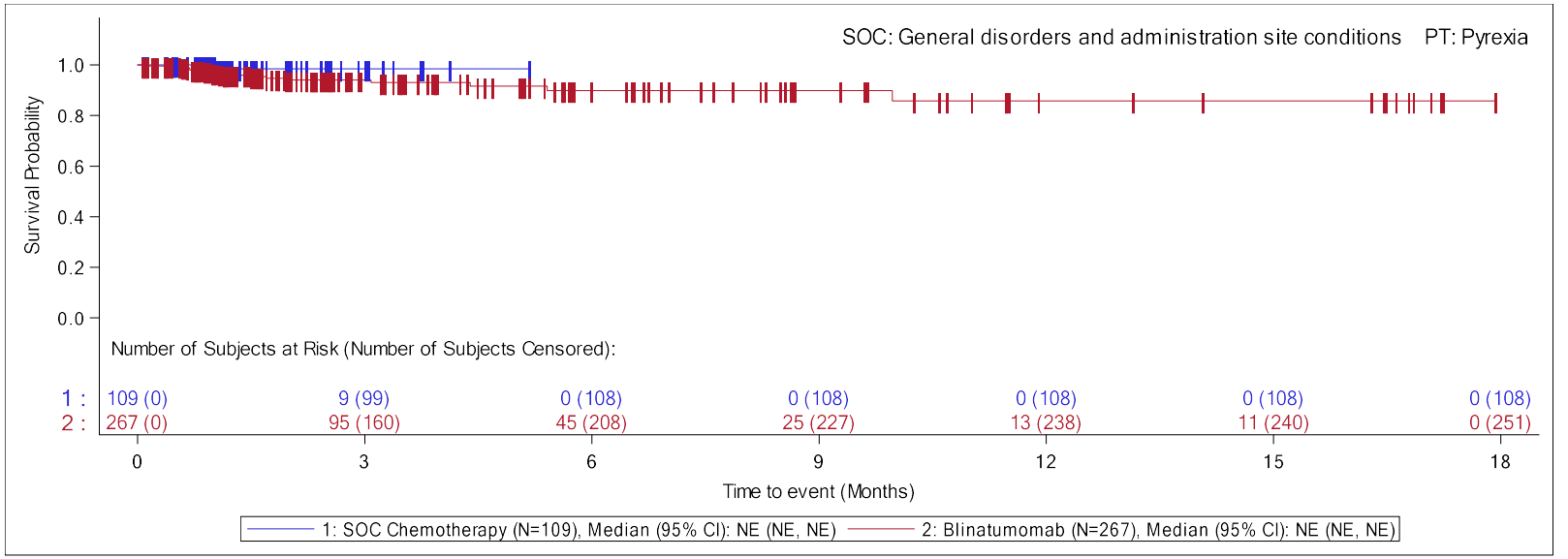

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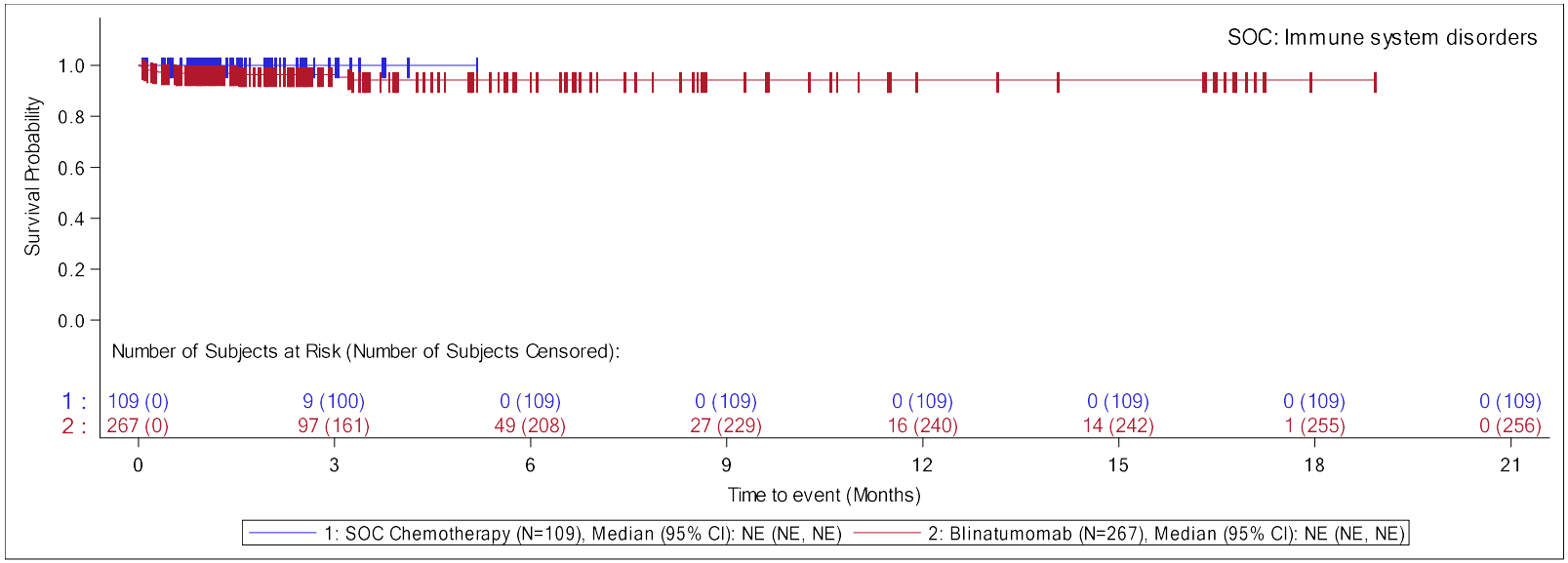

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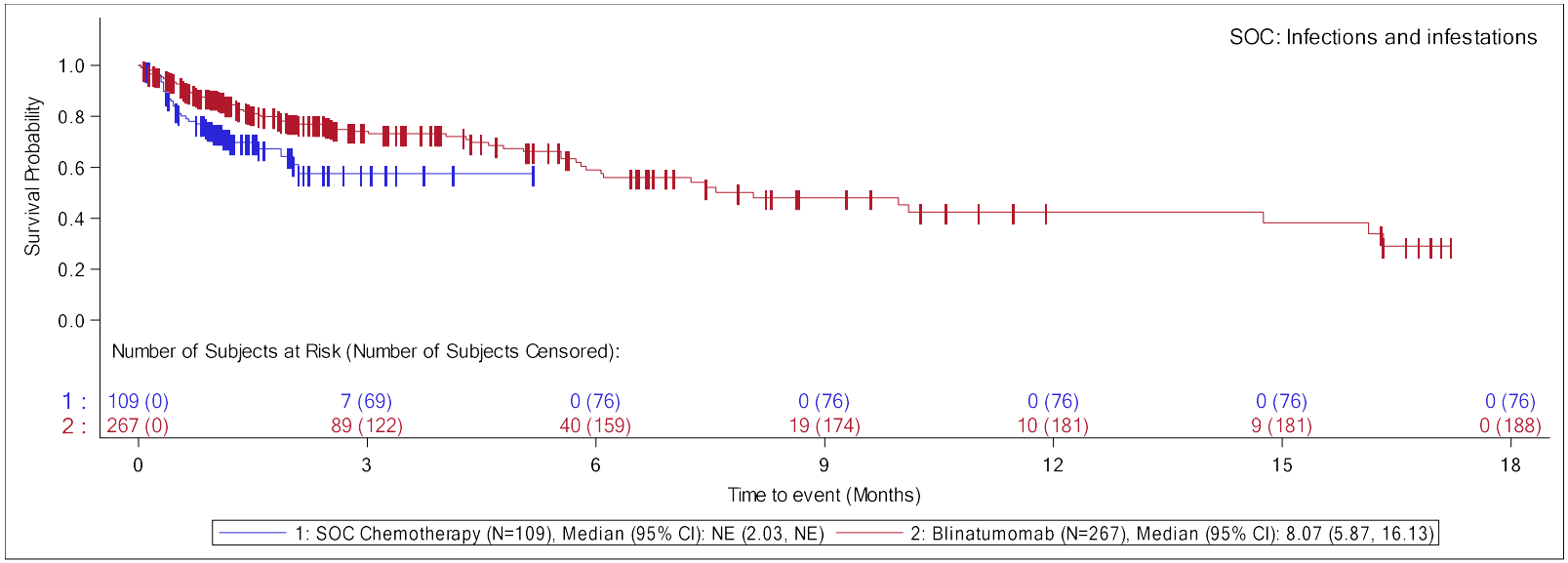

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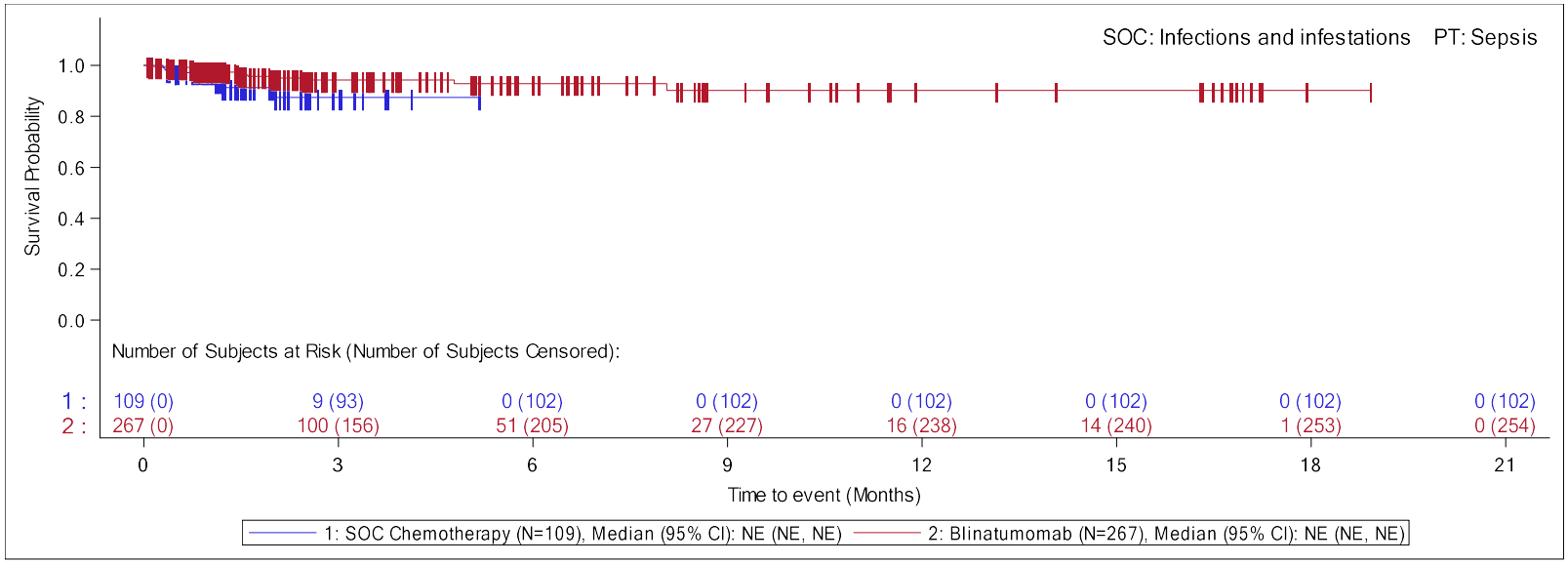

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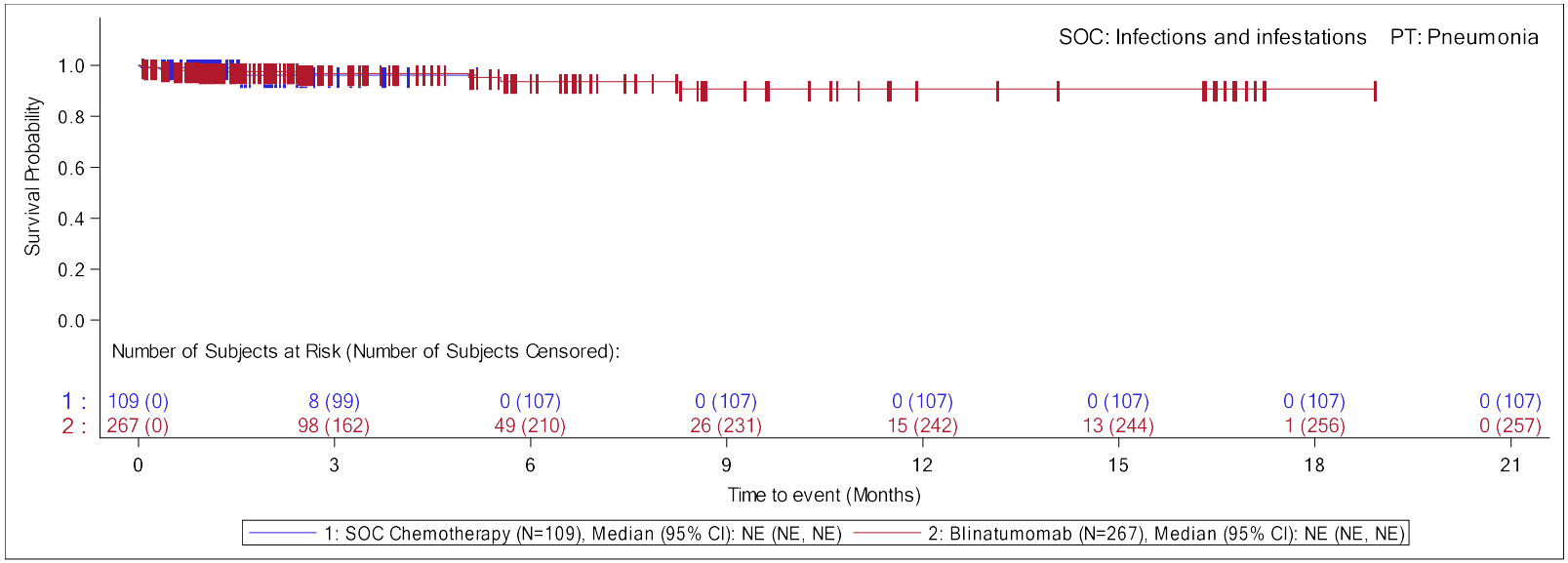

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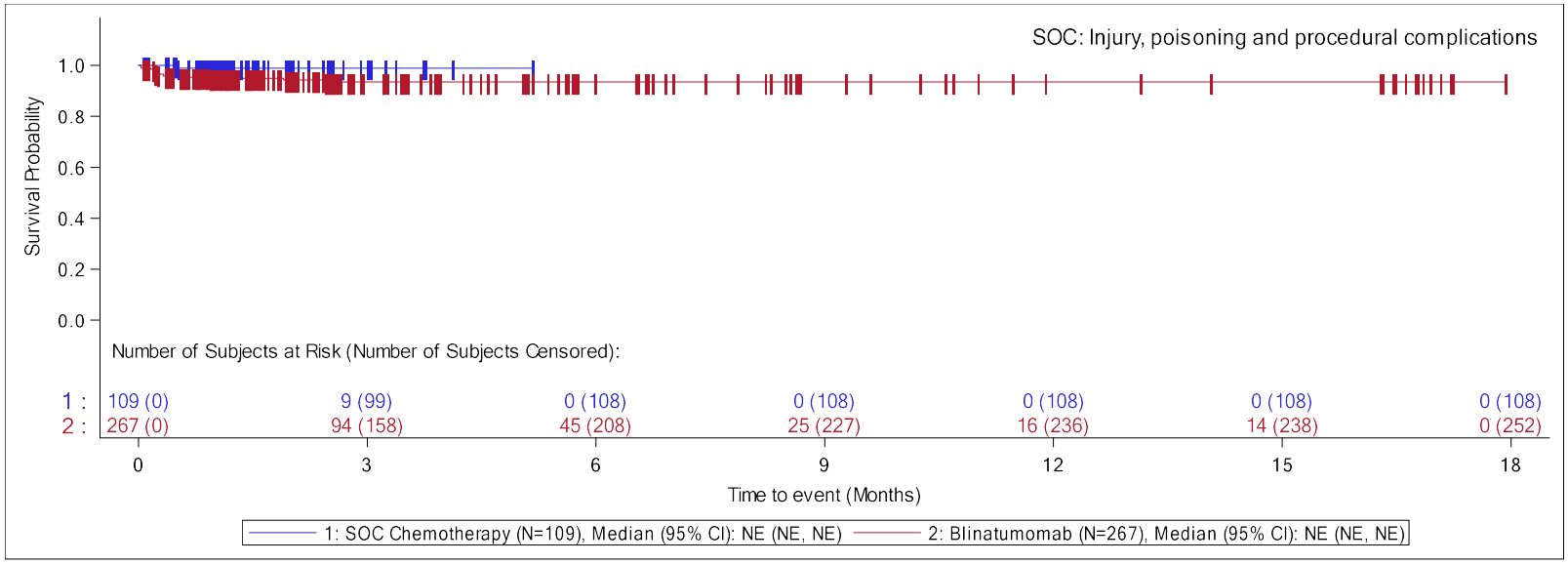

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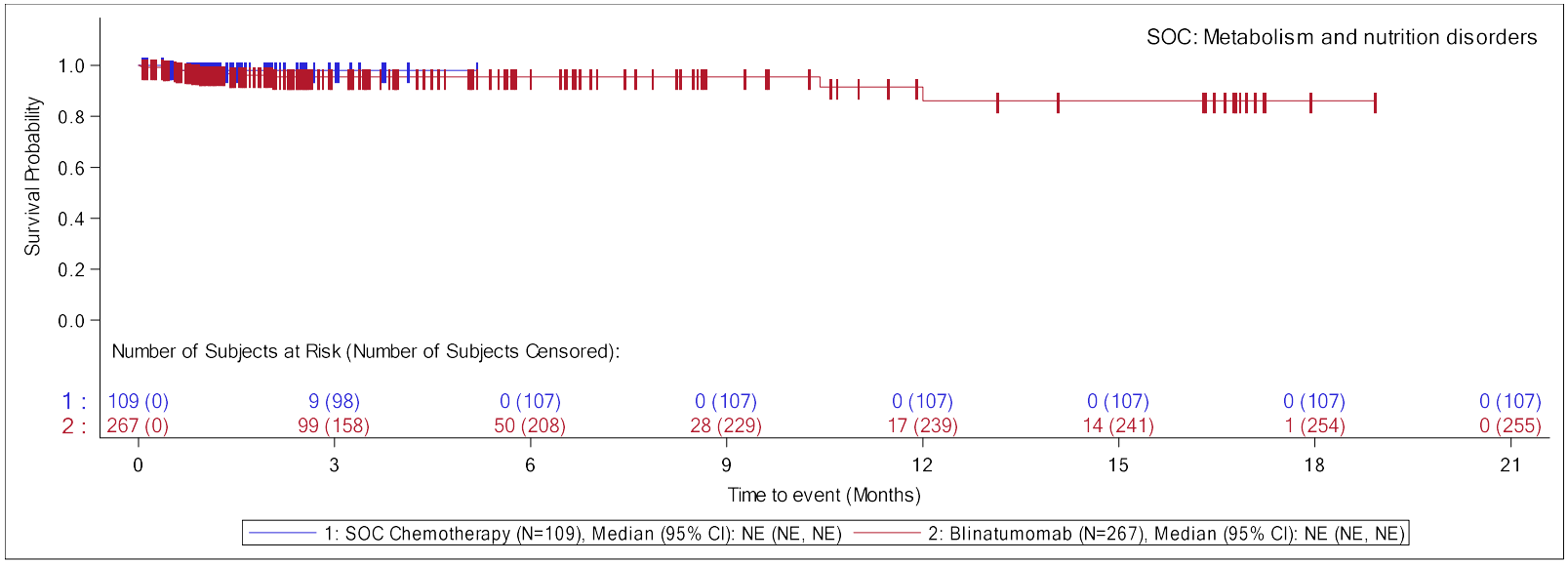

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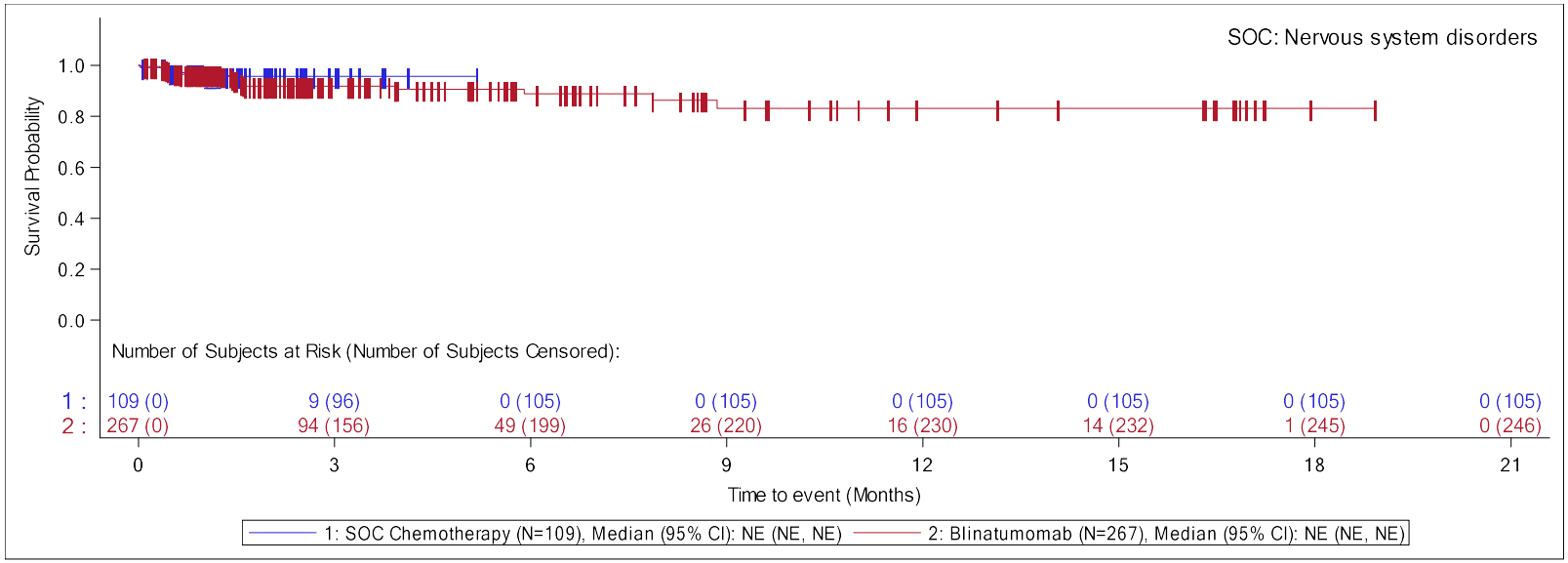

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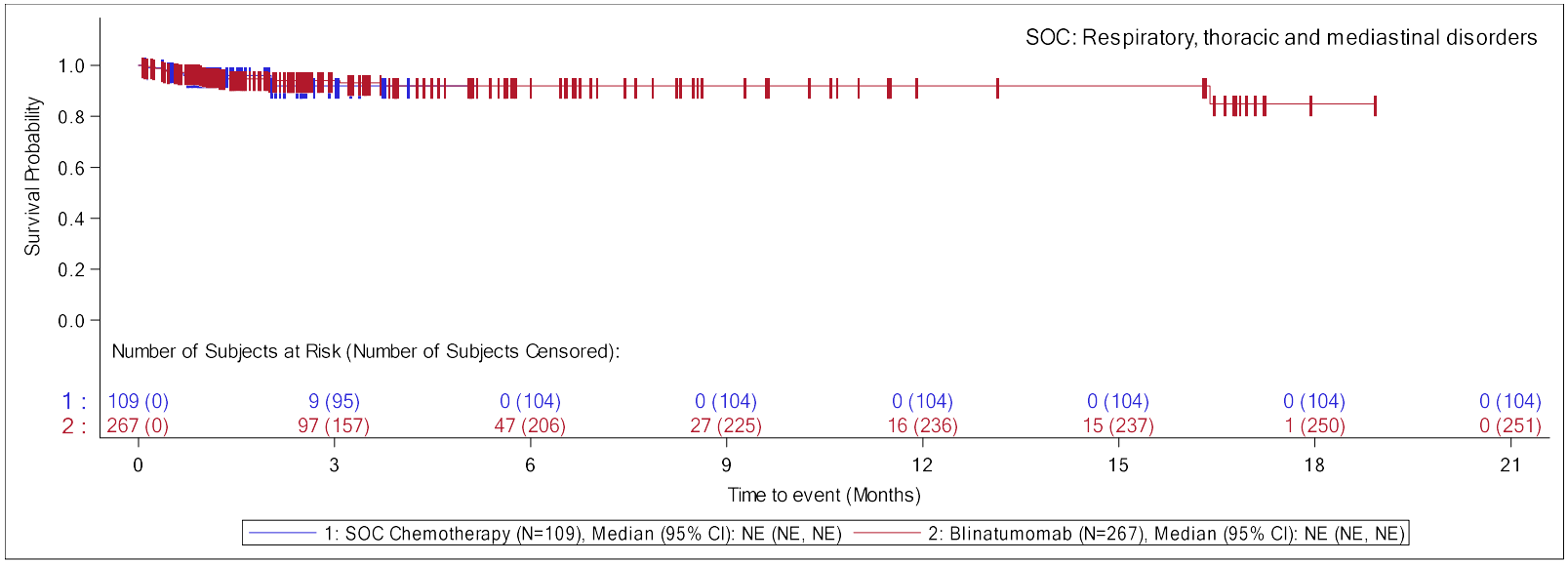

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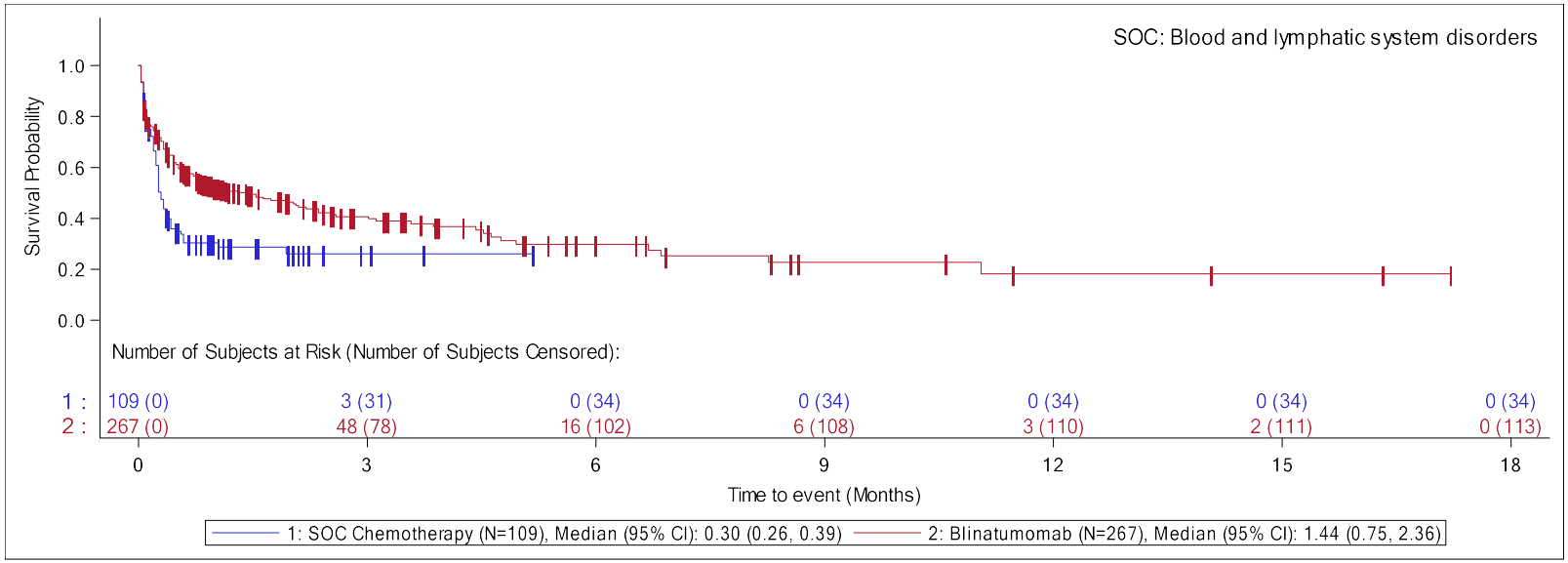
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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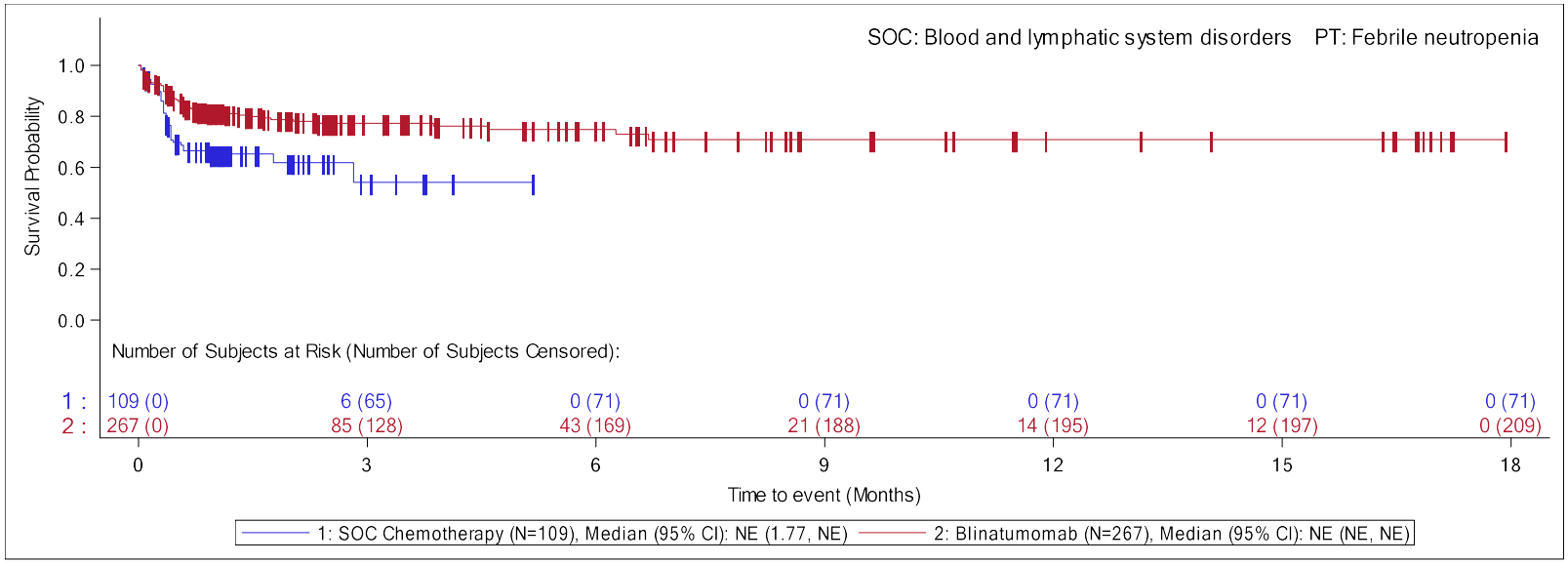

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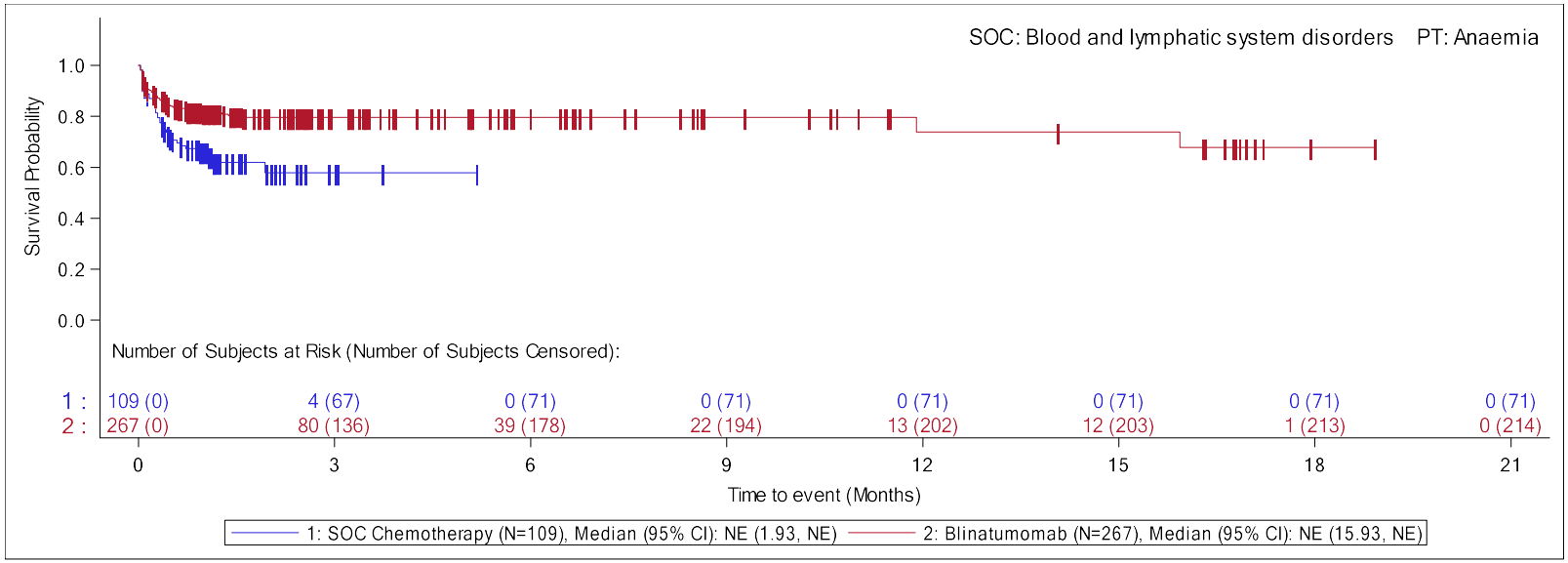

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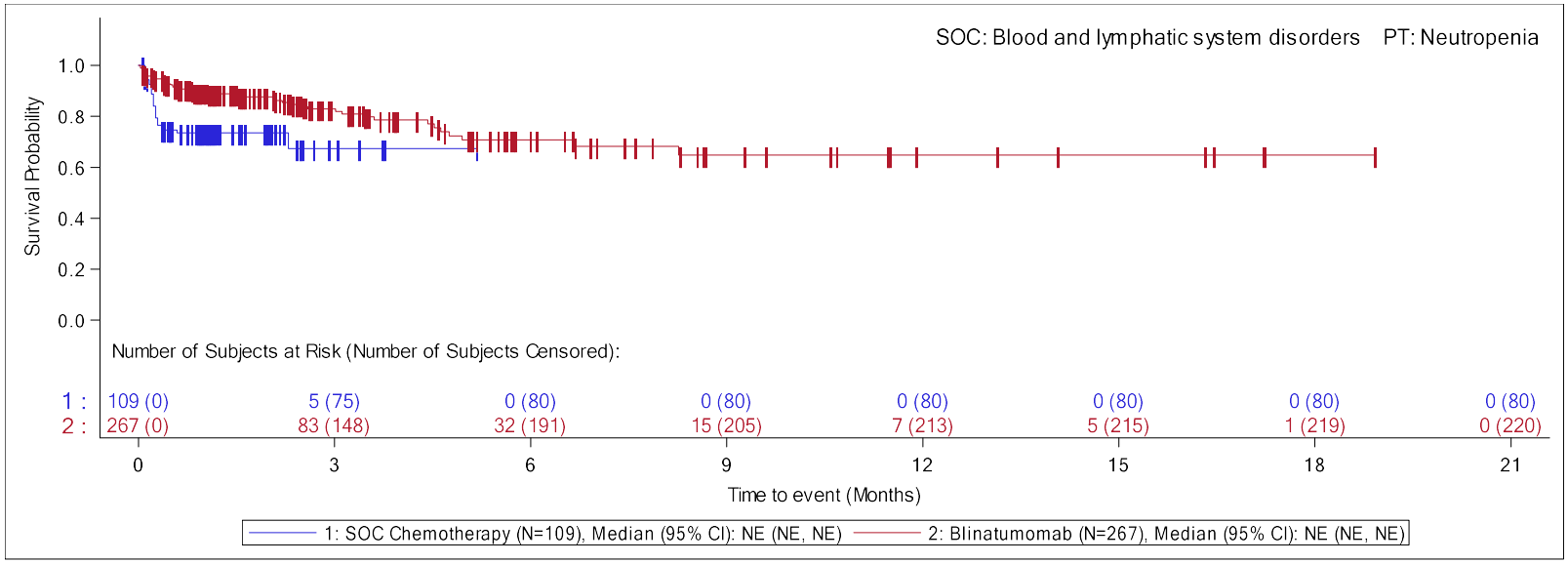

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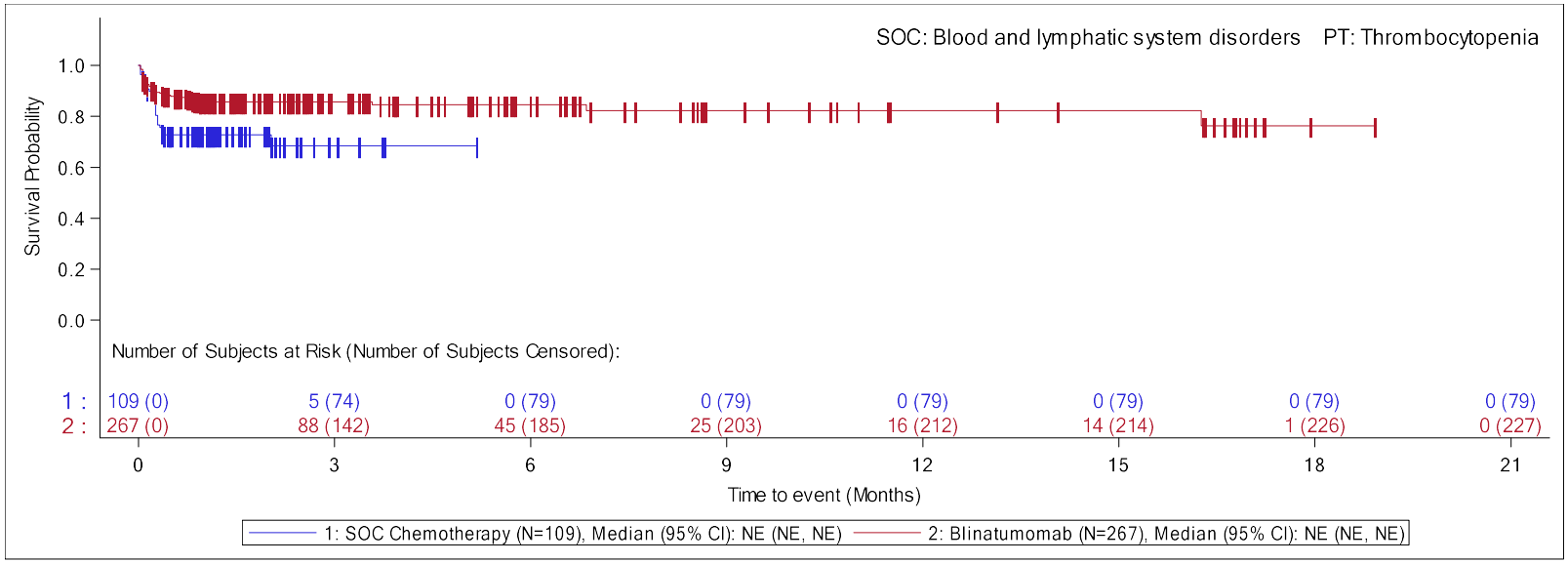

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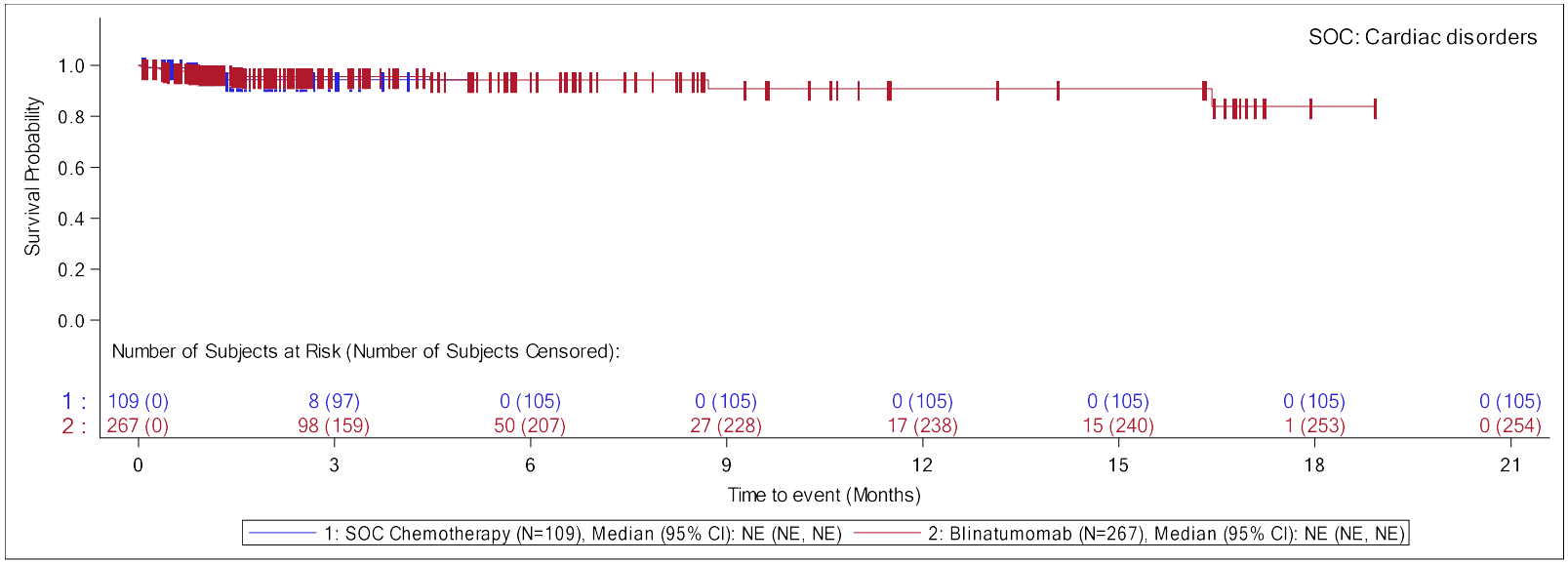

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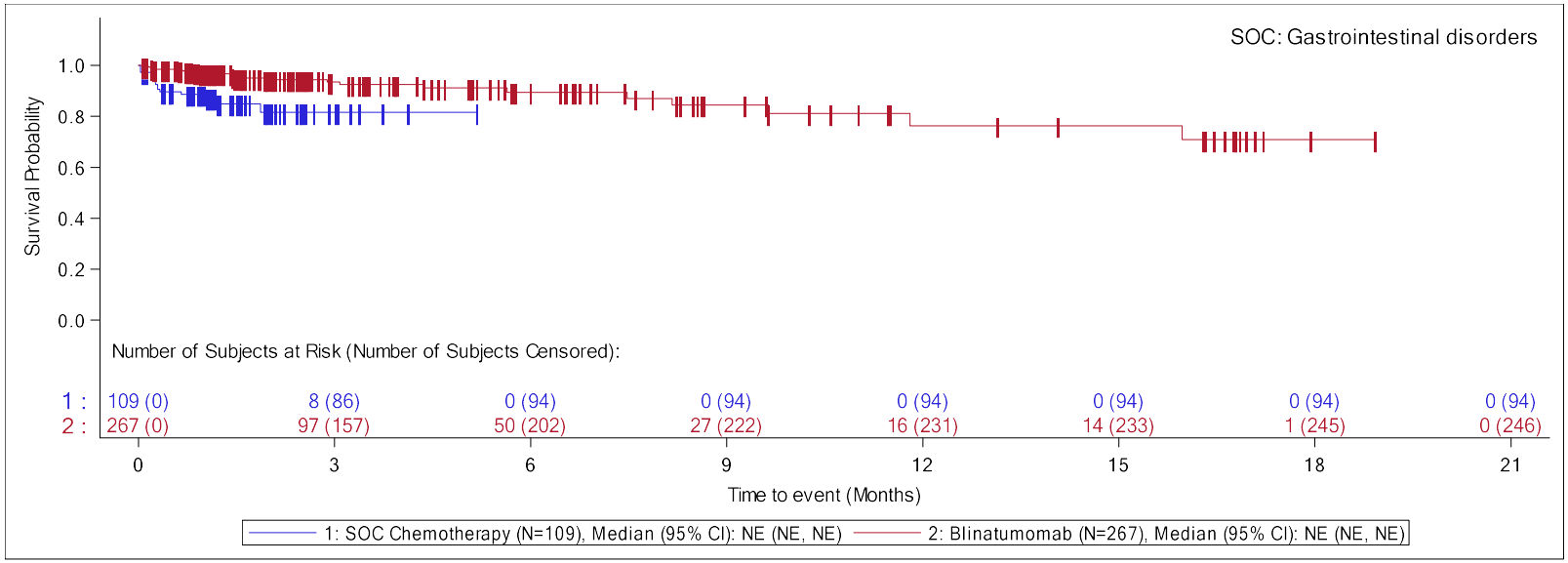

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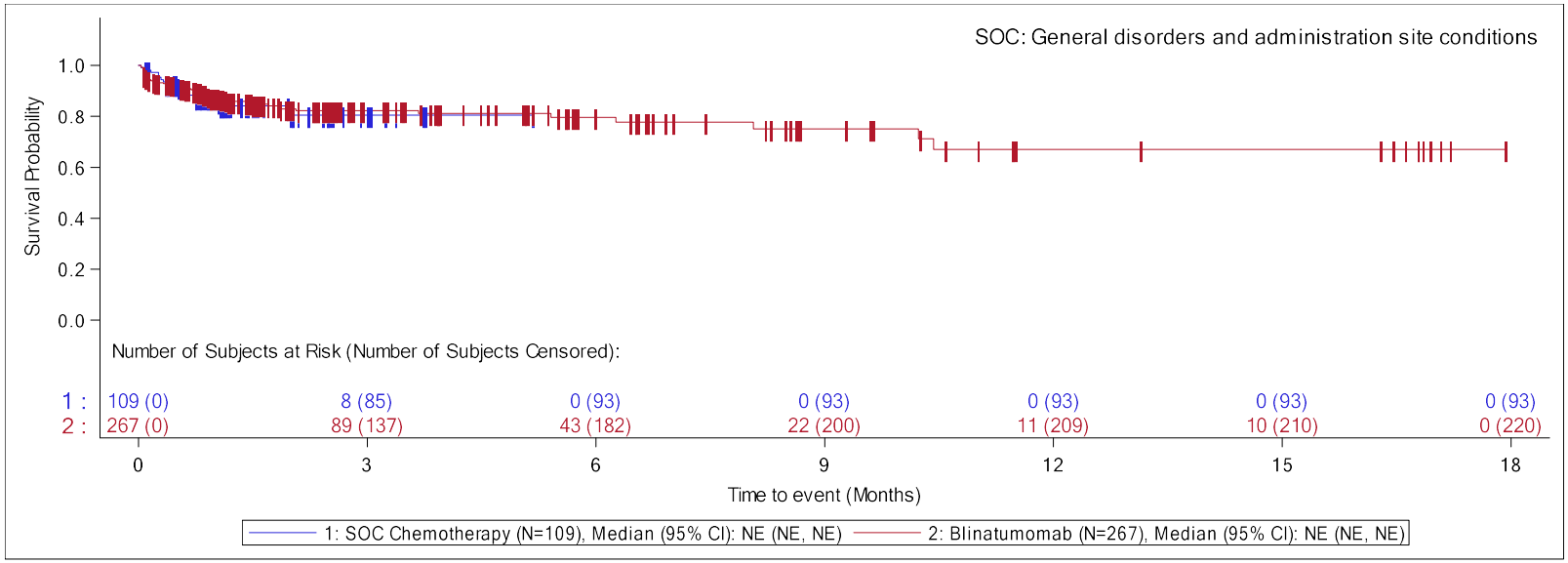

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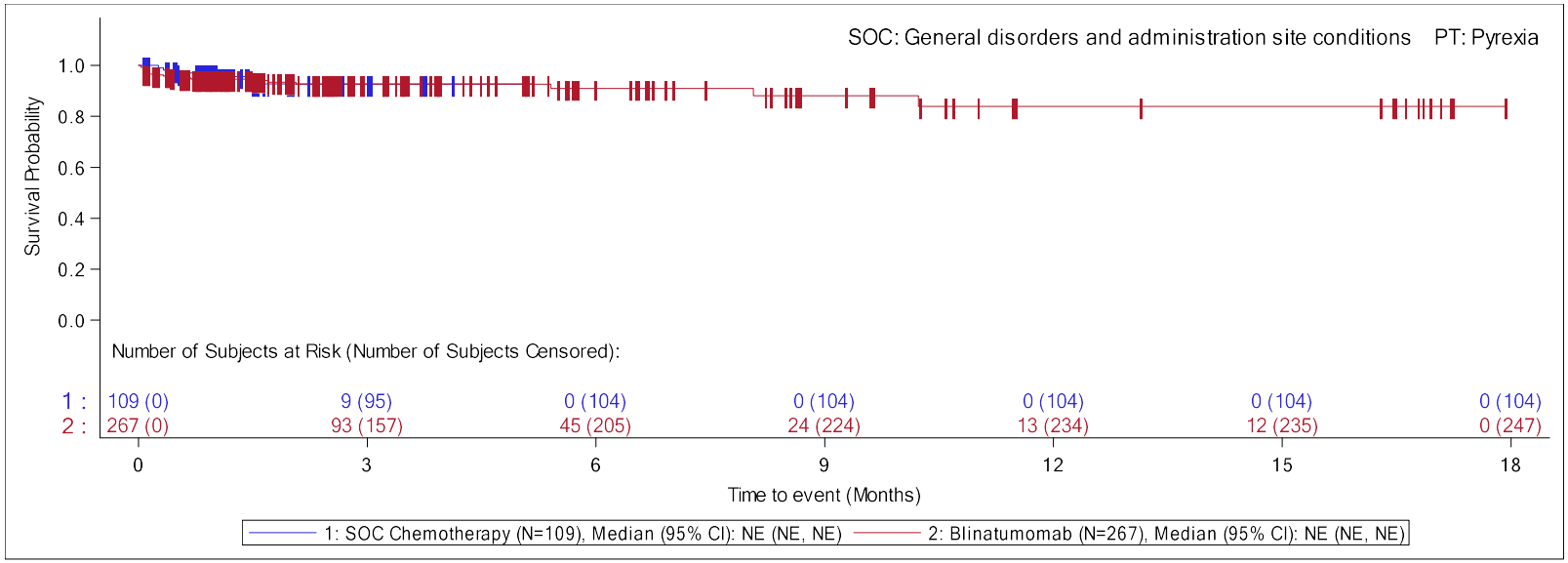

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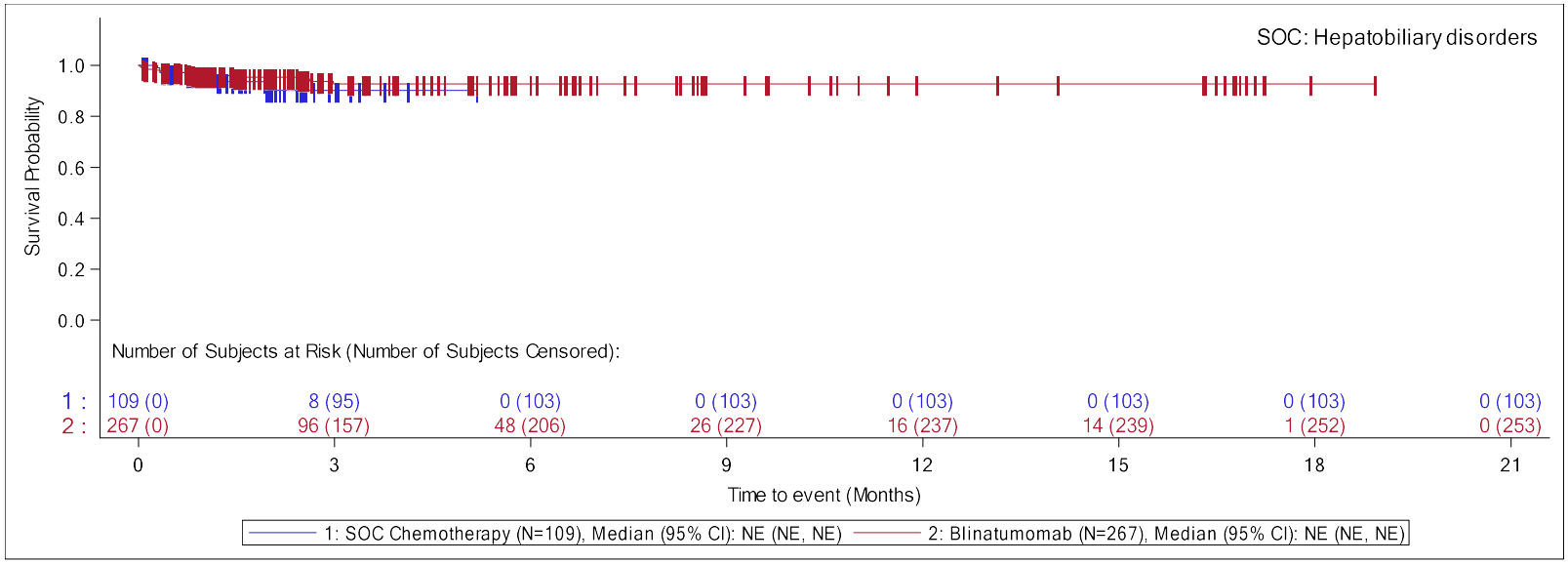

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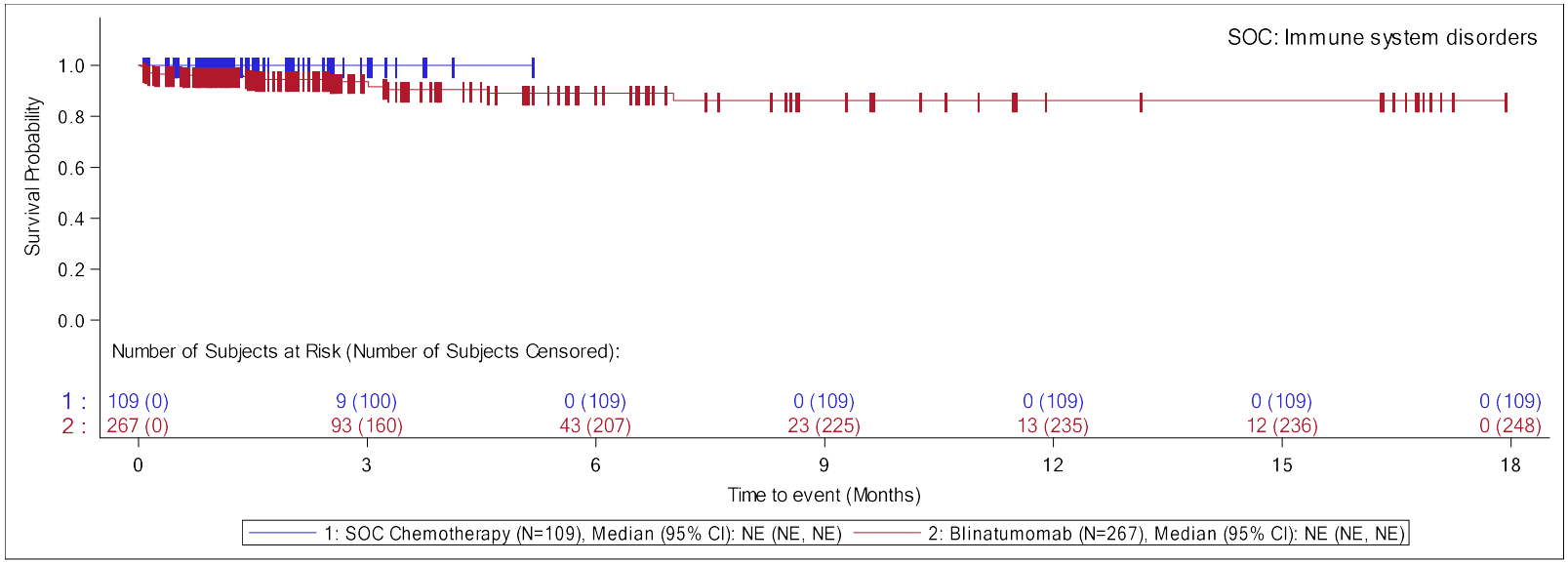

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Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

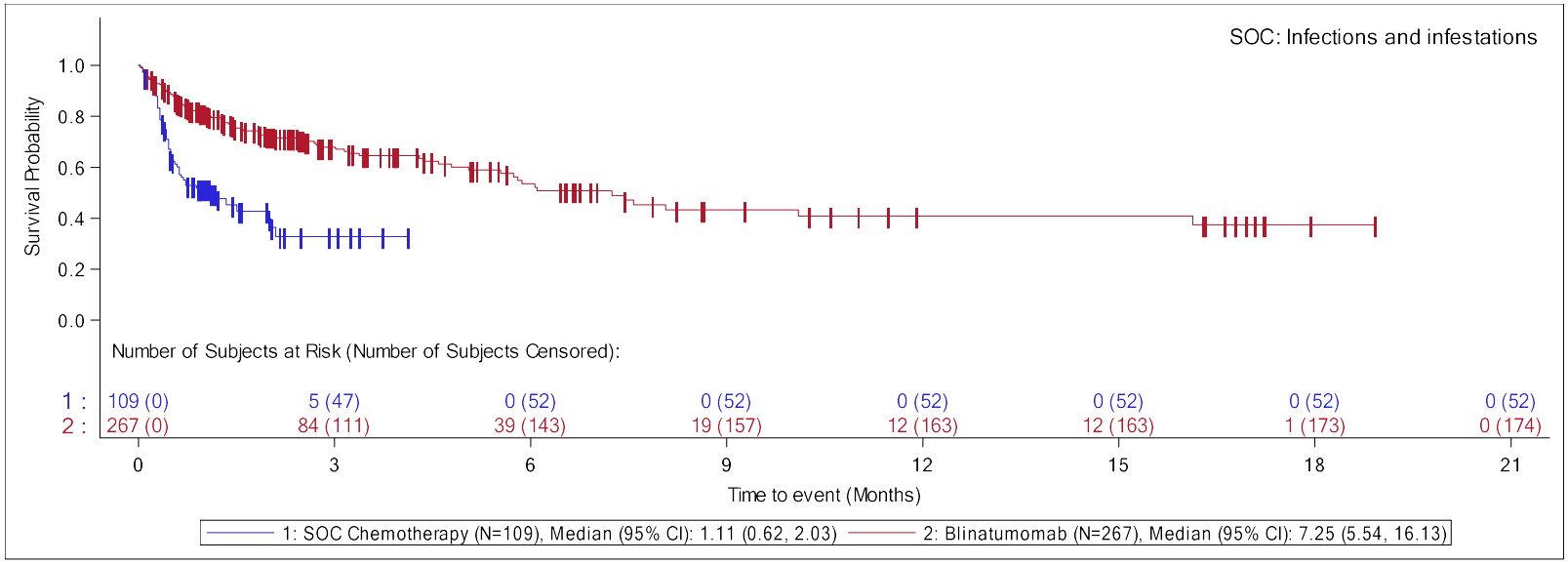

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Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

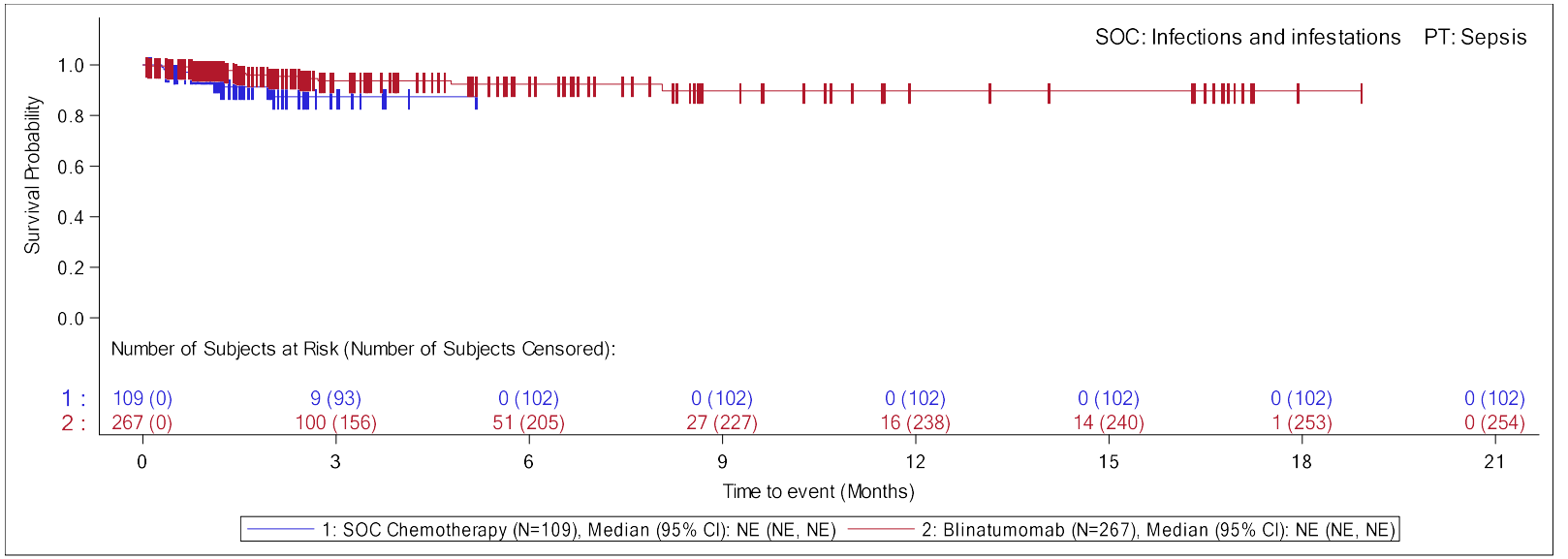

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Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

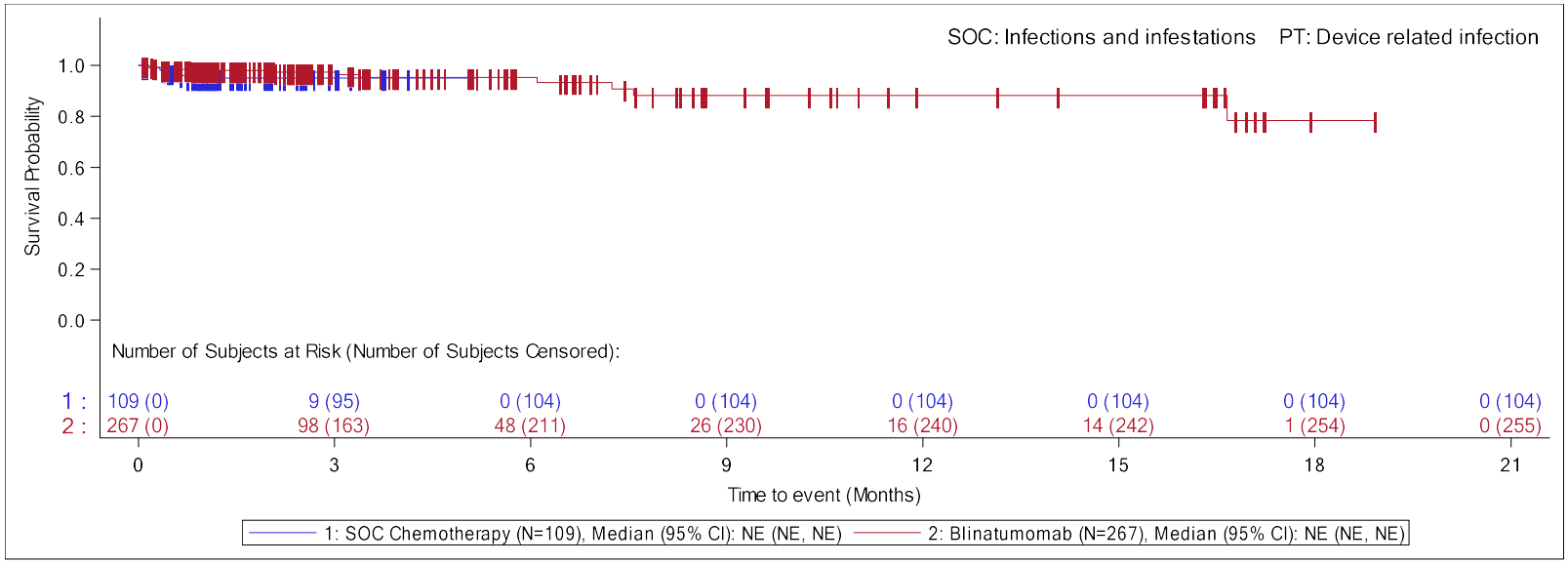

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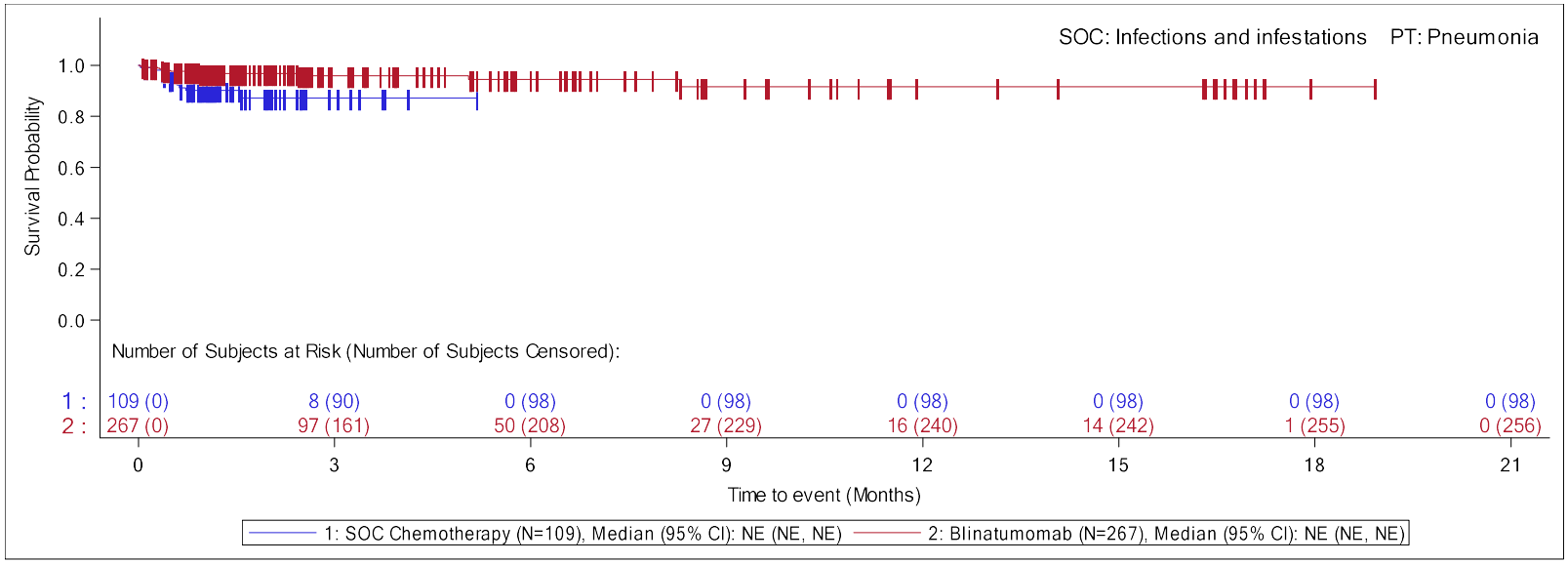
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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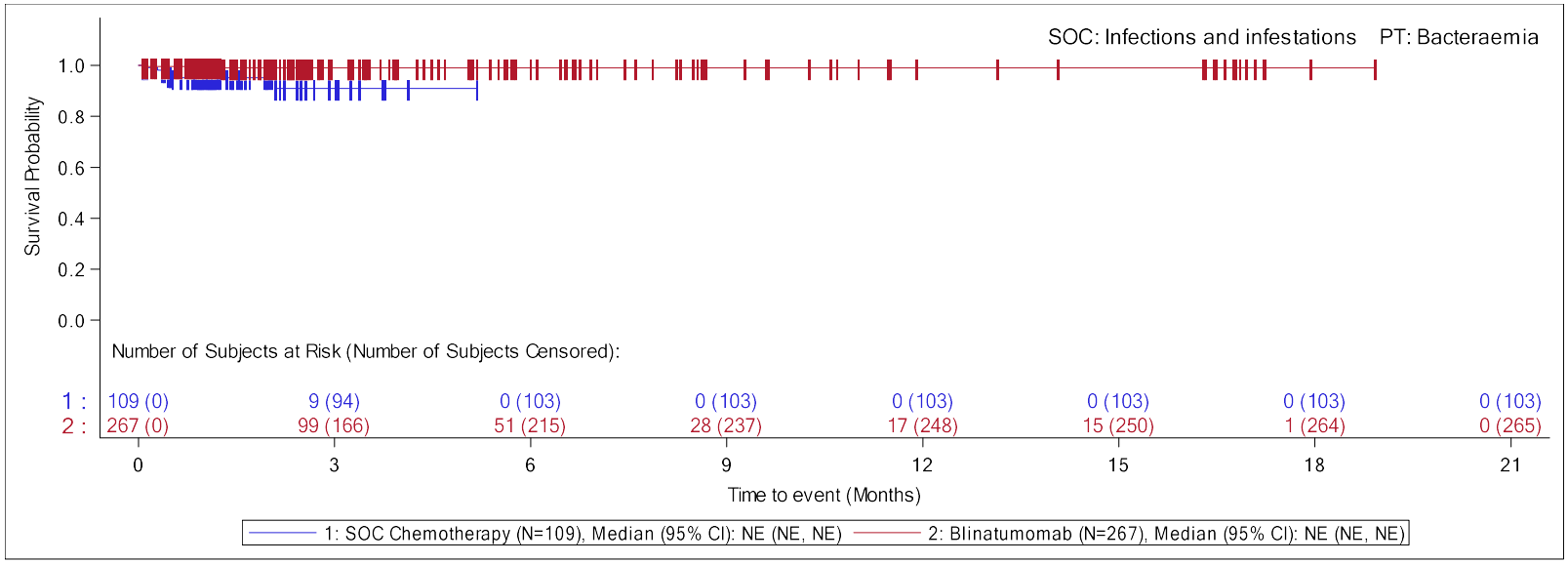

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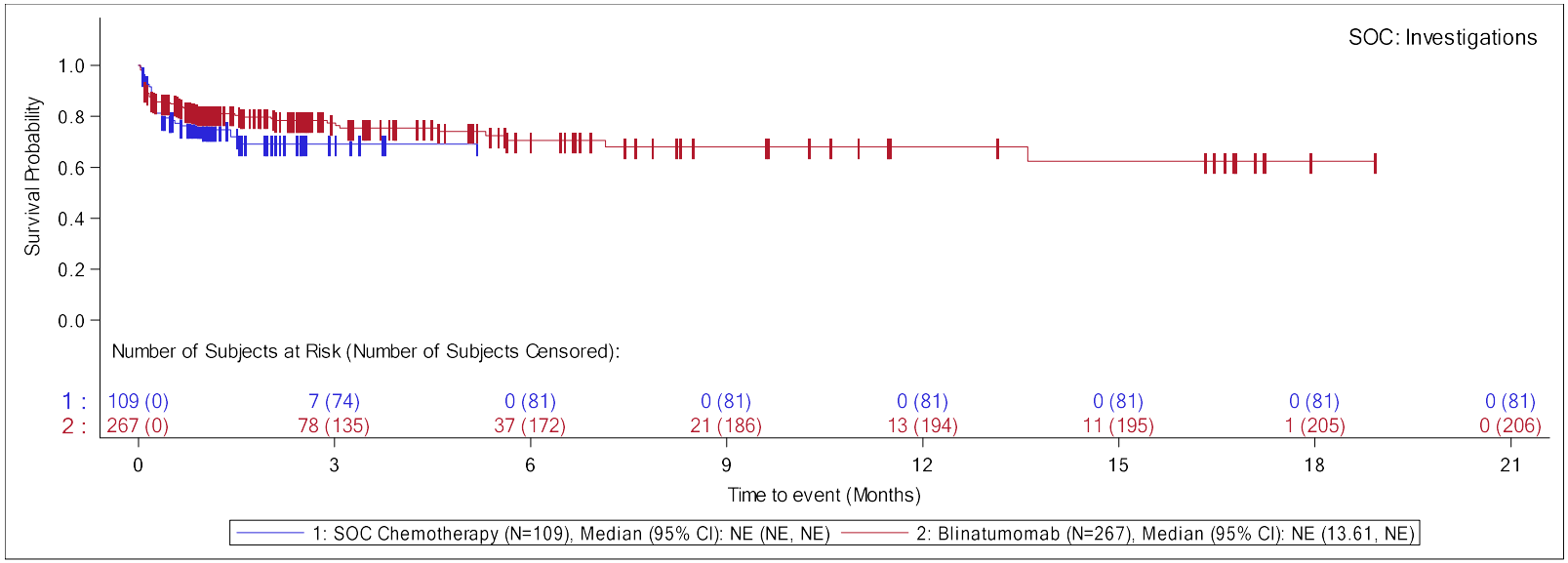

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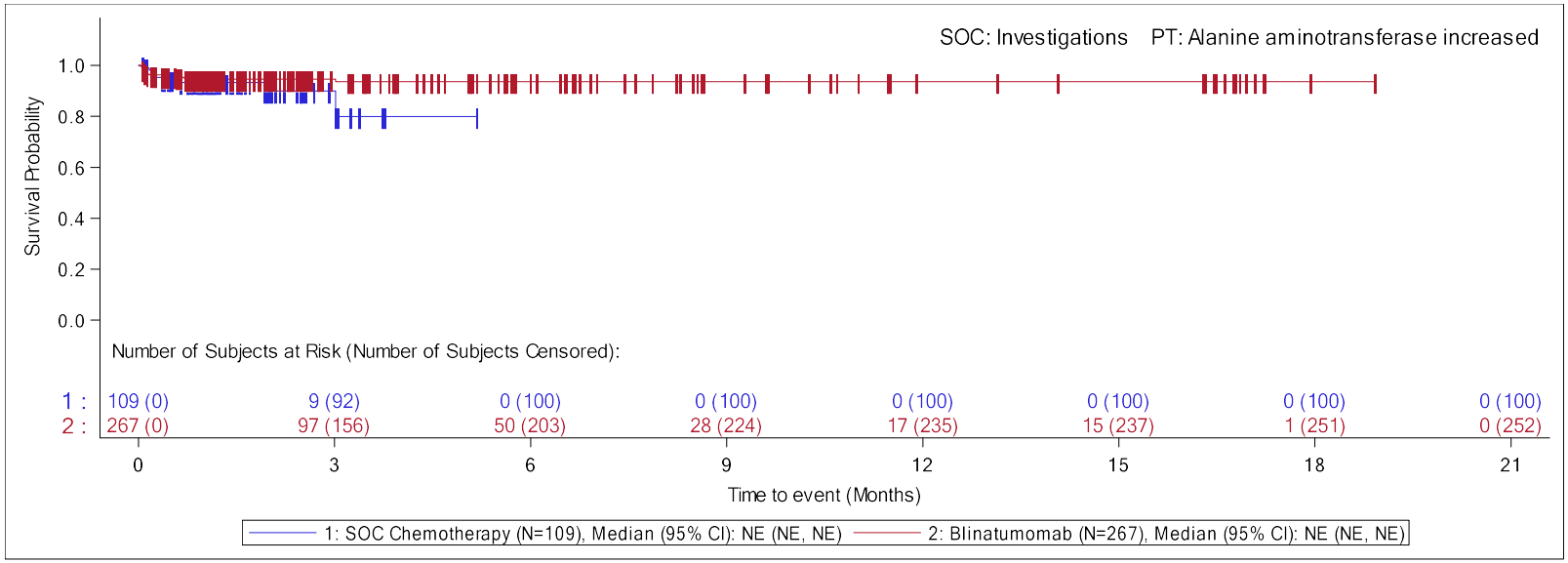

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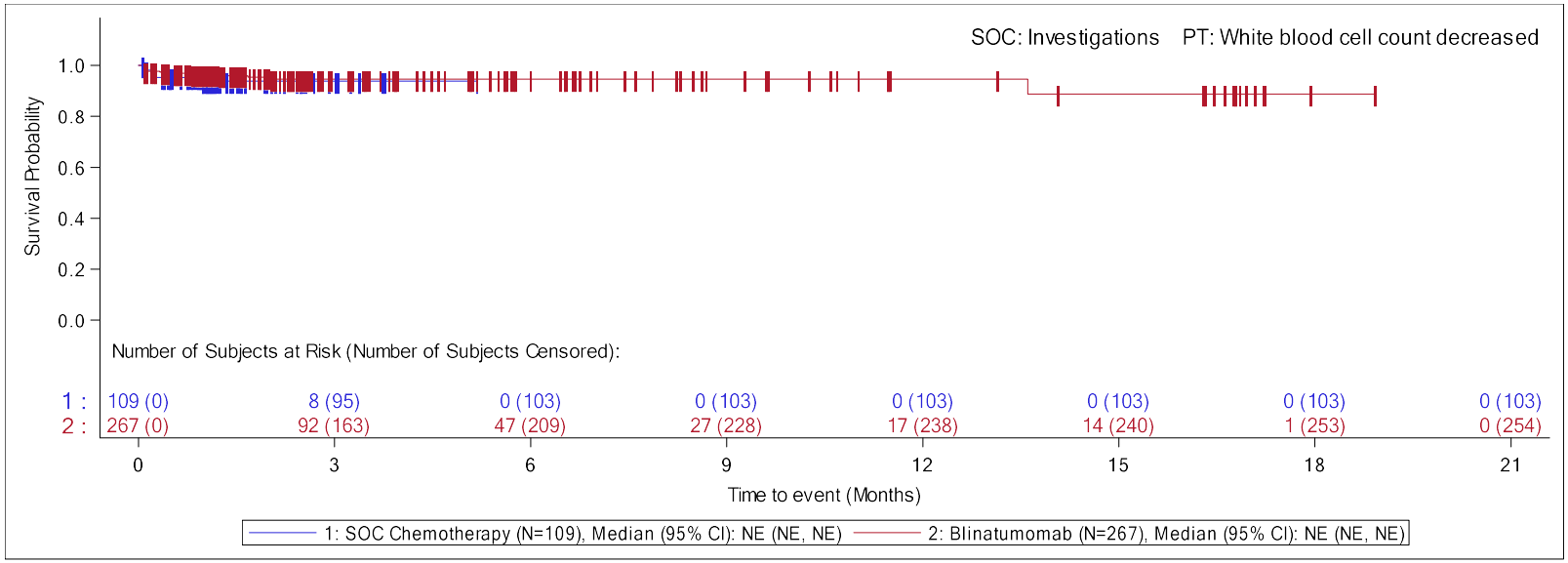

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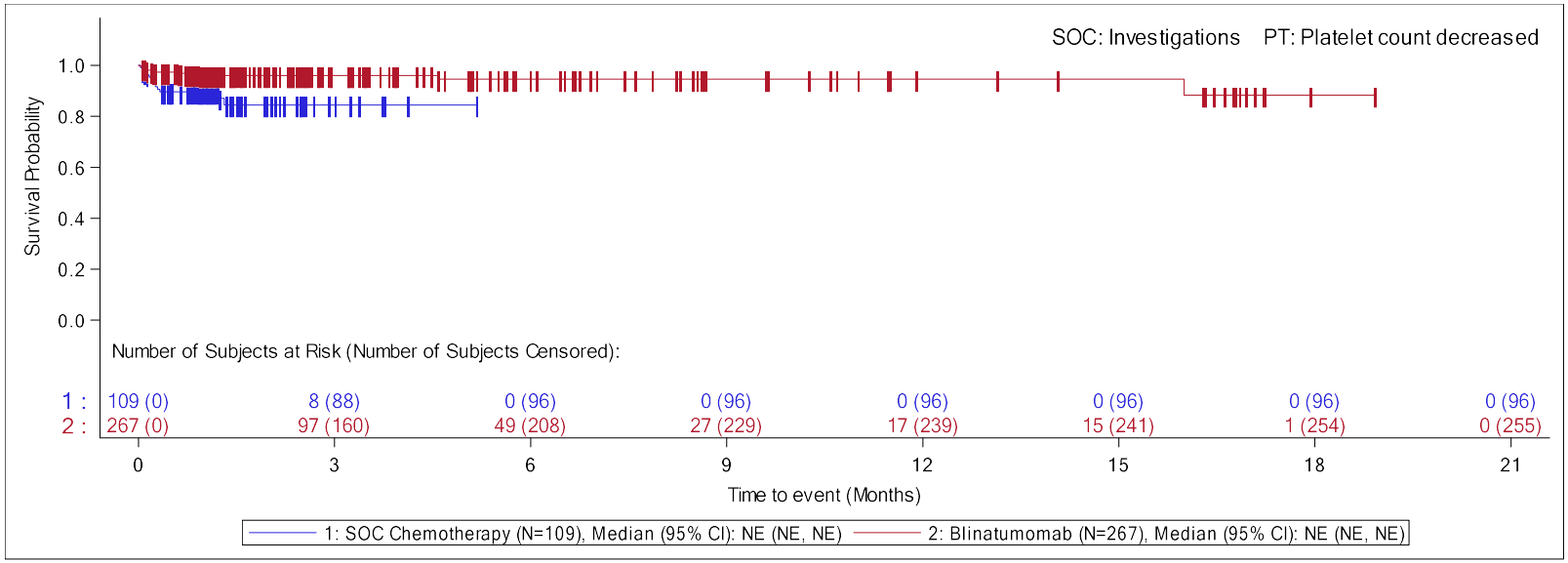
Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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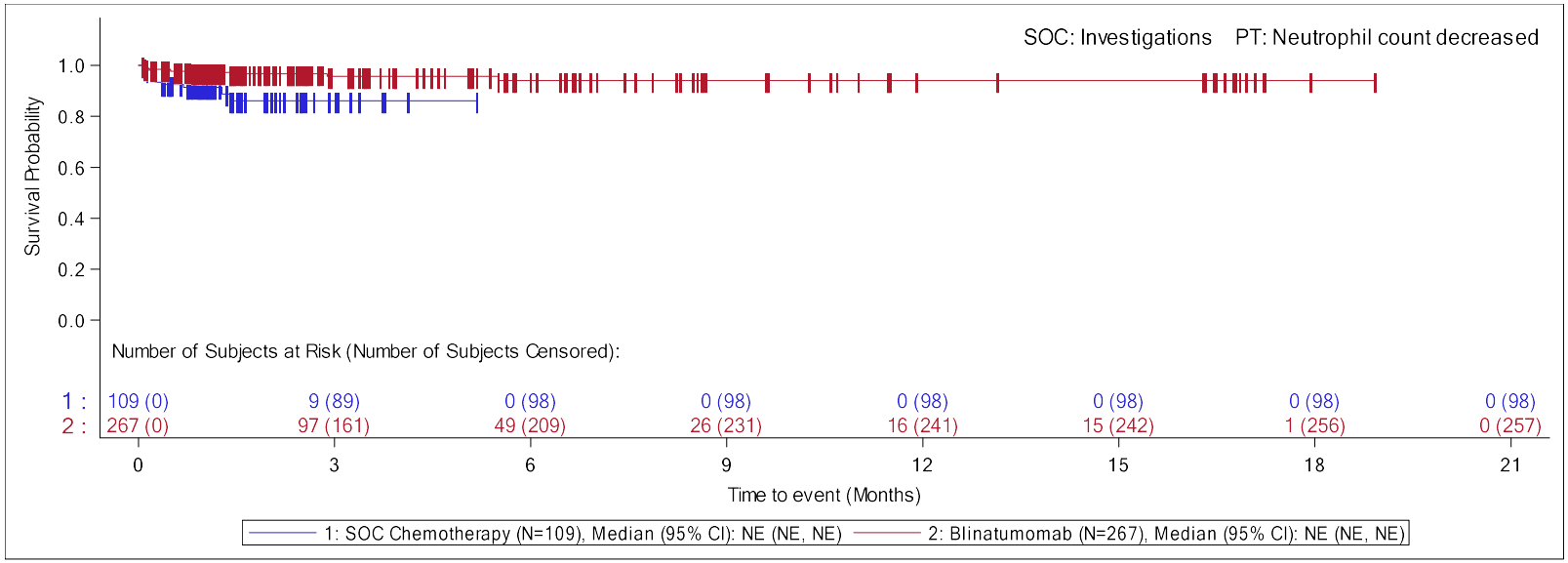

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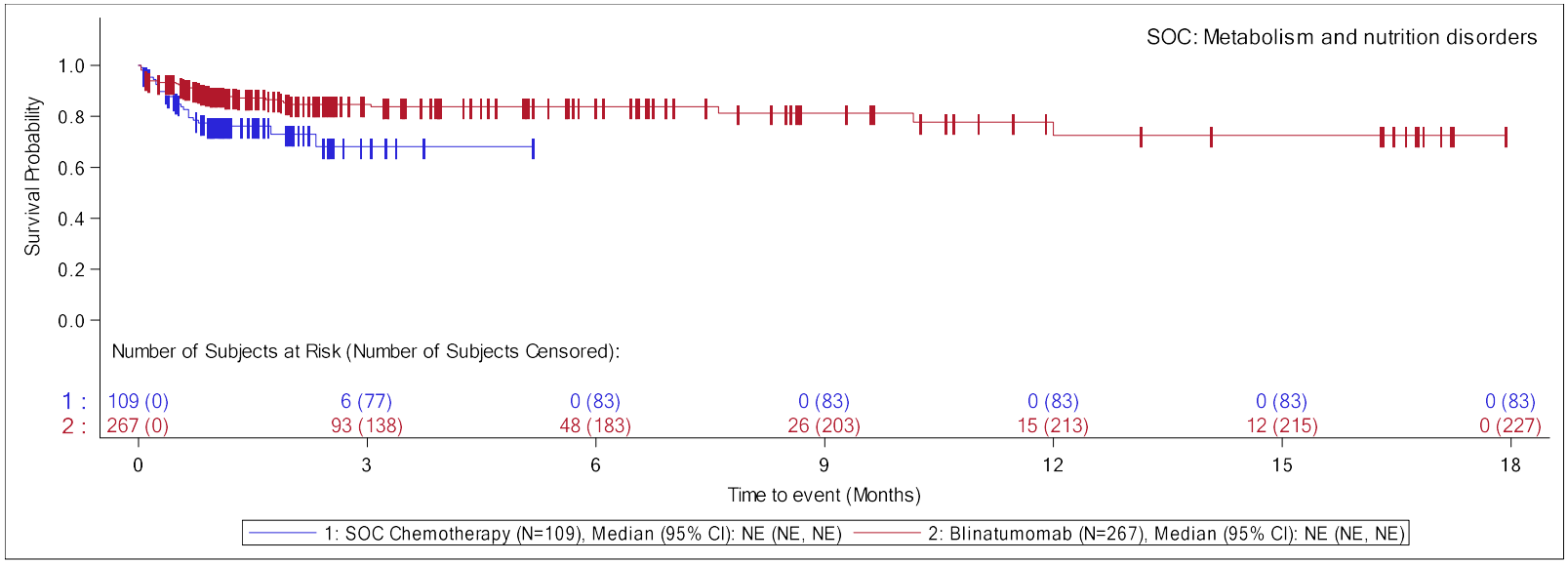

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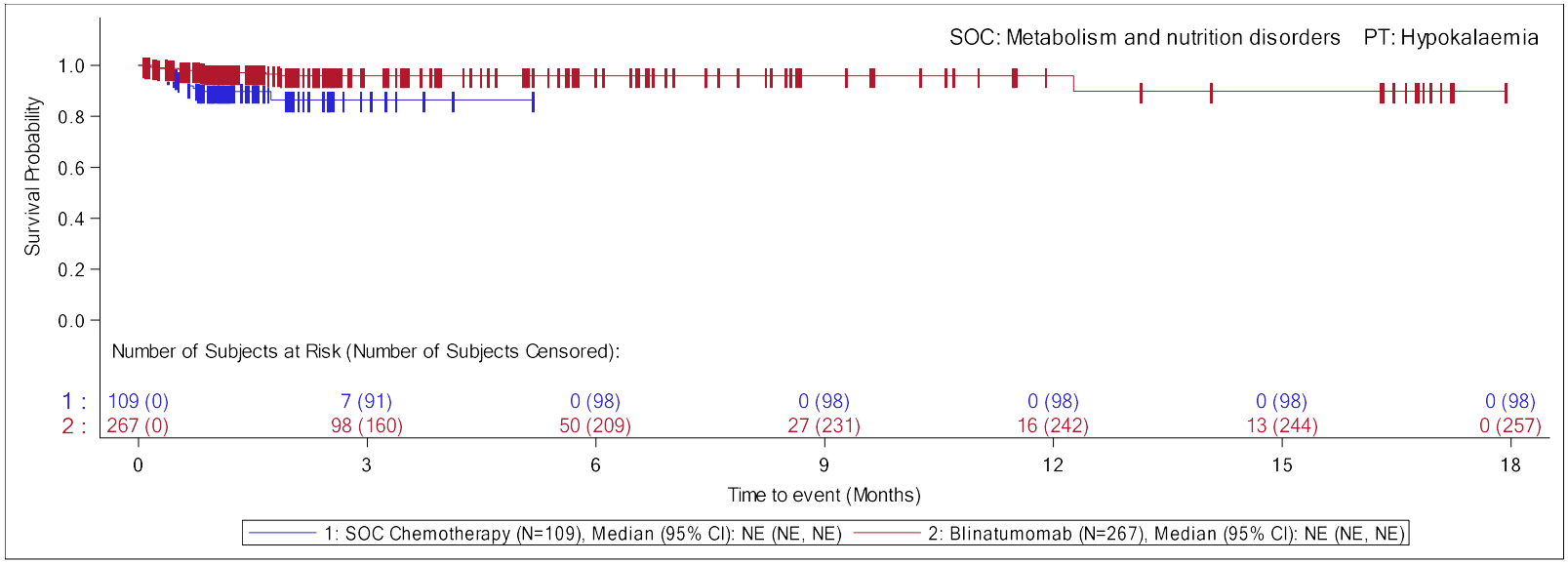

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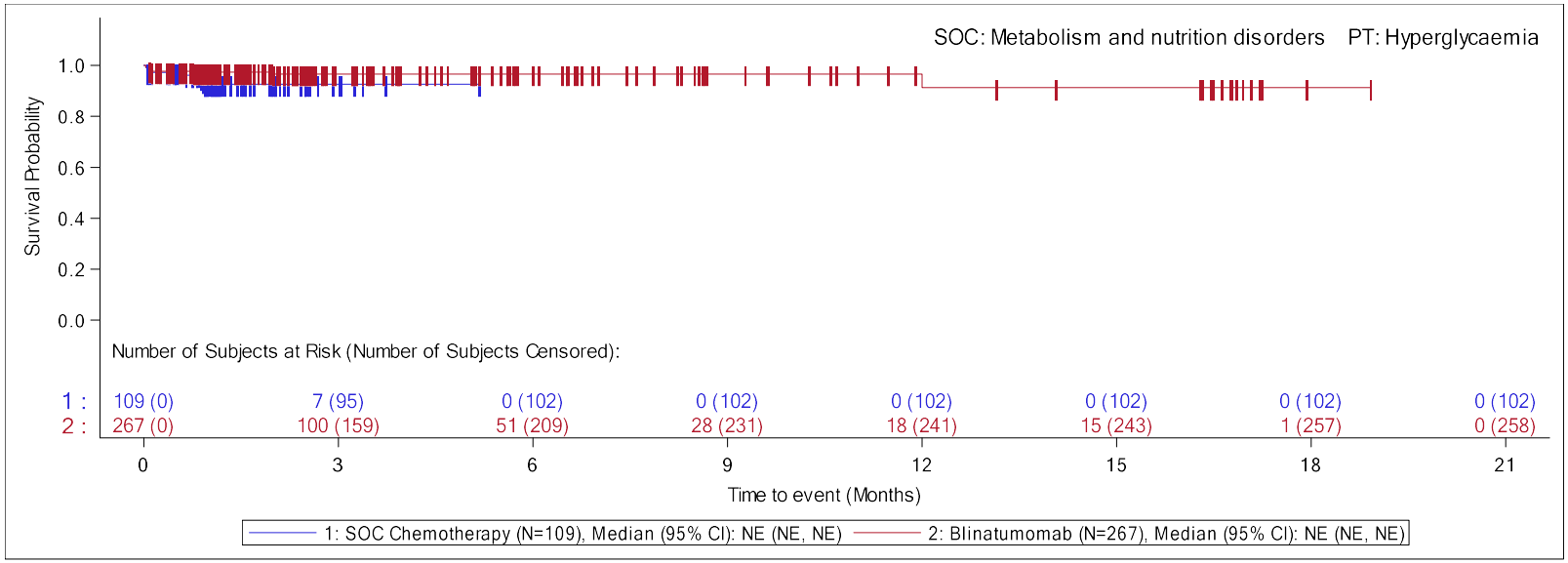

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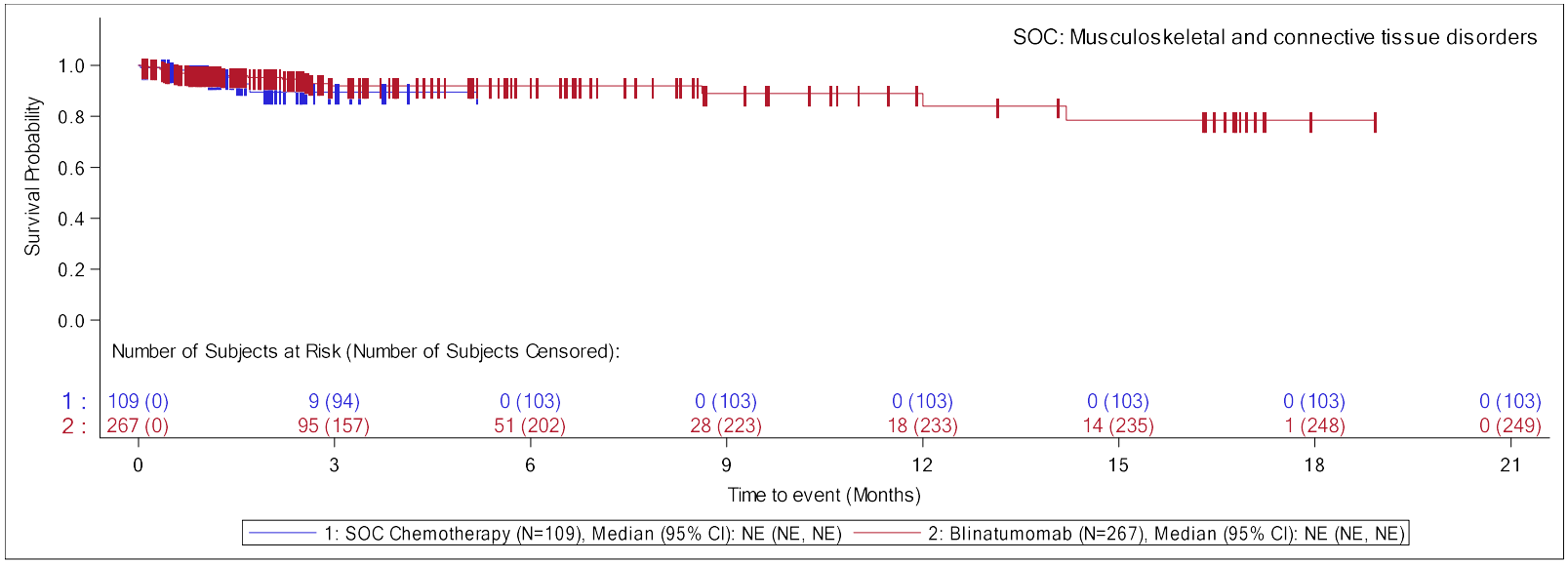

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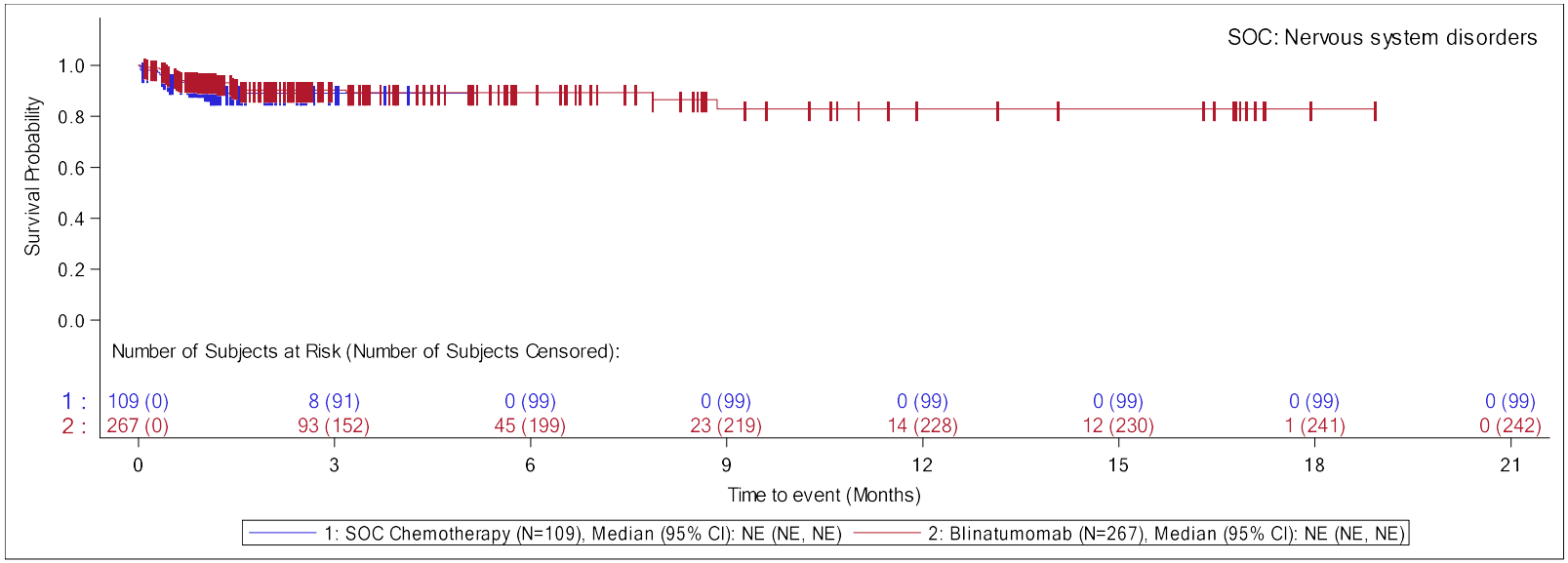

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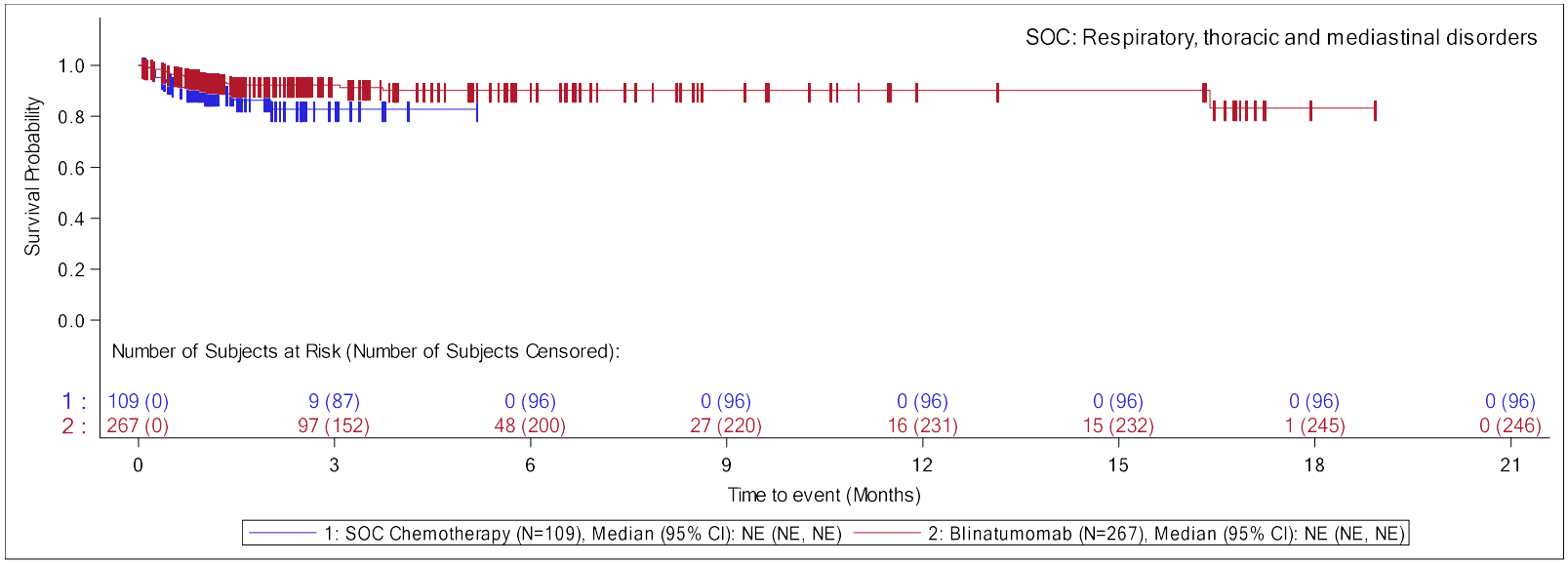

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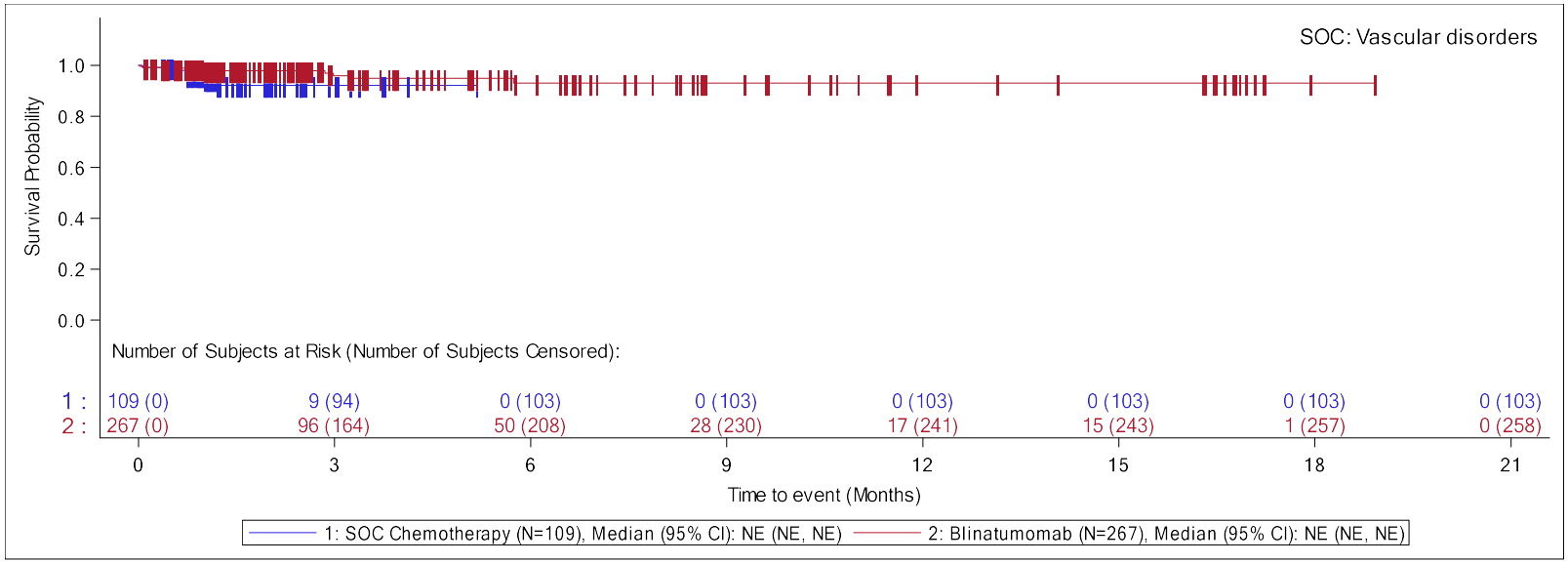

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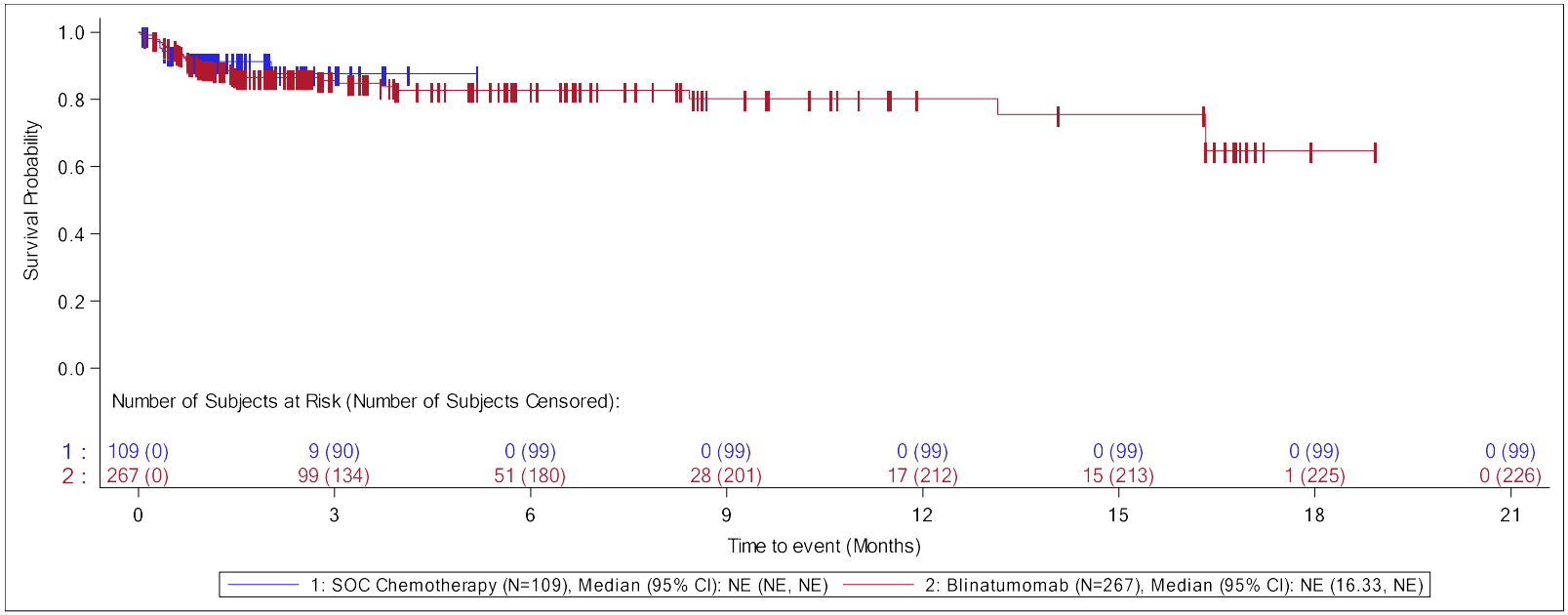
Figure 14-6.1.15. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)



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Anhang 4-G4.4: Subgruppenanalysen zum Datenschnitt 14. März 2017 (Ereigniszeitanalysen)

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Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4616
<35 years	21/37 (56.8)	1.21 (0.49, 2.03)	38/107 (35.5)	7.34 (1.54, NE)	0.42 (0.25, 0.73)	0.0014	
≥35 years	30/49 (61.2)	1.05 (0.52, 1.48)	56/115 (48.7)	2.00 (1.41, 4.59)	0.55 (0.35, 0.87)	0.0074	
Age group 2							0.1010
<35 years	21/37 (56.8)	1.21 (0.49, 2.03)	38/107 (35.5)	7.34 (1.54, NE)	0.42 (0.25, 0.73)	0.0014	
35 - 54 years	13/20 (65.0)	1.05 (0.46, 1.48)	33/66 (50.0)	1.44 (0.95, NE)	0.53 (0.28, 1.03)	0.0433	
55 - 64 years	9/20 (45.0)	1.15 (0.46, NE)	14/23 (60.9)	2.00 (0.49, 3.25)	1.02 (0.42, 2.45)	0.9666	
≥65 years	8/9 (88.9)	0.95 (0.26, 1.48)	9/26 (34.6)	NE (1.41, NE)	0.24 (0.09, 0.65)	0.0024	

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam.adtteqs

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3671
Male	30/50 (60.0)	0.95 (0.49, 2.03)	55/140 (39.3)	4.59 (1.64, 13.77)	0.44 (0.28, 0.69)	0.0002	
Female	21/36 (58.3)	1.21 (0.89, 1.54)	39/82 (47.6)	1.87 (0.98, 4.39)	0.60 (0.35, 1.03)	0.0544	
Region							0.5917
USA	6/10 (60.0)	0.89 (0.26, NE)	7/25 (28.0)	NE (1.11, NE)	0.36 (0.12, 1.07)	0.0605	
Europe	29/53 (54.7)	1.15 (0.92, 2.03)	62/145 (42.8)	2.56 (1.51, 8.13)	0.55 (0.35, 0.86)	0.0058	
Rest of the world	16/23 (69.6)	1.05 (0.49, 1.48)	25/52 (48.1)	2.46 (0.95, NE)	0.44 (0.23, 0.86)	0.0122	
Prior salvage therapy							0.0269
Yes	25/48 (52.1)	1.21 (0.92, 1.77)	59/133 (44.4)	1.54 (1.18, 8.13)	0.71 (0.44, 1.15)	0.1365	
No	26/38 (68.4)	0.95 (0.49, 1.48)	35/89 (39.3)	4.39 (2.46, NE)	0.31 (0.18, 0.52)	<0.0001	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam.adtteqs

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1799
0	29/45 (64.4)	0.95 (0.49, 1.48)	41/98 (41.8)	3.25 (2.46, NE)	0.33 (0.20, 0.54)	<0.0001	
1	14/27 (51.9)	1.15 (0.52, NE)	32/73 (43.8)	1.67 (0.95, NE)	0.70 (0.37, 1.32)	0.2323	
≥2	8/14 (57.1)	1.21 (0.49, NE)	21/51 (41.2)	2.79 (0.95, NE)	0.71 (0.31, 1.63)	0.3961	
Prior alloHSCT							0.4886
Yes	16/28 (57.1)	1.05 (0.49, 2.03)	29/75 (38.7)	7.34 (1.51, NE)	0.44 (0.23, 0.83)	0.0074	
No	35/58 (60.3)	1.15 (0.89, 1.48)	65/147 (44.2)	2.46 (1.41, 4.59)	0.52 (0.34, 0.80)	0.0019	
Race							0.5182
Caucasian	42/70 (60.0)	1.15 (0.52, 1.54)	82/189 (43.4)	2.56 (1.54, 7.34)	0.51 (0.35, 0.75)	0.0004	
Others	9/16 (56.3)	0.95 (0.26, 1.21)	12/33 (36.4)	2.82 (1.41, NE)	0.34 (0.14, 0.86)	0.0175	

ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam.adtteqs

Table 14-4.4.1. Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)

	SOC Chemotherapy (N =86)		Blinatumomab (N =223)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4355
<50%	15/23 (65.2)	0.89 (0.46, 2.39)	29/62 (46.8)	3.25 (1.18, NE)	0.40 (0.21, 0.76)	0.0030	
≥50%	36/61 (59.0)	1.15 (0.92, 1.48)	55/138 (39.9)	2.46 (1.44, 8.13)	0.50 (0.32, 0.77)	0.0011	

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ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
N = Number of subjects in analysis set. CI = Confidence interval. ALLSS = Acute lymphoblastic leukemia symptom scale. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-allss-ts-allas.sas
Output: t14-04-004-001-tte-sub-de-allss-ts-allas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4949
<35 years	20/41 (48.8)	1.38 (0.39, NE)	41/110 (37.3)	8.13 (2.82, NE)	0.49 (0.28, 0.84)	0.0092	
≥35 years	30/54 (55.6)	0.98 (0.49, 2.46)	59/130 (45.4)	3.80 (0.95, NE)	0.67 (0.43, 1.05)	0.0532	
Age group 2							0.0598
<35 years	20/41 (48.8)	1.38 (0.39, NE)	41/110 (37.3)	8.13 (2.82, NE)	0.49 (0.28, 0.84)	0.0092	
35 - 54 years	12/22 (54.5)	0.49 (0.30, NE)	34/74 (45.9)	3.80 (0.72, NE)	0.65 (0.33, 1.26)	0.1488	
55 - 64 years	13/20 (65.0)	0.49 (0.26, NE)	9/30 (30.0)	NE (2.00, NE)	0.29 (0.12, 0.72)	0.0039	
≥65 years	5/12 (41.7)	NE (0.92, NE)	16/26 (61.5)	0.69 (0.49, 4.23)	2.04 (0.74, 5.64)	0.1816	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2533
Male	28/56 (50.0)	1.15 (0.49, NE)	65/146 (44.5)	3.80 (1.48, NE)	0.65 (0.42, 1.03)	0.0560	
Female	22/39 (56.4)	0.98 (0.36, 1.77)	35/94 (37.2)	NE (1.41, NE)	0.49 (0.29, 0.85)	0.0063	
Region							0.9469
USA	8/12 (66.7)	0.39 (0.26, NE)	11/26 (42.3)	NE (0.36, NE)	0.54 (0.21, 1.33)	0.1765	
Europe	31/59 (52.5)	1.15 (0.49, 2.46)	65/157 (41.4)	8.13 (2.00, NE)	0.57 (0.37, 0.88)	0.0071	
Rest of the world	11/24 (45.8)	1.48 (0.26, NE)	24/57 (42.1)	3.80 (0.95, NE)	0.64 (0.31, 1.33)	0.2292	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
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Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.2863
Yes	24/54 (44.4)	1.48 (0.52, NE)	56/143 (39.2)	8.13 (2.00, NE)	0.69 (0.42, 1.12)	0.1099	
No	26/41 (63.4)	0.46 (0.30, 1.48)	44/97 (45.4)	4.23 (1.41, NE)	0.48 (0.29, 0.79)	0.0026	
Number of salvage therapies							0.9385
0	29/49 (59.2)	0.92 (0.36, 1.77)	52/105 (49.5)	2.95 (0.95, NE)	0.59 (0.37, 0.94)	0.0208	
1	13/29 (44.8)	2.46 (0.49, NE)	29/79 (36.7)	6.43 (2.00, NE)	0.63 (0.33, 1.23)	0.1540	
≥2	8/17 (47.1)	1.48 (0.26, NE)	19/56 (33.9)	NE (1.21, NE)	0.54 (0.23, 1.24)	0.1420	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0912
Yes	17/29 (58.6)	0.49 (0.30, 1.38)	29/82 (35.4)	NE (3.61, NE)	0.38 (0.21, 0.71)	0.0013	
No	33/66 (50.0)	1.48 (0.49, NE)	71/158 (44.9)	3.80 (1.41, NE)	0.71 (0.47, 1.07)	0.0868	
Race							0.0362
Caucasian	45/78 (57.7)	0.92 (0.46, 1.48)	82/203 (40.4)	6.43 (2.95, NE)	0.48 (0.33, 0.69)	<0.0001	
Others	5/17 (29.4)	NE (0.52, NE)	18/37 (48.6)	1.54 (0.49, NE)	1.66 (0.61, 4.46)	0.3055	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ghs-eqcas.sas
Output: t14-04-004-002-tte-sub-de-eortc-ghs-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.2. Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4954
<50%	14/25 (56.0)	0.98 (0.36, NE)	25/66 (37.9)	NE (3.80, NE)	0.52 (0.26, 1.01)	0.0317	
≥50%	34/67 (50.7)	1.15 (0.49, NE)	65/151 (43.0)	3.61 (1.41, NE)	0.62 (0.40, 0.94)	0.0213	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable. QoL = Quality of Life.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0289
<35 years	26/41 (63.4)	0.49 (0.30, 0.75)	50/111 (45.0)	11.51 (1.34, NE)	0.47 (0.29, 0.77)	0.0013	
≥35 years	33/53 (62.3)	0.95 (0.49, 1.25)	77/130 (59.2)	0.98 (0.69, 1.87)	0.86 (0.57, 1.30)	0.4067	
Age group 2							0.0442
<35 years	26/41 (63.4)	0.49 (0.30, 0.75)	50/111 (45.0)	11.51 (1.34, NE)	0.47 (0.29, 0.77)	0.0013	
35 - 54 years	13/22 (59.1)	0.95 (0.36, 1.25)	46/73 (63.0)	0.98 (0.69, 1.87)	0.77 (0.41, 1.44)	0.3619	
55 - 64 years	12/19 (63.2)	0.98 (0.33, NE)	11/30 (36.7)	NE (1.48, NE)	0.46 (0.20, 1.06)	0.0569	
≥65 years	8/12 (66.7)	0.97 (0.49, NE)	20/27 (74.1)	0.49 (0.26, 2.79)	1.58 (0.68, 3.64)	0.3234	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8377
Male	36/56 (64.3)	0.75 (0.46, 0.95)	80/145 (55.2)	1.34 (0.56, 3.15)	0.68 (0.46, 1.02)	0.0436	
Female	23/38 (60.5)	1.05 (0.49, 2.46)	47/96 (49.0)	3.02 (0.95, NE)	0.61 (0.36, 1.01)	0.0391	
Region							0.1382
USA	5/12 (41.7)	NE (0.26, NE)	15/26 (57.7)	0.95 (0.52, 3.25)	1.86 (0.67, 5.16)	0.2136	
Europe	34/58 (58.6)	0.92 (0.49, 1.38)	78/158 (49.4)	1.87 (0.95, NE)	0.63 (0.42, 0.95)	0.0190	
Rest of the world	20/24 (83.3)	0.49 (0.33, 0.98)	34/57 (59.6)	1.25 (0.49, 3.15)	0.51 (0.29, 0.91)	0.0104	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.6999
Yes	33/54 (61.1)	0.92 (0.49, 1.05)	76/145 (52.4)	1.44 (0.52, 11.51)	0.70 (0.46, 1.06)	0.0588	
No	26/40 (65.0)	0.52 (0.46, 1.48)	51/96 (53.1)	1.87 (0.95, NE)	0.60 (0.37, 0.97)	0.0299	
Number of salvage therapies							0.8161
0	29/48 (60.4)	0.52 (0.46, 1.48)	57/104 (54.8)	1.87 (0.95, 4.23)	0.66 (0.42, 1.03)	0.0579	
1	18/29 (62.1)	0.98 (0.52, 1.25)	41/82 (50.0)	1.87 (0.95, 11.51)	0.68 (0.38, 1.19)	0.1292	
≥2	12/17 (70.6)	0.39 (0.26, NE)	29/55 (52.7)	0.95 (0.49, NE)	0.59 (0.30, 1.15)	0.0905	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0059
Yes	22/29 (75.9)	0.49 (0.33, 0.75)	36/84 (42.9)	NE (0.95, NE)	0.39 (0.23, 0.66)	0.0001	
No	37/65 (56.9)	0.98 (0.49, 1.48)	91/157 (58.0)	1.48 (0.72, 2.79)	0.84 (0.57, 1.24)	0.3469	
Race							0.1440
Caucasian	50/77 (64.9)	0.52 (0.49, 0.98)	104/204 (51.0)	1.87 (0.95, 4.23)	0.61 (0.43, 0.86)	0.0022	
Others	9/17 (52.9)	0.95 (0.46, NE)	23/37 (62.2)	0.98 (0.49, 3.02)	1.01 (0.46, 2.20)	0.9842	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.3. Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4926
<50%	13/25 (52.0)	0.98 (0.49, NE)	32/64 (50.0)	3.05 (0.95, NE)	0.79 (0.41, 1.52)	0.4682	
≥50%	45/66 (68.2)	0.52 (0.46, 0.95)	81/153 (52.9)	1.48 (0.72, 3.15)	0.57 (0.40, 0.83)	0.0017	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pf-eqcas.sas
Output: t14-04-004-003-tte-sub-de-eortc-pf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.3817
<35 years	28/40 (70.0)	0.26 (0.26, 0.49)	66/112 (58.9)	1.41 (0.52, 2.23)	0.51 (0.32, 0.80)	0.0031	
≥35 years	38/51 (74.5)	0.95 (0.30, 1.25)	75/129 (58.1)	0.95 (0.49, 2.30)	0.66 (0.44, 0.99)	0.0279	
Age group 2							0.2150
<35 years	28/40 (70.0)	0.26 (0.26, 0.49)	66/112 (58.9)	1.41 (0.52, 2.23)	0.51 (0.32, 0.80)	0.0031	
35 - 54 years	14/21 (66.7)	0.95 (0.26, 1.25)	44/73 (60.3)	0.92 (0.49, 0.98)	0.81 (0.44, 1.49)	0.4184	
55 - 64 years	15/19 (78.9)	0.30 (0.26, 1.48)	12/29 (41.4)	2.03 (0.52, NE)	0.35 (0.16, 0.78)	0.0075	
≥65 years	9/11 (81.8)	0.98 (0.26, 1.97)	19/27 (70.4)	0.49 (0.26, 3.31)	0.88 (0.38, 2.03)	0.6642	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1966
Male	36/54 (66.7)	0.49 (0.26, 0.98)	90/145 (62.1)	0.95 (0.49, 1.48)	0.69 (0.47, 1.03)	0.0615	
Female	30/37 (81.1)	0.39 (0.26, 1.05)	51/96 (53.1)	1.41 (0.52, 4.62)	0.46 (0.29, 0.73)	0.0004	
Region							0.9759
USA	9/12 (75.0)	0.26 (0.26, NE)	15/26 (57.7)	0.95 (0.52, 3.25)	0.50 (0.21, 1.18)	0.1402	
Europe	39/56 (69.6)	0.49 (0.26, 1.08)	91/157 (58.0)	0.98 (0.56, 2.03)	0.61 (0.41, 0.89)	0.0066	
Rest of the world	18/23 (78.3)	0.52 (0.26, 1.18)	35/58 (60.3)	0.98 (0.49, 6.52)	0.61 (0.34, 1.09)	0.0726	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4934
Yes	35/53 (66.0)	0.49 (0.26, 0.98)	81/145 (55.9)	0.95 (0.49, 2.03)	0.67 (0.45, 0.99)	0.0364	
No	31/38 (81.6)	0.30 (0.26, 1.08)	60/96 (62.5)	1.02 (0.52, 2.33)	0.50 (0.32, 0.78)	0.0016	
Number of salvage therapies							0.3105
0	38/46 (82.6)	0.30 (0.26, 0.52)	61/103 (59.2)	1.11 (0.72, 2.92)	0.45 (0.29, 0.68)	<0.0001	
1	17/28 (60.7)	0.98 (0.26, 1.41)	47/82 (57.3)	0.95 (0.49, 2.03)	0.79 (0.45, 1.39)	0.3561	
≥2	11/17 (64.7)	0.26 (0.26, NE)	33/56 (58.9)	0.72 (0.49, 4.36)	0.68 (0.34, 1.35)	0.2910	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.3593
Yes	22/28 (78.6)	0.39 (0.26, 0.95)	47/84 (56.0)	0.95 (0.49, 4.13)	0.50 (0.30, 0.84)	0.0049	
No	44/63 (69.8)	0.49 (0.26, 1.25)	94/157 (59.9)	1.02 (0.52, 2.03)	0.62 (0.43, 0.90)	0.0087	
Race							0.7602
Caucasian	55/75 (73.3)	0.49 (0.26, 0.98)	121/203 (59.6)	0.95 (0.52, 1.87)	0.59 (0.43, 0.82)	0.0008	
Others	11/16 (68.8)	0.57 (0.26, 1.18)	20/38 (52.6)	0.98 (0.49, NE)	0.54 (0.26, 1.14)	0.1081	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-rf-eqcas.sas
Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.4. Subgroup Analysis of Time to First Deterioration of at least 10 points - Role Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7535
<50%	16/24 (66.7)	0.98 (0.26, 1.84)	34/65 (52.3)	1.87 (0.49, NE)	0.69 (0.38, 1.26)	0.1638	
≥50%	47/64 (73.4)	0.39 (0.26, 0.95)	91/152 (59.9)	0.95 (0.52, 1.41)	0.57 (0.40, 0.82)	0.0019	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-04-004-004-tte-sub-de-eortc-rf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.1741
<35 years	22/41 (53.7)	1.21 (0.39, 2.13)	44/111 (39.6)	5.21 (1.87, NE)	0.50 (0.30, 0.85)	0.0075	
≥35 years	36/54 (66.7)	0.92 (0.49, 1.48)	82/131 (62.6)	1.41 (0.52, 2.36)	0.71 (0.48, 1.07)	0.0666	
Age group 2							0.4487
<35 years	22/41 (53.7)	1.21 (0.39, 2.13)	44/111 (39.6)	5.21 (1.87, NE)	0.50 (0.30, 0.85)	0.0075	
35 - 54 years	13/22 (59.1)	1.08 (0.49, 1.77)	46/73 (63.0)	1.41 (0.49, 2.82)	0.78 (0.42, 1.48)	0.3311	
55 - 64 years	15/20 (75.0)	0.49 (0.26, 1.48)	18/30 (60.0)	1.41 (0.49, 4.39)	0.54 (0.26, 1.09)	0.0751	
≥65 years	8/12 (66.7)	0.95 (0.26, NE)	18/28 (64.3)	0.95 (0.33, 3.70)	0.87 (0.37, 2.05)	0.7598	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1778
Male	35/56 (62.5)	0.49 (0.39, 1.38)	72/147 (49.0)	2.75 (1.48, 4.66)	0.50 (0.33, 0.76)	0.0006	
Female	23/39 (59.0)	1.18 (0.49, 1.77)	54/95 (56.8)	1.41 (0.52, 2.98)	0.83 (0.50, 1.36)	0.3774	
Region							0.1932
USA	7/12 (58.3)	0.95 (0.26, NE)	9/26 (34.6)	NE (0.98, NE)	0.50 (0.18, 1.33)	0.1607	
Europe	38/59 (64.4)	0.49 (0.39, 1.25)	79/157 (50.3)	2.36 (1.34, 5.21)	0.53 (0.36, 0.79)	0.0008	
Rest of the world	13/24 (54.2)	1.48 (0.46, 2.13)	38/59 (64.4)	1.21 (0.49, 2.36)	0.89 (0.46, 1.71)	0.6763	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.3517
Yes	30/54 (55.6)	0.92 (0.33, 2.13)	78/145 (53.8)	1.54 (0.95, 4.20)	0.69 (0.45, 1.07)	0.0744	
No	28/41 (68.3)	0.95 (0.49, 1.41)	48/97 (49.5)	2.75 (1.41, NE)	0.51 (0.32, 0.83)	0.0039	
Number of salvage therapies							0.2940
0	34/49 (69.4)	0.95 (0.49, 1.41)	56/105 (53.3)	2.36 (1.41, 3.70)	0.50 (0.32, 0.78)	0.0013	
1	14/29 (48.3)	1.25 (0.49, NE)	43/81 (53.1)	1.48 (0.82, 4.39)	0.91 (0.49, 1.68)	0.6306	
≥2	10/17 (58.8)	0.28 (0.26, NE)	27/56 (48.2)	2.36 (0.49, NE)	0.51 (0.25, 1.08)	0.0842	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0257
Yes	19/29 (65.5)	0.49 (0.30, 1.38)	35/83 (42.2)	4.39 (1.57, NE)	0.36 (0.20, 0.65)	0.0003	
No	39/66 (59.1)	1.08 (0.49, 1.48)	91/159 (57.2)	1.41 (0.82, 2.75)	0.78 (0.53, 1.14)	0.1456	
Race							0.2013
Caucasian	51/78 (65.4)	0.52 (0.46, 1.25)	108/204 (52.9)	2.00 (0.98, 3.25)	0.56 (0.40, 0.79)	0.0005	
Others	7/17 (41.2)	2.13 (0.95, NE)	18/38 (47.4)	2.36 (1.41, NE)	0.94 (0.39, 2.28)	0.8239	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.5. Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3224
<50%	17/25 (68.0)	0.46 (0.26, 1.70)	35/66 (53.0)	2.36 (1.08, NE)	0.45 (0.25, 0.82)	0.0080	
≥50%	40/67 (59.7)	1.08 (0.49, 1.41)	74/152 (48.7)	2.75 (0.98, 4.36)	0.63 (0.42, 0.93)	0.0107	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cf-eqcas.sas
Output: t14-04-004-005-tte-sub-de-eortc-cf-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4588
<35 years	16/41 (39.0)	2.79 (0.95, NE)	31/111 (27.9)	11.51 (6.66, NE)	0.44 (0.24, 0.83)	0.0087	
≥35 years	19/53 (35.8)	NE (1.18, NE)	44/130 (33.8)	NE (4.36, NE)	0.71 (0.41, 1.24)	0.2229	
Age group 2							0.3871
<35 years	16/41 (39.0)	2.79 (0.95, NE)	31/111 (27.9)	11.51 (6.66, NE)	0.44 (0.24, 0.83)	0.0087	
35 - 54 years	9/21 (42.9)	1.77 (0.49, NE)	23/72 (31.9)	NE (2.36, NE)	0.49 (0.22, 1.08)	0.0674	
55 - 64 years	7/20 (35.0)	NE (0.95, NE)	9/30 (30.0)	4.36 (3.02, NE)	0.48 (0.16, 1.46)	0.1863	
≥65 years	3/12 (25.0)	NE (0.46, NE)	12/28 (42.9)	6.92 (0.95, NE)	1.56 (0.43, 5.59)	0.4912	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1075
Male	17/55 (30.9)	NE (1.84, NE)	47/147 (32.0)	8.13 (4.36, NE)	0.76 (0.43, 1.33)	0.3189	
Female	18/39 (46.2)	1.77 (0.49, NE)	28/94 (29.8)	11.51 (11.51, NE)	0.41 (0.22, 0.76)	0.0035	
Region							0.2895
USA	4/11 (36.4)	NE (0.46, NE)	10/26 (38.5)	3.80 (0.95, NE)	1.09 (0.33, 3.54)	0.8846	
Europe	18/59 (30.5)	NE (1.77, NE)	44/156 (28.2)	NE (6.66, NE)	0.63 (0.36, 1.11)	0.1021	
Rest of the world	13/24 (54.2)	0.95 (0.39, NE)	21/59 (35.6)	11.51 (2.82, NE)	0.39 (0.18, 0.81)	0.0077	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.5851
Yes	17/53 (32.1)	NE (1.05, NE)	41/145 (28.3)	11.51 (8.13, NE)	0.66 (0.37, 1.18)	0.1573	
No	18/41 (43.9)	2.30 (1.18, NE)	34/96 (35.4)	NE (3.02, NE)	0.49 (0.27, 0.88)	0.0153	
Number of salvage therapies							0.6922
0	19/49 (38.8)	2.79 (1.77, NE)	41/104 (39.4)	6.92 (2.82, NE)	0.62 (0.36, 1.10)	0.0985	
1	8/28 (28.6)	NE (1.05, NE)	17/81 (21.0)	11.51 (11.51, NE)	0.55 (0.23, 1.30)	0.1561	
≥2	8/17 (47.1)	NE (0.26, NE)	17/56 (30.4)	NE (1.51, NE)	0.50 (0.21, 1.17)	0.0963	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0317
Yes	13/29 (44.8)	2.30 (0.49, NE)	21/82 (25.6)	NE (6.66, NE)	0.34 (0.16, 0.71)	0.0022	
No	22/65 (33.8)	NE (1.54, NE)	54/159 (34.0)	8.13 (3.80, 11.51)	0.74 (0.45, 1.23)	0.2431	
Race							0.6644
Caucasian	29/77 (37.7)	2.79 (1.54, NE)	62/203 (30.5)	NE (6.66, NE)	0.56 (0.36, 0.88)	0.0106	
Others	6/17 (35.3)	NE (0.95, NE)	13/38 (34.2)	11.51 (1.87, NE)	0.64 (0.23, 1.78)	0.3889	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.6. Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7503
<50%	6/25 (24.0)	NE (NE, NE)	19/66 (28.8)	NE (4.43, NE)	0.63 (0.24, 1.64)	0.3366	
≥50%	27/66 (40.9)	1.84 (1.15, NE)	49/152 (32.2)	11.51 (3.80, NE)	0.62 (0.38, 1.00)	0.0417	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-ef-eqcas.sas
Output: t14-04-004-006-tte-sub-de-eortc-ef-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0610
<35 years	24/41 (58.5)	0.49 (0.26, NE)	56/111 (50.5)	1.41 (0.95, 11.51)	0.58 (0.35, 0.94)	0.0238	
≥35 years	29/53 (54.7)	1.15 (0.92, 1.84)	80/131 (61.1)	0.95 (0.56, 2.00)	1.00 (0.65, 1.54)	0.8850	
Age group 2							0.1623
<35 years	24/41 (58.5)	0.49 (0.26, NE)	56/111 (50.5)	1.41 (0.95, 11.51)	0.58 (0.35, 0.94)	0.0238	
35 - 54 years	10/21 (47.6)	1.15 (0.52, NE)	44/74 (59.5)	0.95 (0.52, 2.75)	1.11 (0.55, 2.23)	0.8567	
55 - 64 years	14/20 (70.0)	0.95 (0.30, 1.84)	18/30 (60.0)	1.54 (0.49, 5.31)	0.69 (0.34, 1.42)	0.2983	
≥65 years	5/12 (41.7)	NE (0.26, NE)	18/27 (66.7)	0.95 (0.26, 3.25)	1.56 (0.57, 4.22)	0.3793	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2733
Male	29/55 (52.7)	0.98 (0.49, NE)	86/147 (58.5)	0.95 (0.52, 1.80)	0.93 (0.61, 1.41)	0.6956	
Female	24/39 (61.5)	0.95 (0.46, 1.48)	50/95 (52.6)	2.10 (0.95, 5.31)	0.61 (0.37, 1.01)	0.0374	
Region							0.4582
USA	6/11 (54.5)	0.85 (0.26, NE)	11/26 (42.3)	5.31 (0.56, NE)	0.47 (0.17, 1.34)	0.1673	
Europe	29/59 (49.2)	1.25 (0.92, NE)	88/158 (55.7)	1.34 (0.95, 2.33)	0.94 (0.62, 1.44)	0.7317	
Rest of the world	18/24 (75.0)	0.52 (0.39, 0.95)	37/58 (63.8)	0.56 (0.49, 2.10)	0.64 (0.36, 1.14)	0.0923	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.9509
Yes	30/53 (56.6)	0.95 (0.49, 1.77)	79/145 (54.5)	1.05 (0.92, 2.00)	0.80 (0.52, 1.22)	0.2570	
No	23/41 (56.1)	1.08 (0.30, 1.90)	57/97 (58.8)	1.34 (0.56, 3.25)	0.78 (0.47, 1.28)	0.2797	
Number of salvage therapies							0.8888
0	27/49 (55.1)	1.08 (0.46, 1.90)	63/105 (60.0)	1.11 (0.75, 2.75)	0.83 (0.52, 1.31)	0.4034	
1	16/28 (57.1)	0.95 (0.39, 2.46)	47/80 (58.8)	0.95 (0.56, 2.10)	0.79 (0.44, 1.40)	0.3632	
≥2	10/17 (58.8)	0.59 (0.26, NE)	26/57 (45.6)	5.31 (0.49, NE)	0.68 (0.32, 1.41)	0.2646	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1452
Yes	19/29 (65.5)	0.59 (0.26, 1.48)	43/83 (51.8)	1.05 (0.49, NE)	0.65 (0.38, 1.12)	0.0788	
No	34/65 (52.3)	1.15 (0.49, 2.46)	93/159 (58.5)	1.15 (0.95, 2.10)	0.89 (0.60, 1.32)	0.5339	
Race							0.9264
Caucasian	43/77 (55.8)	1.05 (0.49, 1.77)	113/204 (55.4)	1.21 (0.95, 2.10)	0.79 (0.55, 1.13)	0.1554	
Others	10/17 (58.8)	0.95 (0.26, NE)	23/38 (60.5)	0.95 (0.49, 5.77)	0.82 (0.38, 1.73)	0.6187	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sf-eqcas.sas
Output: t14-04-004-007-tte-sub-de-eortc-sf-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.7. Subgroup Analysis of Time to First Deterioration of at least 10 points - Social Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0653
<50%	6/25 (24.0)	NE (1.84, NE)	31/66 (47.0)	4.39 (0.95, NE)	1.71 (0.70, 4.13)	0.2433	
≥50%	44/66 (66.7)	0.59 (0.39, 1.08)	91/152 (59.9)	0.95 (0.52, 1.54)	0.69 (0.48, 1.00)	0.0335	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.2340
<35 years	30/40 (75.0)	0.26 (0.26, 0.49)	60/112 (53.6)	0.98 (0.49, 4.36)	0.46 (0.29, 0.71)	0.0002	
≥35 years	39/54 (72.2)	0.46 (0.26, 0.95)	80/130 (61.5)	0.95 (0.49, 1.51)	0.59 (0.40, 0.87)	0.0040	
Age group 2							0.0323
<35 years	30/40 (75.0)	0.26 (0.26, 0.49)	60/112 (53.6)	0.98 (0.49, 4.36)	0.46 (0.29, 0.71)	0.0002	
35 - 54 years	17/22 (77.3)	0.30 (0.26, 1.05)	46/73 (63.0)	0.95 (0.49, 1.41)	0.53 (0.30, 0.93)	0.0148	
55 - 64 years	16/20 (80.0)	0.28 (0.26, 0.49)	15/30 (50.0)	2.33 (0.56, NE)	0.29 (0.14, 0.62)	0.0007	
≥65 years	6/12 (50.0)	1.48 (0.46, NE)	19/27 (70.4)	0.49 (0.26, 2.26)	1.58 (0.62, 4.03)	0.3527	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0168
Male	38/55 (69.1)	0.49 (0.26, 0.52)	93/146 (63.7)	0.52 (0.49, 0.98)	0.70 (0.48, 1.03)	0.0475	
Female	31/39 (79.5)	0.30 (0.26, 0.49)	47/96 (49.0)	2.26 (0.98, NE)	0.33 (0.20, 0.53)	<0.0001	
Region							0.6885
USA	9/12 (75.0)	0.39 (0.26, NE)	11/26 (42.3)	2.10 (0.52, NE)	0.44 (0.18, 1.07)	0.0795	
Europe	43/59 (72.9)	0.30 (0.26, 0.49)	95/158 (60.1)	0.98 (0.49, 1.51)	0.50 (0.34, 0.72)	<0.0001	
Rest of the world	17/23 (73.9)	0.46 (0.26, 1.05)	34/58 (58.6)	0.52 (0.49, 4.36)	0.64 (0.35, 1.16)	0.0763	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
Output: t14-04-004-008-tte-sub-de-eortc-fs-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.6680
Yes	38/53 (71.7)	0.30 (0.26, 0.52)	84/146 (57.5)	0.95 (0.49, 1.54)	0.56 (0.38, 0.82)	0.0020	
No	31/41 (75.6)	0.36 (0.26, 0.49)	56/96 (58.3)	1.41 (0.52, 3.05)	0.47 (0.30, 0.74)	0.0005	
Number of salvage therapies							0.6549
0	37/49 (75.5)	0.30 (0.26, 0.49)	61/104 (58.7)	1.41 (0.52, 2.33)	0.46 (0.30, 0.69)	<0.0001	
1	19/28 (67.9)	0.46 (0.26, 1.05)	45/82 (54.9)	0.52 (0.49, 3.05)	0.63 (0.36, 1.07)	0.0537	
≥2	13/17 (76.5)	0.30 (0.26, 1.08)	34/56 (60.7)	0.72 (0.49, 2.10)	0.56 (0.29, 1.07)	0.0734	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fs-eqcas.sas
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Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1123
Yes	25/28 (89.3)	0.28 (0.26, 0.49)	48/84 (57.1)	0.95 (0.49, 3.05)	0.37 (0.23, 0.61)	<0.0001	
No	44/66 (66.7)	0.46 (0.26, 0.95)	92/158 (58.2)	1.41 (0.52, 2.26)	0.61 (0.42, 0.88)	0.0047	
Race							0.6089
Caucasian	60/78 (76.9)	0.30 (0.26, 0.49)	123/204 (60.3)	0.95 (0.49, 1.48)	0.49 (0.36, 0.67)	<0.0001	
Others	9/16 (56.3)	0.95 (0.26, NE)	17/38 (44.7)	2.10 (0.52, NE)	0.65 (0.29, 1.48)	0.3075	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.8. Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5442
<50%	14/25 (56.0)	0.49 (0.36, NE)	34/65 (52.3)	2.33 (0.52, NE)	0.63 (0.34, 1.20)	0.1540	
≥50%	52/66 (78.8)	0.30 (0.26, 0.49)	89/153 (58.2)	0.95 (0.49, 1.41)	0.50 (0.35, 0.70)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.3291
<35 years	30/41 (73.2)	0.49 (0.30, 0.89)	61/112 (54.5)	1.64 (1.34, 4.03)	0.46 (0.30, 0.73)	0.0003	
≥35 years	37/53 (69.8)	0.49 (0.46, 1.18)	74/133 (55.6)	1.41 (0.95, 2.36)	0.61 (0.41, 0.91)	0.0102	
Age group 2							0.5143
<35 years	30/41 (73.2)	0.49 (0.30, 0.89)	61/112 (54.5)	1.64 (1.34, 4.03)	0.46 (0.30, 0.73)	0.0003	
35 - 54 years	16/21 (76.2)	0.49 (0.30, 1.15)	40/75 (53.3)	0.95 (0.52, 5.08)	0.51 (0.28, 0.93)	0.0145	
55 - 64 years	14/20 (70.0)	0.70 (0.26, 1.54)	18/30 (60.0)	1.87 (0.95, 2.46)	0.55 (0.26, 1.14)	0.0946	
≥65 years	7/12 (58.3)	1.70 (0.26, NE)	16/28 (57.1)	1.41 (0.95, NE)	1.01 (0.41, 2.47)	0.9935	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9268
Male	41/56 (73.2)	0.49 (0.46, 1.08)	80/147 (54.4)	1.54 (0.95, 2.79)	0.56 (0.38, 0.82)	0.0011	
Female	26/38 (68.4)	0.39 (0.26, 1.18)	55/98 (56.1)	1.41 (0.95, 2.56)	0.51 (0.32, 0.82)	0.0040	
Region							0.5535
USA	8/12 (66.7)	1.31 (0.26, NE)	10/26 (38.5)	2.46 (0.95, NE)	0.60 (0.23, 1.52)	0.2460	
Europe	44/59 (74.6)	0.49 (0.30, 0.49)	91/160 (56.9)	1.41 (0.95, 2.00)	0.47 (0.32, 0.68)	<0.0001	
Rest of the world	15/23 (65.2)	0.95 (0.39, 1.44)	34/59 (57.6)	1.41 (0.49, 4.36)	0.72 (0.39, 1.33)	0.2404	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1725
Yes	36/54 (66.7)	0.52 (0.39, 1.15)	82/148 (55.4)	1.41 (0.95, 1.90)	0.64 (0.43, 0.96)	0.0154	
No	31/40 (77.5)	0.49 (0.30, 0.89)	53/97 (54.6)	1.87 (1.34, 4.98)	0.42 (0.26, 0.66)	<0.0001	
Number of salvage therapies							0.3841
0	36/48 (75.0)	0.49 (0.36, 0.89)	58/105 (55.2)	1.87 (0.95, 4.59)	0.42 (0.27, 0.64)	<0.0001	
1	19/29 (65.5)	0.52 (0.39, 1.54)	47/83 (56.6)	1.41 (0.95, 1.87)	0.69 (0.40, 1.19)	0.1251	
≥2	12/17 (70.6)	0.49 (0.26, 1.44)	30/57 (52.6)	1.41 (0.49, NE)	0.60 (0.31, 1.18)	0.0952	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.1896
Yes	21/29 (72.4)	0.46 (0.30, 0.49)	44/84 (52.4)	1.90 (0.95, 4.98)	0.41 (0.24, 0.71)	0.0005	
No	46/65 (70.8)	0.49 (0.46, 1.15)	91/161 (56.5)	1.41 (0.95, 2.36)	0.61 (0.42, 0.87)	0.0037	
Race							0.1894
Caucasian	58/78 (74.4)	0.49 (0.39, 0.89)	112/206 (54.4)	1.54 (1.34, 2.00)	0.50 (0.36, 0.69)	<0.0001	
Others	9/16 (56.3)	0.95 (0.46, NE)	23/39 (59.0)	1.11 (0.56, 2.56)	0.80 (0.37, 1.75)	0.5698	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.9. Subgroup Analysis of Time to First Deterioration of at least 10 points - Pain from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7022
<50%	18/25 (72.0)	0.49 (0.30, 1.70)	37/67 (55.2)	2.79 (1.41, 5.08)	0.42 (0.23, 0.76)	0.0026	
≥50%	48/66 (72.7)	0.49 (0.39, 0.95)	81/154 (52.6)	1.41 (0.95, 1.87)	0.53 (0.37, 0.77)	0.0003	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-pas-eqcas.sas
Output: t14-04-004-009-tte-sub-de-eortc-pas-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0088
<35 years	26/40 (65.0)	0.39 (0.26, 1.11)	32/111 (28.8)	6.26 (3.28, NE)	0.21 (0.12, 0.37)	<0.0001	
≥35 years	28/54 (51.9)	1.25 (0.30, NE)	60/131 (45.8)	3.25 (2.10, 6.46)	0.53 (0.33, 0.84)	0.0081	
Age group 2							0.0138
<35 years	26/40 (65.0)	0.39 (0.26, 1.11)	32/111 (28.8)	6.26 (3.28, NE)	0.21 (0.12, 0.37)	<0.0001	
35 - 54 years	16/22 (72.7)	0.30 (0.26, 1.25)	36/74 (48.6)	2.79 (1.38, NE)	0.29 (0.15, 0.54)	<0.0001	
55 - 64 years	7/20 (35.0)	NE (0.26, NE)	15/30 (50.0)	2.56 (0.52, 6.46)	0.94 (0.37, 2.41)	0.9448	
≥65 years	5/12 (41.7)	NE (0.26, NE)	9/27 (33.3)	5.41 (2.33, NE)	0.49 (0.15, 1.58)	0.2300	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
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Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1678
Male	26/55 (47.3)	1.87 (0.46, NE)	51/145 (35.2)	4.23 (2.79, NE)	0.45 (0.27, 0.73)	0.0013	
Female	28/39 (71.8)	0.30 (0.26, 1.11)	41/97 (42.3)	4.16 (2.33, NE)	0.29 (0.17, 0.48)	<0.0001	
Region							0.7346
USA	8/12 (66.7)	0.51 (0.26, NE)	10/26 (38.5)	2.56 (0.95, NE)	0.41 (0.16, 1.05)	0.0674	
Europe	34/59 (57.6)	0.49 (0.26, 1.87)	60/159 (37.7)	4.16 (3.25, NE)	0.32 (0.20, 0.50)	<0.0001	
Rest of the world	12/23 (52.2)	2.79 (0.26, NE)	22/57 (38.6)	6.49 (1.87, NE)	0.48 (0.23, 1.00)	0.0403	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
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Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1611
Yes	27/53 (50.9)	1.11 (0.49, NE)	53/146 (36.3)	5.41 (2.43, NE)	0.46 (0.29, 0.74)	0.0014	
No	27/41 (65.9)	0.30 (0.26, 1.87)	39/96 (40.6)	4.03 (3.02, NE)	0.27 (0.16, 0.45)	<0.0001	
Number of salvage therapies							0.2596
0	35/49 (71.4)	0.26 (0.26, 0.49)	48/104 (46.2)	3.28 (2.33, 5.67)	0.29 (0.18, 0.46)	<0.0001	
1	11/28 (39.3)	NE (0.49, NE)	22/82 (26.8)	NE (6.26, NE)	0.45 (0.21, 0.95)	0.0339	
≥2	8/17 (47.1)	1.11 (0.26, NE)	22/56 (39.3)	2.56 (1.41, NE)	0.61 (0.27, 1.39)	0.2327	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
Output: t14-04-004-010-tte-sub-de-eortc-nvs-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0930
Yes	20/28 (71.4)	0.41 (0.26, 1.11)	33/84 (39.3)	5.67 (2.79, NE)	0.24 (0.13, 0.44)	<0.0001	
No	34/66 (51.5)	1.25 (0.30, NE)	59/158 (37.3)	4.16 (2.56, NE)	0.44 (0.29, 0.68)	0.0003	
Race							0.2099
Caucasian	44/78 (56.4)	0.75 (0.36, 1.87)	82/205 (40.0)	4.03 (3.15, 6.46)	0.39 (0.26, 0.57)	<0.0001	
Others	10/16 (62.5)	0.28 (0.26, NE)	10/37 (27.0)	NE (2.56, NE)	0.26 (0.11, 0.64)	0.0022	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
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Table 14-4.4.10. Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9772
<50%	13/25 (52.0)	1.87 (0.26, NE)	24/64 (37.5)	NE (3.15, NE)	0.40 (0.20, 0.82)	0.0101	
≥50%	39/66 (59.1)	0.52 (0.26, 1.77)	56/154 (36.4)	3.38 (2.43, 6.26)	0.35 (0.23, 0.54)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-nvs-eqcas.sas
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Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.8249
<35 years	15/40 (37.5)	NE (0.75, NE)	32/111 (28.8)	NE (NE, NE)	0.66 (0.36, 1.23)	0.1680	
≥35 years	24/53 (45.3)	2.33 (0.95, NE)	43/130 (33.1)	NE (2.79, NE)	0.55 (0.33, 0.93)	0.0199	
Age group 2							0.7719
<35 years	15/40 (37.5)	NE (0.75, NE)	32/111 (28.8)	NE (NE, NE)	0.66 (0.36, 1.23)	0.1680	
35 - 54 years	8/21 (38.1)	1.54 (0.95, NE)	26/72 (36.1)	NE (1.48, NE)	0.75 (0.34, 1.67)	0.4555	
55 - 64 years	11/20 (55.0)	2.46 (0.30, NE)	9/30 (30.0)	NE (2.00, NE)	0.33 (0.13, 0.82)	0.0142	
≥65 years	5/12 (41.7)	2.33 (0.26, NE)	8/28 (28.6)	NE (1.87, NE)	0.62 (0.20, 1.97)	0.4040	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
Output: t14-04-004-011-tte-sub-de-eortc-dys-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7703
Male	22/55 (40.0)	2.56 (0.95, NE)	45/146 (30.8)	NE (NE, NE)	0.65 (0.39, 1.09)	0.0896	
Female	17/38 (44.7)	1.77 (1.05, NE)	30/95 (31.6)	NE (4.52, NE)	0.53 (0.29, 0.98)	0.0335	
Region							0.1649
USA	8/12 (66.7)	0.89 (0.26, NE)	6/26 (23.1)	NE (1.11, NE)	0.29 (0.10, 0.85)	0.0177	
Europe	23/58 (39.7)	2.46 (1.38, NE)	47/157 (29.9)	NE (NE, NE)	0.59 (0.36, 0.98)	0.0332	
Rest of the world	8/23 (34.8)	NE (0.52, NE)	22/58 (37.9)	5.31 (1.21, NE)	1.05 (0.46, 2.40)	0.9493	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
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Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.9467
Yes	20/53 (37.7)	2.46 (1.05, NE)	42/145 (29.0)	NE (5.31, NE)	0.58 (0.34, 1.00)	0.0409	
No	19/40 (47.5)	2.33 (0.89, NE)	33/96 (34.4)	NE (4.52, NE)	0.63 (0.36, 1.12)	0.1031	
Number of salvage therapies							0.4974
0	22/48 (45.8)	1.77 (0.95, NE)	33/104 (31.7)	NE (NE, NE)	0.56 (0.32, 0.97)	0.0306	
1	13/29 (44.8)	2.46 (0.52, NE)	25/82 (30.5)	NE (2.00, NE)	0.50 (0.25, 1.00)	0.0403	
≥2	4/16 (25.0)	NE (0.89, NE)	17/55 (30.9)	NE (1.57, NE)	1.10 (0.37, 3.31)	0.8964	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
Output: t14-04-004-011-tte-sub-de-eortc-dys-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6469
Yes	11/29 (37.9)	NE (0.95, NE)	21/83 (25.3)	NE (NE, NE)	0.55 (0.26, 1.14)	0.0931	
No	28/64 (43.8)	2.33 (0.95, NE)	54/158 (34.2)	NE (2.79, NE)	0.63 (0.40, 1.01)	0.0434	
Race							0.6956
Caucasian	31/77 (40.3)	2.46 (1.54, NE)	59/204 (28.9)	NE (NE, NE)	0.59 (0.38, 0.91)	0.0144	
Others	8/16 (50.0)	0.95 (0.52, NE)	16/37 (43.2)	4.52 (0.95, NE)	0.71 (0.30, 1.70)	0.3868	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.11. Subgroup Analysis of Time to First Deterioration of at least 10 points - Dyspnea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7540
<50%	7/25 (28.0)	2.56 (2.33, NE)	16/64 (25.0)	NE (NE, NE)	0.60 (0.24, 1.52)	0.2703	
≥50%	32/65 (49.2)	1.38 (0.89, NE)	50/153 (32.7)	NE (2.43, NE)	0.56 (0.36, 0.87)	0.0075	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dys-eqcas.sas
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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0074
<35 years	26/40 (65.0)	0.46 (0.26, 1.08)	41/111 (36.9)	5.05 (2.36, NE)	0.22 (0.13, 0.38)	<0.0001	
≥35 years	33/53 (62.3)	0.92 (0.36, 1.25)	71/130 (54.6)	2.33 (0.98, 3.25)	0.61 (0.40, 0.93)	0.0169	
Age group 2							0.0242
<35 years	26/40 (65.0)	0.46 (0.26, 1.08)	41/111 (36.9)	5.05 (2.36, NE)	0.22 (0.13, 0.38)	<0.0001	
35 - 54 years	15/21 (71.4)	0.36 (0.26, 1.15)	40/73 (54.8)	1.87 (0.72, 3.25)	0.46 (0.25, 0.84)	0.0084	
55 - 64 years	13/20 (65.0)	0.70 (0.26, NE)	15/30 (50.0)	2.56 (1.48, 7.54)	0.41 (0.18, 0.91)	0.0261	
≥65 years	5/12 (41.7)	NE (0.49, NE)	16/27 (59.3)	3.25 (0.49, 6.43)	1.33 (0.47, 3.77)	0.6215	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
Output: t14-04-004-012-tte-sub-de-eortc-aps-eqcas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0741
Male	33/55 (60.0)	0.92 (0.46, 1.44)	68/145 (46.9)	3.15 (1.48, 3.70)	0.50 (0.33, 0.77)	0.0013	
Female	26/38 (68.4)	0.46 (0.26, 1.05)	44/96 (45.8)	3.34 (1.44, 7.54)	0.30 (0.18, 0.51)	<0.0001	
Region							0.7792
USA	9/12 (75.0)	0.51 (0.26, NE)	14/26 (53.8)	2.03 (0.95, 3.25)	0.51 (0.22, 1.18)	0.1223	
Europe	34/58 (58.6)	0.49 (0.30, 2.56)	71/158 (44.9)	4.23 (2.46, 6.43)	0.43 (0.28, 0.66)	<0.0001	
Rest of the world	16/23 (69.6)	0.49 (0.26, 1.11)	27/57 (47.4)	2.36 (0.95, NE)	0.39 (0.20, 0.75)	0.0027	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.8716
Yes	34/53 (64.2)	0.92 (0.39, 1.11)	64/145 (44.1)	3.15 (1.44, 6.26)	0.43 (0.28, 0.66)	<0.0001	
No	25/40 (62.5)	0.46 (0.26, NE)	48/96 (50.0)	3.25 (1.97, 5.05)	0.40 (0.24, 0.66)	0.0002	
Number of salvage therapies							0.4838
0	31/48 (64.6)	0.46 (0.26, 0.92)	50/104 (48.1)	3.70 (1.97, 7.54)	0.35 (0.22, 0.57)	<0.0001	
1	19/28 (67.9)	0.92 (0.26, 1.25)	38/82 (46.3)	2.36 (1.38, NE)	0.46 (0.26, 0.80)	0.0043	
≥2	9/17 (52.9)	1.08 (0.26, NE)	24/55 (43.6)	2.56 (1.21, NE)	0.55 (0.25, 1.21)	0.1220	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0142
Yes	21/28 (75.0)	0.36 (0.26, 0.52)	37/84 (44.0)	3.44 (1.44, NE)	0.21 (0.11, 0.37)	<0.0001	
No	38/65 (58.5)	0.92 (0.46, 1.44)	75/157 (47.8)	3.15 (1.97, 4.23)	0.53 (0.36, 0.80)	0.0016	
Race							0.5038
Caucasian	47/77 (61.0)	0.52 (0.39, 1.15)	95/204 (46.6)	3.25 (2.03, 5.05)	0.43 (0.30, 0.62)	<0.0001	
Others	12/16 (75.0)	0.46 (0.26, 0.95)	17/37 (45.9)	2.56 (0.52, NE)	0.34 (0.16, 0.74)	0.0039	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-aps-eqcas.sas
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Table 14-4.4.12. Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3662
<50%	15/25 (60.0)	0.49 (0.26, NE)	25/64 (39.1)	7.54 (3.25, NE)	0.34 (0.17, 0.68)	0.0014	
≥50%	42/65 (64.6)	0.52 (0.39, 1.05)	74/153 (48.4)	2.36 (1.44, 3.70)	0.42 (0.28, 0.62)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0012
<35 years	25/40 (62.5)	0.49 (0.26, 2.13)	48/112 (42.9)	5.41 (2.00, 10.00)	0.39 (0.23, 0.64)	<0.0001	
≥35 years	23/54 (42.6)	2.46 (0.92, NE)	72/130 (55.4)	0.95 (0.62, 3.70)	1.30 (0.81, 2.08)	0.3219	
Age group 2							0.0010
<35 years	25/40 (62.5)	0.49 (0.26, 2.13)	48/112 (42.9)	5.41 (2.00, 10.00)	0.39 (0.23, 0.64)	<0.0001	
35 - 54 years	12/22 (54.5)	0.95 (0.49, NE)	36/73 (49.3)	3.15 (0.75, NE)	0.70 (0.36, 1.36)	0.2560	
55 - 64 years	9/20 (45.0)	2.46 (0.30, NE)	19/30 (63.3)	0.52 (0.30, 7.54)	1.48 (0.66, 3.31)	0.3508	
≥65 years	2/12 (16.7)	NE (0.92, NE)	17/27 (63.0)	0.95 (0.26, 1.61)	5.93 (1.36, 25.81)	0.0066	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
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Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1744
Male	26/55 (47.3)	1.15 (0.92, NE)	75/146 (51.4)	1.64 (0.95, 5.41)	0.93 (0.59, 1.46)	0.6519	
Female	22/39 (56.4)	0.52 (0.39, NE)	45/96 (46.9)	3.70 (1.15, NE)	0.57 (0.34, 0.97)	0.0294	
Region							0.5973
USA	8/12 (66.7)	0.82 (0.26, NE)	13/26 (50.0)	1.44 (0.49, NE)	0.70 (0.29, 1.68)	0.4232	
Europe	28/59 (47.5)	2.26 (0.49, NE)	72/158 (45.6)	4.75 (1.54, 7.54)	0.69 (0.44, 1.07)	0.0839	
Rest of the world	12/23 (52.2)	0.92 (0.39, NE)	35/58 (60.3)	0.62 (0.26, 3.93)	1.10 (0.56, 2.14)	0.9420	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.5310
Yes	25/53 (47.2)	1.15 (0.75, 2.46)	69/146 (47.3)	4.75 (0.98, 6.92)	0.84 (0.53, 1.33)	0.3781	
No	23/41 (56.1)	0.52 (0.30, NE)	51/96 (53.1)	2.00 (0.95, 5.41)	0.68 (0.41, 1.12)	0.1141	
Number of salvage therapies							0.4480
0	28/49 (57.1)	0.49 (0.36, NE)	57/104 (54.8)	2.00 (0.95, 5.41)	0.67 (0.42, 1.07)	0.0788	
1	11/28 (39.3)	2.46 (0.92, NE)	38/82 (46.3)	2.00 (0.95, NE)	1.09 (0.55, 2.14)	0.9036	
≥2	9/17 (52.9)	0.75 (0.33, NE)	25/56 (44.6)	4.75 (0.52, NE)	0.66 (0.30, 1.43)	0.2680	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0024
Yes	19/28 (67.9)	0.49 (0.30, 1.05)	36/84 (42.9)	5.41 (1.64, NE)	0.36 (0.20, 0.65)	0.0002	
No	29/66 (43.9)	2.13 (0.92, NE)	84/158 (53.2)	1.44 (0.95, 3.70)	1.08 (0.70, 1.65)	0.7965	
Race							0.9869
Caucasian	40/78 (51.3)	0.95 (0.49, NE)	102/204 (50.0)	2.00 (1.15, 5.41)	0.76 (0.52, 1.10)	0.1125	
Others	8/16 (50.0)	0.95 (0.30, NE)	18/38 (47.4)	6.23 (0.49, NE)	0.83 (0.35, 1.94)	0.5520	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.13. Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0677
<50%	7/25 (28.0)	NE (2.13, NE)	32/65 (49.2)	3.93 (1.44, 7.54)	1.32 (0.57, 3.06)	0.5069	
≥50%	38/66 (57.6)	0.92 (0.49, 1.15)	72/153 (47.1)	1.64 (0.95, 10.00)	0.65 (0.44, 0.97)	0.0240	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-sls-eqcas.sas
Output: t14-04-004-013-tte-sub-de-eortc-sls-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.1102
<35 years	20/40 (50.0)	1.21 (0.52, NE)	27/110 (24.5)	NE (NE, NE)	0.38 (0.21, 0.68)	0.0006	
≥35 years	23/54 (42.6)	1.97 (0.98, NE)	46/130 (35.4)	5.05 (3.28, NE)	0.62 (0.37, 1.03)	0.0606	
Age group 2							0.1120
<35 years	20/40 (50.0)	1.21 (0.52, NE)	27/110 (24.5)	NE (NE, NE)	0.38 (0.21, 0.68)	0.0006	
35 - 54 years	6/22 (27.3)	NE (1.08, NE)	27/73 (37.0)	5.05 (2.62, NE)	0.99 (0.40, 2.45)	0.9826	
55 - 64 years	8/20 (40.0)	NE (0.26, NE)	11/30 (36.7)	4.30 (1.64, NE)	0.74 (0.29, 1.88)	0.5476	
≥65 years	9/12 (75.0)	0.95 (0.26, 1.97)	8/27 (29.6)	NE (2.33, NE)	0.28 (0.10, 0.77)	0.0061	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
Output: t14-04-004-014-tte-sub-de-eortc-cos-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0299
Male	27/55 (49.1)	1.70 (0.49, NE)	35/145 (24.1)	NE (NE, NE)	0.35 (0.21, 0.59)	<0.0001	
Female	16/39 (41.0)	1.54 (0.98, NE)	38/95 (40.0)	4.30 (2.49, NE)	0.77 (0.42, 1.40)	0.3242	
Region							0.5826
USA	5/12 (41.7)	1.70 (0.75, NE)	8/26 (30.8)	3.48 (1.87, NE)	0.60 (0.19, 1.90)	0.3784	
Europe	25/58 (43.1)	1.97 (0.89, NE)	48/157 (30.6)	NE (NE, NE)	0.55 (0.34, 0.90)	0.0158	
Rest of the world	13/24 (54.2)	1.21 (0.46, NE)	17/57 (29.8)	NE (2.62, NE)	0.35 (0.16, 0.75)	0.0038	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
Output: t14-04-004-014-tte-sub-de-eortc-cos-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1688
Yes	19/53 (35.8)	NE (0.98, NE)	43/144 (29.9)	NE (NE, NE)	0.69 (0.40, 1.19)	0.1686	
No	24/41 (58.5)	1.41 (0.49, 1.97)	30/96 (31.3)	NE (4.30, NE)	0.34 (0.19, 0.60)	<0.0001	
Number of salvage therapies							0.1981
0	27/49 (55.1)	1.21 (0.49, 1.97)	31/104 (29.8)	NE (4.62, NE)	0.33 (0.19, 0.56)	<0.0001	
1	10/29 (34.5)	NE (0.98, NE)	23/81 (28.4)	NE (2.62, NE)	0.75 (0.36, 1.59)	0.4279	
≥2	6/16 (37.5)	NE (0.26, NE)	19/55 (34.5)	NE (3.28, NE)	0.80 (0.32, 2.01)	0.6109	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
Output: t14-04-004-014-tte-sub-de-eortc-cos-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.4301
Yes	11/29 (37.9)	NE (0.62, NE)	26/83 (31.3)	NE (NE, NE)	0.74 (0.36, 1.50)	0.3842	
No	32/65 (49.2)	1.54 (0.89, NE)	47/157 (29.9)	NE (4.23, NE)	0.42 (0.26, 0.66)	0.0001	
Race							0.9765
Caucasian	36/77 (46.8)	1.54 (0.75, NE)	63/203 (31.0)	NE (NE, NE)	0.52 (0.34, 0.79)	0.0015	
Others	7/17 (41.2)	1.70 (0.46, NE)	10/37 (27.0)	4.30 (2.62, NE)	0.32 (0.11, 0.93)	0.0275	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
Output: t14-04-004-014-tte-sub-de-eortc-cos-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.14. Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.8911
<50%	14/25 (56.0)	0.98 (0.46, NE)	23/64 (35.9)	NE (3.48, NE)	0.44 (0.22, 0.88)	0.0130	
≥50%	29/66 (43.9)	1.54 (0.95, NE)	39/152 (25.7)	NE (NE, NE)	0.45 (0.27, 0.73)	0.0009	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-cos-eqcas.sas
Output: t14-04-004-014-tte-sub-de-eortc-cos-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4688
<35 years	24/41 (58.5)	0.52 (0.49, 2.49)	34/110 (30.9)	5.54 (4.36, NE)	0.26 (0.15, 0.46)	<0.0001	
≥35 years	28/53 (52.8)	0.95 (0.49, NE)	44/130 (33.8)	NE (3.02, NE)	0.42 (0.26, 0.69)	0.0004	
Age group 2							0.3560
<35 years	24/41 (58.5)	0.52 (0.49, 2.49)	34/110 (30.9)	5.54 (4.36, NE)	0.26 (0.15, 0.46)	<0.0001	
35 - 54 years	13/22 (59.1)	0.49 (0.30, NE)	26/73 (35.6)	3.28 (2.46, NE)	0.27 (0.13, 0.55)	0.0001	
55 - 64 years	8/19 (42.1)	NE (0.26, NE)	12/29 (41.4)	3.41 (0.56, NE)	0.76 (0.30, 1.92)	0.5753	
≥65 years	7/12 (58.3)	0.95 (0.26, NE)	6/28 (21.4)	NE (NE, NE)	0.33 (0.11, 1.00)	0.0367	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0887
Male	30/55 (54.5)	0.95 (0.49, NE)	52/146 (35.6)	4.43 (2.56, NE)	0.43 (0.27, 0.68)	0.0002	
Female	22/39 (56.4)	0.49 (0.36, NE)	26/94 (27.7)	NE (5.05, NE)	0.26 (0.14, 0.47)	<0.0001	
Region							0.1270
USA	6/12 (50.0)	1.08 (0.26, NE)	13/26 (50.0)	1.44 (0.95, 3.25)	0.97 (0.37, 2.55)	0.9793	
Europe	33/58 (56.9)	0.49 (0.49, NE)	44/157 (28.0)	NE (5.05, NE)	0.30 (0.19, 0.48)	<0.0001	
Rest of the world	13/24 (54.2)	0.59 (0.39, NE)	21/57 (36.8)	4.36 (1.67, NE)	0.31 (0.14, 0.65)	0.0012	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.8771
Yes	27/53 (50.9)	1.05 (0.49, NE)	42/145 (29.0)	NE (4.36, NE)	0.35 (0.21, 0.58)	<0.0001	
No	25/41 (61.0)	0.49 (0.36, 2.49)	36/95 (37.9)	5.05 (2.89, NE)	0.34 (0.20, 0.58)	<0.0001	
Number of salvage therapies							0.7190
0	30/49 (61.2)	0.49 (0.39, 0.95)	38/103 (36.9)	5.05 (3.25, NE)	0.31 (0.19, 0.52)	<0.0001	
1	15/28 (53.6)	0.92 (0.39, NE)	25/81 (30.9)	NE (2.33, NE)	0.42 (0.22, 0.80)	0.0070	
≥2	7/17 (41.2)	4.13 (0.49, NE)	15/56 (26.8)	5.97 (2.46, NE)	0.37 (0.15, 0.95)	0.0337	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0558
Yes	21/29 (72.4)	0.49 (0.26, 1.05)	26/80 (32.5)	5.05 (3.28, NE)	0.18 (0.10, 0.33)	<0.0001	
No	31/65 (47.7)	0.95 (0.49, NE)	52/160 (32.5)	NE (3.25, NE)	0.48 (0.30, 0.75)	0.0013	
Race							0.4024
Caucasian	45/77 (58.4)	0.49 (0.49, 2.49)	66/203 (32.5)	5.97 (3.28, NE)	0.32 (0.21, 0.47)	<0.0001	
Others	7/17 (41.2)	NE (0.30, NE)	12/37 (32.4)	NE (1.11, NE)	0.54 (0.21, 1.42)	0.2008	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.15. Subgroup Analysis of Time to First Deterioration of at least 10 points - Diarrhea from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5287
<50%	13/25 (52.0)	0.49 (0.36, NE)	21/65 (32.3)	5.05 (3.28, NE)	0.24 (0.11, 0.51)	0.0001	
≥50%	38/66 (57.6)	0.75 (0.49, 2.49)	51/152 (33.6)	5.97 (2.56, NE)	0.40 (0.26, 0.61)	<0.0001	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-dis-eqcas.sas
Output: t14-04-004-015-tte-sub-de-eortc-dis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.0514
<35 years	16/41 (39.0)	NE (0.49, NE)	30/108 (27.8)	17.74 (2.95, NE)	0.47 (0.25, 0.88)	0.0155	
≥35 years	15/53 (28.3)	2.46 (2.03, NE)	49/130 (37.7)	18.62 (2.75, NE)	1.18 (0.66, 2.12)	0.6314	
Age group 2							0.0691
<35 years	16/41 (39.0)	NE (0.49, NE)	30/108 (27.8)	17.74 (2.95, NE)	0.47 (0.25, 0.88)	0.0155	
35 - 54 years	7/21 (33.3)	NE (1.05, NE)	27/74 (36.5)	18.62 (2.75, NE)	0.82 (0.35, 1.90)	0.5867	
55 - 64 years	3/20 (15.0)	NE (2.30, NE)	13/30 (43.3)	3.02 (0.49, NE)	3.00 (0.84, 10.69)	0.0814	
≥65 years	5/12 (41.7)	2.03 (0.26, NE)	9/26 (34.6)	NE (0.79, NE)	0.77 (0.26, 2.31)	0.6333	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9991
Male	19/55 (34.5)	2.46 (1.70, NE)	48/143 (33.6)	NE (2.95, NE)	0.77 (0.45, 1.32)	0.3036	
Female	12/39 (30.8)	NE (1.08, NE)	31/95 (32.6)	17.74 (17.74, NE)	0.86 (0.44, 1.69)	0.6513	
Region							0.9426
USA	4/11 (36.4)	1.70 (0.26, NE)	7/26 (26.9)	NE (2.75, NE)	0.62 (0.18, 2.15)	0.4304	
Europe	20/59 (33.9)	2.46 (1.80, NE)	54/155 (34.8)	17.74 (4.39, NE)	0.80 (0.48, 1.35)	0.3899	
Rest of the world	7/24 (29.2)	NE (1.05, NE)	18/57 (31.6)	NE (2.82, NE)	0.89 (0.36, 2.18)	0.7569	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4113
Yes	15/53 (28.3)	NE (2.03, NE)	45/141 (31.9)	NE (2.95, NE)	0.96 (0.54, 1.74)	0.8898	
No	16/41 (39.0)	2.30 (1.08, NE)	34/97 (35.1)	17.74 (3.02, NE)	0.64 (0.35, 1.18)	0.1322	
Number of salvage therapies							0.6434
0	17/49 (34.7)	NE (1.70, NE)	36/104 (34.6)	17.74 (3.02, NE)	0.70 (0.39, 1.27)	0.2253	
1	7/28 (25.0)	2.46 (2.03, NE)	24/80 (30.0)	NE (NE, NE)	1.14 (0.49, 2.66)	0.8105	
≥2	7/17 (41.2)	NE (0.26, NE)	19/54 (35.2)	4.39 (1.38, NE)	0.60 (0.25, 1.45)	0.2717	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6156
Yes	10/29 (34.5)	NE (0.85, NE)	33/82 (40.2)	17.74 (2.00, NE)	0.92 (0.45, 1.90)	0.7969	
No	21/65 (32.3)	2.46 (1.70, NE)	46/156 (29.5)	NE (NE, NE)	0.73 (0.43, 1.24)	0.2229	
Race							0.8904
Caucasian	26/77 (33.8)	2.46 (1.80, NE)	67/200 (33.5)	17.74 (3.25, NE)	0.77 (0.49, 1.23)	0.2448	
Others	5/17 (29.4)	NE (0.26, NE)	12/38 (31.6)	NE (1.41, NE)	0.99 (0.35, 2.81)	0.9929	

EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.4.16. Subgroup Analysis of Time to First Deterioration of at least 10 points - Financial Impact from EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)

	SOC Chemotherapy (N = 95)		Blinatumomab (N = 247)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7053
<50%	11/25 (44.0)	2.30 (0.49, NE)	27/65 (41.5)	17.74 (2.82, NE)	0.59 (0.29, 1.24)	0.1539	
≥50%	20/66 (30.3)	NE (1.80, NE)	43/149 (28.9)	NE (4.39, NE)	0.81 (0.48, 1.39)	0.4278	

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EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
N = Number of subjects in analysis set. CI = Confidence interval. EORTC QLQ = European organization for research and treatment of cancer quality of life questionnaire. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-de-eortc-fis-eqcas.sas
Output: t14-04-004-016-tte-sub-de-eortc-fis-eqcas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

Table 14-4.5.1. Overall Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.8351
<35 years	35/60 (58.3)	4.49 (2.49, 6.39)	78/123 (63.4)	9.87 (7.11, 11.51)	0.77 (0.51, 1.14)	0.1923	
≥35 years	55/74 (74.3)	3.79 (2.56, 5.48)	106/148 (71.6)	5.57 (3.87, 8.30)	0.81 (0.59, 1.13)	0.2141	
Age group 2							0.8620
<35 years	35/60 (58.3)	4.49 (2.49, 6.39)	79/124 (63.7)	9.87 (7.11, 11.51)	0.78 (0.52, 1.16)	0.2178	
35 - 54 years	23/33 (69.7)	2.66 (1.97, 6.95)	55/80 (68.8)	6.13 (4.00, 10.16)	0.71 (0.43, 1.15)	0.1644	
55 - 64 years	21/26 (80.8)	3.72 (2.23, 5.31)	26/34 (76.5)	4.15 (2.46, 9.57)	0.83 (0.47, 1.48)	0.5270	
≥65 years	11/15 (73.3)	3.97 (1.34, 10.23)	24/33 (72.7)	5.67 (2.46, 9.38)	1.04 (0.51, 2.13)	0.9168	
Sex							0.9293
Male	52/77 (67.5)	3.70 (2.56, 5.48)	115/162 (71.0)	6.89 (4.85, 9.57)	0.78 (0.56, 1.09)	0.1404	
Female	38/57 (66.7)	4.49 (2.56, 6.59)	69/109 (63.3)	8.39 (4.85, 11.51)	0.78 (0.52, 1.16)	0.2174	

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Overall Survival (OS) is calculated from time of randomization until death due to any cause.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-os-fas.sas
Output: t14-04-005-001-tte-sub-os-fas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

Table 14-4.5.1. Overall Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.4324
USA	11/15 (73.3)	3.74 (1.64, 20.23)	25/31 (80.6)	7.11 (3.21, 10.39)	1.00 (0.49, 2.06)	0.9997	
Europe	57/85 (67.1)	4.46 (2.89, 6.39)	123/180 (68.3)	7.67 (4.95, 9.57)	0.83 (0.60, 1.13)	0.2368	
Rest of the world	22/34 (64.7)	3.70 (1.25, 6.07)	36/60 (60.0)	9.38 (4.00, 14.62)	0.60 (0.35, 1.03)	0.0623	
Prior salvage therapy							0.6637
Yes	58/80 (72.5)	3.21 (2.23, 4.49)	125/164 (76.2)	4.85 (3.21, 7.70)	0.82 (0.60, 1.12)	0.2199	
No	32/54 (59.3)	6.39 (3.70, 20.23)	59/107 (55.1)	10.16 (7.87, 15.57)	0.70 (0.46, 1.08)	0.1086	
Number of salvage therapies							0.2019
0	39/65 (60.0)	5.51 (3.70, 9.05)	63/114 (55.3)	10.89 (8.23, 17.08)	0.68 (0.46, 1.02)	0.0621	
1	34/43 (79.1)	3.31 (1.87, 4.07)	67/91 (73.6)	5.08 (3.21, 8.85)	0.60 (0.40, 0.92)	0.0167	
≥2	17/26 (65.4)	3.05 (1.70, 6.03)	54/66 (81.8)	3.67 (1.84, 6.89)	1.15 (0.67, 1.99)	0.6108	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Overall Survival (OS) is calculated from time of randomization until death due to any cause.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-os-fas.sas
Output: t14-04-005-001-tte-sub-os-fas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

Table 14-4.5.1. Overall Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.9925
Yes	27/46 (58.7)	5.31 (1.87, 6.95)	61/94 (64.9)	7.70 (3.64, 10.82)	0.80 (0.51, 1.26)	0.3304	
No	63/88 (71.6)	3.72 (2.82, 5.31)	123/177 (69.5)	7.54 (5.08, 9.57)	0.78 (0.57, 1.06)	0.1094	
Race							0.4979
Caucasian	78/112 (69.6)	4.43 (2.89, 5.51)	154/228 (67.5)	7.67 (5.31, 9.57)	0.76 (0.58, 1.00)	0.0488	
Others	12/22 (54.5)	3.70 (1.25, NE)	30/43 (69.8)	7.54 (3.61, 11.87)	0.98 (0.50, 1.94)	0.9637	
Central laboratory baseline bone marrow blasts							0.3284
<50%	19/36 (52.8)	6.79 (2.13, NE)	38/73 (52.1)	11.87 (9.87, NE)	0.64 (0.37, 1.11)	0.1093	
≥50%	66/93 (71.0)	3.74 (2.66, 5.31)	126/170 (74.1)	4.85 (3.48, 6.56)	0.89 (0.66, 1.21)	0.4664	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Overall Survival (OS) is calculated from time of randomization until death due to any cause.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-os-fas.sas
Output: t14-04-005-001-tte-sub-os-fas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

Table 14-4.5.2. Event Free Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.7295
<35 years	54/60 (90.0)	0.03 (NE, NE)	96/123 (78.0)	0.03 (0.03, 3.25)	0.67 (0.48, 0.94)	0.0277	
≥35 years	66/74 (89.2)	0.03 (NE, NE)	124/148 (83.8)	0.03 (0.03, 2.56)	0.58 (0.43, 0.79)	0.0004	
Age group 2							0.4049
<35 years	54/60 (90.0)	0.03 (NE, NE)	97/124 (78.2)	0.03 (0.03, 3.25)	0.68 (0.48, 0.94)	0.0300	
35 - 54 years	29/33 (87.9)	0.03 (NE, NE)	66/80 (82.5)	0.03 (0.03, 4.69)	0.51 (0.32, 0.80)	0.0065	
55 - 64 years	25/26 (96.2)	0.03 (NE, NE)	28/34 (82.4)	0.03 (0.03, 4.03)	0.54 (0.31, 0.94)	0.0299	
≥65 years	12/15 (80.0)	2.56 (0.03, 2.79)	29/33 (87.9)	0.03 (0.03, 2.56)	0.97 (0.49, 1.92)	0.6720	
Sex							0.1386
Male	68/77 (88.3)	0.03 (NE, NE)	141/162 (87.0)	0.03 (NE, NE)	0.73 (0.54, 0.98)	0.0353	
Female	52/57 (91.2)	0.03 (NE, NE)	79/109 (72.5)	3.48 (0.03, 5.70)	0.52 (0.37, 0.75)	0.0007	

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
EFS is calculated from the time of randomization until the date of a disease assessment indicating a relapse event or death, whichever occurs first.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-efs-fas.sas
Output: t14-04-005-002-tte-sub-efs-fas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

Table 14-4.5.2. Event Free Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.1140
USA	12/15 (80.0)	0.03 (0.03, 2.82)	28/31 (90.3)	0.03 (0.03, 3.97)	1.21 (0.60, 2.43)	0.5438	
Europe	76/85 (89.4)	0.03 (NE, NE)	140/180 (77.8)	0.03 (0.03, 2.98)	0.60 (0.45, 0.79)	0.0007	
Rest of the world	32/34 (94.1)	0.03 (NE, NE)	52/60 (86.7)	0.03 (0.03, 5.15)	0.54 (0.34, 0.86)	0.0043	
Prior salvage therapy							0.6757
Yes	78/80 (97.5)	0.03 (NE, NE)	147/164 (89.6)	0.03 (NE, NE)	0.57 (0.43, 0.76)	0.0001	
No	42/54 (77.8)	0.03 (0.03, 2.23)	73/107 (68.2)	3.57 (0.03, 6.59)	0.68 (0.46, 1.00)	0.0495	
Number of salvage therapies							0.5516
0	52/65 (80.0)	0.03 (NE, NE)	81/114 (71.1)	2.82 (0.03, 6.52)	0.70 (0.49, 0.99)	0.0619	
1	42/43 (97.7)	0.03 (NE, NE)	77/91 (84.6)	0.03 (NE, NE)	0.51 (0.34, 0.75)	0.0002	
≥2	26/26 (100.0)	0.03 (NE, NE)	62/66 (93.9)	0.03 (NE, NE)	0.48 (0.29, 0.79)	0.0005	

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
EFS is calculated from the time of randomization until the date of a disease assessment indicating a relapse event or death, whichever occurs first.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-efs-fas.sas
Output: t14-04-005-002-tte-sub-efs-fas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

Table 14-4.5.2. Event Free Survival - Subgroup Analysis (Full Analysis Set)

	SOC Chemotherapy (N = 134)		Blinatumomab (N = 271)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0046
Yes	45/46 (97.8)	0.03 (NE, NE)	74/94 (78.7)	0.03 (0.03, 2.95)	0.44 (0.30, 0.65)	<0.0001	
No	75/88 (85.2)	0.03 (NE, NE)	146/177 (82.5)	0.03 (0.03, 2.82)	0.78 (0.59, 1.04)	0.1522	
Race							0.4444
Caucasian	101/112 (90.2)	0.03 (NE, NE)	180/228 (78.9)	0.03 (0.03, 2.30)	0.61 (0.48, 0.79)	<0.0001	
Others	19/22 (86.4)	0.03 (NE, NE)	40/43 (93.0)	0.03 (0.03, 5.34)	0.74 (0.42, 1.28)	0.4481	
Central laboratory baseline bone marrow blasts							0.1738
<50%	29/36 (80.6)	0.03 (NE, NE)	51/73 (69.9)	5.61 (3.31, 7.84)	0.45 (0.28, 0.72)	0.0018	
≥50%	86/93 (92.5)	0.03 (NE, NE)	147/170 (86.5)	0.03 (NE, NE)	0.73 (0.56, 0.95)	0.0152	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
EFS is calculated from the time of randomization until the date of a disease assessment indicating a relapse event or death, whichever occurs first.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-efs-fas.sas
Output: t14-04-005-002-tte-sub-efs-fas.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

Table 14-6.2.1. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4536
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	123/123 (100.0)	0.07 (NE, NE)	0.91 (0.65, 1.27)	0.5535	
≥35 years	59/59 (100.0)	0.07 (0.03, 0.07)	140/144 (97.2)	0.07 (0.03, 0.07)	1.09 (0.80, 1.48)	0.7769	
Age group 2							0.8972
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	124/124 (100.0)	0.07 (NE, NE)	0.92 (0.66, 1.28)	0.5805	
35 - 54 years	25/25 (100.0)	0.07 (0.03, 0.10)	76/77 (98.7)	0.07 (0.03, 0.07)	1.10 (0.70, 1.74)	0.8750	
55 - 64 years	22/22 (100.0)	0.07 (0.03, 0.10)	32/33 (97.0)	0.03 (0.03, 0.07)	1.09 (0.63, 1.90)	0.8594	
≥65 years	12/12 (100.0)	0.05 (0.03, 0.20)	31/33 (93.9)	0.07 (0.03, 0.07)	0.96 (0.49, 1.88)	0.7941	
Sex							0.2493
Male	63/64 (98.4)	0.07 (0.03, 0.07)	156/159 (98.1)	0.07 (NE, NE)	0.90 (0.67, 1.21)	0.4162	
Female	45/45 (100.0)	0.07 (0.03, 0.07)	107/108 (99.1)	0.07 (0.03, 0.07)	1.22 (0.86, 1.74)	0.3363	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-saf.sas
Output: t14-06-002-001-tte-sub-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.1. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.3482
USA	12/13 (92.3)	0.07 (0.03, 0.16)	30/30 (100.0)	0.07 (0.03, 0.07)	1.54 (0.78, 3.03)	0.1887	
Europe	68/68 (100.0)	0.07 (0.03, 0.07)	174/177 (98.3)	0.07 (NE, NE)	0.91 (0.69, 1.21)	0.3724	
Rest of the world	28/28 (100.0)	0.07 (0.03, 0.07)	59/60 (98.3)	0.05 (0.03, 0.07)	1.09 (0.69, 1.72)	0.7975	
Prior salvage therapy							0.1701
Yes	62/63 (98.4)	0.07 (0.07, 0.10)	159/161 (98.8)	0.07 (NE, NE)	1.13 (0.84, 1.52)	0.5362	
No	46/46 (100.0)	0.07 (0.03, 0.07)	104/106 (98.1)	0.07 (NE, NE)	0.84 (0.60, 1.20)	0.2717	
Number of salvage therapies							0.1573
0	55/55 (100.0)	0.03 (0.03, 0.07)	110/112 (98.2)	0.07 (NE, NE)	0.81 (0.59, 1.12)	0.1401	
1	33/34 (97.1)	0.07 (0.07, 0.10)	89/91 (97.8)	0.07 (0.03, 0.07)	1.13 (0.76, 1.69)	0.5886	
≥2	20/20 (100.0)	0.10 (0.07, 0.13)	64/64 (100.0)	0.07 (0.03, 0.07)	1.36 (0.81, 2.29)	0.2734	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-saf.sas
Output: t14-06-002-001-tte-sub-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.1. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.8878
Yes	35/35 (100.0)	0.07 (0.03, 0.07)	92/93 (98.9)	0.07 (0.03, 0.07)	0.95 (0.64, 1.42)	0.5578	
No	73/74 (98.6)	0.07 (NE, NE)	171/174 (98.3)	0.07 (NE, NE)	1.01 (0.77, 1.33)	0.9247	
Race							0.8263
Caucasian	90/90 (100.0)	0.07 (0.03, 0.07)	222/226 (98.2)	0.07 (NE, NE)	0.99 (0.77, 1.26)	0.6685	
Others	18/19 (94.7)	0.07 (0.03, 0.07)	41/41 (100.0)	0.07 (0.03, 0.07)	1.04 (0.59, 1.81)	0.7449	
Central laboratory baseline bone marrow blasts							0.3812
<50%	27/27 (100.0)	0.07 (0.03, 0.07)	70/73 (95.9)	0.07 (0.03, 0.07)	0.96 (0.61, 1.50)	0.7252	
≥50%	76/77 (98.7)	0.07 (NE, NE)	168/168 (100.0)	0.07 (NE, NE)	1.14 (0.87, 1.50)	0.4141	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-saf.sas
Output: t14-06-002-001-tte-sub-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.7633
<35 years	21/50 (42.0)	2.82 (1.02, NE)	74/123 (60.2)	1.48 (1.02, 3.87)	1.12 (0.68, 1.83)	0.6555	
≥35 years	28/59 (47.5)	1.84 (0.69, NE)	94/144 (65.3)	1.57 (1.15, 2.46)	0.98 (0.63, 1.51)	0.9239	
Age group 2							0.4128
<35 years	21/50 (42.0)	2.82 (1.02, NE)	75/124 (60.5)	1.48 (1.02, 3.87)	1.13 (0.69, 1.85)	0.6125	
35 - 54 years	12/25 (48.0)	1.87 (0.39, NE)	42/77 (54.5)	1.87 (1.15, 5.41)	0.66 (0.34, 1.28)	0.2160	
55 - 64 years	10/22 (45.5)	1.57 (0.43, NE)	26/33 (78.8)	1.51 (0.95, 3.70)	1.03 (0.48, 2.22)	0.9502	
≥65 years	6/12 (50.0)	1.85 (0.20, NE)	25/33 (75.8)	0.49 (0.23, 2.36)	1.49 (0.60, 3.72)	0.4021	
Sex							0.3373
Male	27/64 (42.2)	2.82 (1.11, NE)	100/159 (62.9)	1.48 (1.08, 3.08)	1.17 (0.76, 1.80)	0.4820	
Female	22/45 (48.9)	1.28 (0.52, NE)	68/108 (63.0)	1.64 (1.15, 2.59)	0.88 (0.54, 1.45)	0.6205	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-saf.sas
Output: t14-06-002-002-tte-sub-ser-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.2057
USA	4/13 (30.8)	1.84 (0.89, NE)	22/30 (73.3)	1.08 (0.46, 2.92)	2.36 (0.80, 6.91)	0.1102	
Europe	28/68 (41.2)	2.03 (1.57, NE)	99/177 (55.9)	2.52 (1.51, 4.59)	0.97 (0.63, 1.49)	0.8799	
Rest of the world	17/28 (60.7)	0.46 (0.33, NE)	47/60 (78.3)	0.92 (0.56, 1.31)	0.94 (0.53, 1.65)	0.8316	
Prior salvage therapy							0.1714
Yes	27/63 (42.9)	1.84 (1.02, NE)	106/161 (65.8)	1.28 (0.95, 1.64)	1.24 (0.81, 1.91)	0.3188	
No	22/46 (47.8)	1.87 (0.52, NE)	62/106 (58.5)	2.56 (1.44, 5.54)	0.78 (0.47, 1.30)	0.3424	
Number of salvage therapies							0.8083
0	24/55 (43.6)	2.82 (0.75, NE)	63/112 (56.3)	3.08 (1.44, 5.54)	0.91 (0.56, 1.48)	0.7087	
1	15/34 (44.1)	1.57 (0.62, NE)	61/91 (67.0)	1.15 (0.75, 1.64)	1.14 (0.64, 2.03)	0.6535	
≥2	10/20 (50.0)	1.84 (0.39, NE)	44/64 (68.8)	1.28 (0.95, 2.52)	0.99 (0.49, 1.99)	0.9684	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-saf.sas
Output: t14-06-002-002-tte-sub-ser-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0071
Yes	22/35 (62.9)	0.92 (0.39, 2.82)	61/93 (65.6)	1.74 (1.18, 3.93)	0.56 (0.34, 0.94)	0.0260	
No	27/74 (36.5)	2.03 (1.84, NE)	107/174 (61.5)	1.48 (1.05, 2.46)	1.43 (0.93, 2.20)	0.0978	
Race							0.6490
Caucasian	40/90 (44.4)	1.87 (1.02, NE)	141/226 (62.4)	1.64 (1.34, 2.59)	1.02 (0.71, 1.45)	0.9290	
Others	9/19 (47.4)	1.84 (0.43, NE)	27/41 (65.9)	1.05 (0.72, 2.56)	1.28 (0.59, 2.74)	0.5329	
Central laboratory baseline bone marrow blasts							0.1303
<50%	15/27 (55.6)	1.87 (0.52, NE)	45/73 (61.6)	3.28 (1.44, 5.74)	0.58 (0.31, 1.08)	0.0840	
≥50%	32/77 (41.6)	2.82 (1.11, NE)	107/168 (63.7)	1.41 (1.05, 1.87)	1.25 (0.84, 1.87)	0.2769	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-saf.sas
Output: t14-06-002-002-tte-sub-ser-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6965
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	102/123 (82.9)	0.36 (0.23, 0.59)	0.63 (0.44, 0.90)	0.0098	
≥35 years	55/59 (93.2)	0.23 (0.13, 0.26)	129/144 (89.6)	0.16 (0.10, 0.33)	0.72 (0.52, 1.00)	0.0376	
Age group 2							0.8483
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	103/124 (83.1)	0.34 (0.20, 0.59)	0.63 (0.44, 0.91)	0.0111	
35 - 54 years	24/25 (96.0)	0.23 (0.13, 0.26)	69/77 (89.6)	0.26 (0.13, 0.43)	0.61 (0.38, 1.01)	0.0440	
55 - 64 years	21/22 (95.5)	0.21 (0.10, 0.26)	29/33 (87.9)	0.10 (0.07, 0.46)	0.68 (0.37, 1.24)	0.1644	
≥65 years	10/12 (83.3)	0.23 (0.03, 0.56)	30/33 (90.9)	0.13 (0.07, 0.33)	0.97 (0.47, 2.02)	0.9315	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8112
Male	56/64 (87.5)	0.21 (0.13, 0.30)	135/159 (84.9)	0.33 (0.23, 0.46)	0.68 (0.49, 0.93)	0.0156	
Female	44/45 (97.8)	0.23 (0.16, 0.26)	96/108 (88.9)	0.13 (0.10, 0.30)	0.68 (0.47, 1.00)	0.0333	
Region							0.0941
USA	10/13 (76.9)	0.26 (0.07, 0.89)	28/30 (93.3)	0.13 (0.07, 0.33)	1.42 (0.69, 2.94)	0.3534	
Europe	63/68 (92.6)	0.23 (0.16, 0.26)	147/177 (83.1)	0.30 (0.16, 0.39)	0.64 (0.47, 0.87)	0.0028	
Rest of the world	27/28 (96.4)	0.16 (0.07, 0.26)	56/60 (93.3)	0.38 (0.13, 0.56)	0.55 (0.34, 0.89)	0.0130	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4910
Yes	58/63 (92.1)	0.23 (0.16, 0.26)	143/161 (88.8)	0.30 (0.16, 0.39)	0.70 (0.51, 0.96)	0.0186	
No	42/46 (91.3)	0.23 (0.10, 0.26)	88/106 (83.0)	0.26 (0.13, 0.43)	0.65 (0.45, 0.95)	0.0241	
Number of salvage therapies							0.7257
0	50/55 (90.9)	0.23 (0.13, 0.26)	92/112 (82.1)	0.26 (0.13, 0.39)	0.68 (0.47, 0.96)	0.0284	
1	31/34 (91.2)	0.20 (0.10, 0.26)	81/91 (89.0)	0.33 (0.16, 0.46)	0.60 (0.39, 0.93)	0.0184	
≥2	19/20 (95.0)	0.25 (0.10, 0.43)	58/64 (90.6)	0.23 (0.07, 0.36)	0.75 (0.44, 1.29)	0.2124	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.3. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6028
Yes	35/35 (100.0)	0.23 (0.16, 0.26)	81/93 (87.1)	0.20 (0.13, 0.36)	0.60 (0.39, 0.91)	0.0113	
No	65/74 (87.8)	0.21 (0.13, 0.26)	150/174 (86.2)	0.33 (0.16, 0.43)	0.71 (0.53, 0.96)	0.0217	
Race							0.3064
Caucasian	83/90 (92.2)	0.21 (0.16, 0.26)	194/226 (85.8)	0.26 (0.16, 0.36)	0.66 (0.50, 0.86)	0.0013	
Others	17/19 (89.5)	0.26 (0.10, 0.43)	37/41 (90.2)	0.39 (0.10, 0.59)	0.80 (0.44, 1.43)	0.4404	
Central laboratory baseline bone marrow blasts							0.0619
<50%	24/27 (88.9)	0.23 (0.10, 0.26)	58/73 (79.5)	0.66 (0.33, 1.44)	0.46 (0.28, 0.77)	0.0018	
≥50%	71/77 (92.2)	0.20 (0.16, 0.26)	151/168 (89.9)	0.18 (0.10, 0.33)	0.81 (0.61, 1.08)	0.1172	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-saf.sas
Output: t14-06-002-003-tte-sub-sev-teae-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.3328
<35 years	2/50 (4.0)	NE (NE, NE)	15/123 (12.2)	NE (16.33, NE)	2.33 (0.53, 10.32)	0.2521	
≥35 years	8/59 (13.6)	NE (NE, NE)	27/144 (18.8)	NE (13.15, NE)	0.99 (0.44, 2.22)	0.9786	
Age group 2							0.7767
<35 years	2/50 (4.0)	NE (NE, NE)	16/124 (12.9)	NE (16.33, NE)	2.52 (0.57, 11.09)	0.2053	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	11/77 (14.3)	NE (NE, NE)	1.01 (0.22, 4.75)	0.9850	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	7/33 (21.2)	13.15 (3.70, NE)	0.74 (0.20, 2.77)	0.6571	
≥65 years	2/12 (16.7)	NE (0.75, NE)	8/33 (24.2)	16.33 (16.33, NE)	1.32 (0.27, 6.39)	0.7266	
Sex							0.6791
Male	6/64 (9.4)	NE (NE, NE)	28/159 (17.6)	NE (16.33, NE)	1.33 (0.54, 3.27)	0.5273	
Female	4/45 (8.9)	NE (2.03, NE)	14/108 (13.0)	NE (13.15, NE)	1.12 (0.36, 3.49)	0.8465	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-trt-disc-saf.sas
Output: t14-06-002-004-tte-sub-teae-trt-disc-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.8867
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (3.02, NE)	NE (NE, NE)	0.0986	
Europe	7/68 (10.3)	NE (NE, NE)	27/177 (15.3)	NE (16.33, NE)	1.01 (0.43, 2.39)	0.9766	
Rest of the world	3/28 (10.7)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)	1.03 (0.27, 3.89)	0.9683	
Prior salvage therapy							0.9858
Yes	10/63 (15.9)	NE (NE, NE)	31/161 (19.3)	16.33 (13.15, NE)	0.85 (0.41, 1.77)	0.6697	
No	0/46 (0.0)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	NE (NE, NE)	0.0581	
Number of salvage therapies							0.5364
0	2/55 (3.6)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	2.23 (0.49, 10.19)	0.2861	
1	6/34 (17.6)	NE (NE, NE)	19/91 (20.9)	16.33 (13.15, NE)	0.83 (0.33, 2.12)	0.6969	
≥2	2/20 (10.0)	NE (2.03, NE)	10/64 (15.6)	NE (NE, NE)	1.20 (0.26, 5.60)	0.8162	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-trt-disc-saf.sas
Output: t14-06-002-004-tte-sub-teae-trt-disc-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.5328
Yes	4/35 (11.4)	NE (NE, NE)	16/93 (17.2)	NE (16.33, NE)	0.93 (0.30, 2.91)	0.9054	
No	6/74 (8.1)	NE (NE, NE)	26/174 (14.9)	NE (16.33, NE)	1.47 (0.60, 3.62)	0.3968	
Race							0.7085
Caucasian	8/90 (8.9)	NE (NE, NE)	36/226 (15.9)	NE (16.33, NE)	1.33 (0.61, 2.90)	0.4744	
Others	2/19 (10.5)	NE (NE, NE)	6/41 (14.6)	NE (NE, NE)	1.01 (0.20, 5.13)	0.9911	
Central laboratory baseline bone marrow blasts							0.0036
<50%	6/27 (22.2)	NE (2.03, NE)	8/73 (11.0)	NE (16.33, NE)	0.27 (0.08, 0.87)	0.0192	
≥50%	3/77 (3.9)	NE (NE, NE)	27/168 (16.1)	NE (NE, NE)	3.30 (0.99, 10.98)	0.0388	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-trt-disc-saf.sas
Output: t14-06-002-004-tte-sub-teae-trt-disc-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Capillary leak syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow	54/109 (49.5)	1.11 (0.56, NE)	164/267 (61.4)	0.92 (0.52, 1.44)	1.20 (0.88, 1.64)	0.2400	
Age group 1							0.1614
<35 years	26/50 (52.0)	1.11 (0.43, NE)	70/123 (56.9)	1.44 (0.79, 2.85)	0.90 (0.57, 1.41)	0.6372	
≥35 years	28/59 (47.5)	NE (0.49, NE)	94/144 (65.3)	0.52 (0.33, 1.08)	1.53 (1.00, 2.34)	0.0466	
Age group 2							0.4790
<35 years	26/50 (52.0)	1.11 (0.43, NE)	71/124 (57.3)	1.44 (0.79, 2.85)	0.91 (0.58, 1.43)	0.6784	
35 - 54 years	14/25 (56.0)	0.79 (0.30, NE)	56/77 (72.7)	0.46 (0.20, 0.72)	1.37 (0.76, 2.47)	0.2915	
55 - 64 years	10/22 (45.5)	NE (0.23, NE)	17/33 (51.5)	1.90 (0.33, NE)	1.12 (0.51, 2.46)	0.7729	
≥65 years	4/12 (33.3)	NE (0.13, NE)	20/33 (60.6)	0.79 (0.13, 2.79)	2.17 (0.73, 6.38)	0.1522	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5447
Male	29/64 (45.3)	1.41 (0.72, NE)	87/159 (54.7)	1.44 (0.75, 2.85)	1.11 (0.73, 1.69)	0.6321	
Female	25/45 (55.6)	0.72 (0.39, NE)	77/108 (71.3)	0.46 (0.23, 0.92)	1.38 (0.87, 2.17)	0.1675	
Region							0.4350
USA	5/13 (38.5)	NE (0.10, NE)	18/30 (60.0)	0.69 (0.43, NE)	1.67 (0.62, 4.50)	0.3015	
Europe	30/68 (44.1)	NE (0.72, NE)	102/177 (57.6)	1.28 (0.59, 2.10)	1.33 (0.88, 2.01)	0.1701	
Rest of the world	19/28 (67.9)	0.46 (0.10, 1.31)	44/60 (73.3)	0.39 (0.13, 1.28)	0.87 (0.50, 1.51)	0.6068	
Prior salvage therapy							0.7235
Yes	28/63 (44.4)	1.41 (0.72, NE)	93/161 (57.8)	1.08 (0.59, 1.70)	1.27 (0.83, 1.94)	0.2759	
No	26/46 (56.5)	0.84 (0.33, NE)	71/106 (67.0)	0.62 (0.36, 1.44)	1.15 (0.73, 1.80)	0.5514	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6131
0	31/55 (56.4)	0.72 (0.30, NE)	74/112 (66.1)	0.79 (0.43, 1.44)	1.08 (0.70, 1.64)	0.7335	
1	16/34 (47.1)	0.89 (0.49, NE)	54/91 (59.3)	0.95 (0.39, 1.90)	1.35 (0.77, 2.36)	0.3115	
≥2	7/20 (35.0)	1.41 (0.49, NE)	36/64 (56.3)	1.08 (0.46, 3.02)	1.54 (0.68, 3.48)	0.2968	
Prior alloHSCT							0.4537
Yes	20/35 (57.1)	0.82 (0.26, NE)	59/93 (63.4)	0.75 (0.33, 1.90)	0.96 (0.57, 1.62)	0.8844	
No	34/74 (45.9)	NE (0.52, NE)	105/174 (60.3)	0.92 (0.52, 1.44)	1.32 (0.90, 1.95)	0.1584	
Race							0.9310
Caucasian	44/90 (48.9)	0.98 (0.52, NE)	135/226 (59.7)	0.79 (0.49, 1.48)	1.23 (0.88, 1.73)	0.2328	
Others	10/19 (52.6)	1.11 (0.10, NE)	29/41 (70.7)	1.08 (0.36, 1.44)	1.01 (0.49, 2.10)	0.9936	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0325
<50%	16/27 (59.3)	0.56 (0.13, NE)	39/73 (53.4)	2.85 (0.49, NE)	0.76 (0.42, 1.36)	0.3353	
≥50%	36/77 (46.8)	1.31 (0.72, NE)	113/168 (67.3)	0.62 (0.43, 1.08)	1.52 (1.05, 2.22)	0.0270	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Cytokine release syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	43/267 (16.1)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Age group 1							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/123 (14.6)	NE (NE, NE)	NE (NE, NE)	0.0057	
≥35 years	0/59 (0.0)	NE (NE, NE)	25/144 (17.4)	NE (NE, NE)	NE (NE, NE)	0.0013	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/124 (14.5)	NE (NE, NE)	NE (NE, NE)	0.0059	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	12/77 (15.6)	NE (NE, NE)	NE (NE, NE)	0.0463	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	7/33 (21.2)	NE (NE, NE)	NE (NE, NE)	0.0272	
≥65 years	0/12 (0.0)	NE (NE, NE)	6/33 (18.2)	8.33 (8.33, NE)	NE (NE, NE)	0.1600	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	NE (NE, NE)	23/159 (14.5)	NE (NE, NE)	NE (NE, NE)	0.0018	
Female	0/45 (0.0)	NE (NE, NE)	20/108 (18.5)	NE (NE, NE)	NE (NE, NE)	0.0042	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (NE, NE)	NE (NE, NE)	0.0629	
Europe	0/68 (0.0)	NE (NE, NE)	18/177 (10.2)	NE (NE, NE)	NE (NE, NE)	0.0106	
Rest of the world	0/28 (0.0)	NE (NE, NE)	18/60 (30.0)	NE (NE, NE)	NE (NE, NE)	0.0022	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	NE (NE, NE)	31/161 (19.3)	NE (NE, NE)	NE (NE, NE)	0.0003	
No	0/46 (0.0)	NE (NE, NE)	12/106 (11.3)	NE (NE, NE)	NE (NE, NE)	0.0273	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	NE (NE, NE)	0.0141	
1	0/34 (0.0)	NE (NE, NE)	21/91 (23.1)	NE (NE, NE)	NE (NE, NE)	0.0033	
≥2	0/20 (0.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)	NE (NE, NE)	0.0979	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	NE (NE, NE)	13/93 (14.0)	NE (NE, NE)	NE (NE, NE)	0.0283	
No	0/74 (0.0)	NE (NE, NE)	30/174 (17.2)	NE (NE, NE)	NE (NE, NE)	0.0003	
Race							0.9997
Caucasian	0/90 (0.0)	NE (NE, NE)	40/226 (17.7)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Others	0/19 (0.0)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	NE (NE, NE)	0.2831	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	NE (NE, NE)	11/73 (15.1)	NE (NE, NE)	NE (NE, NE)	0.0353	
≥50%	0/77 (0.0)	NE (NE, NE)	28/168 (16.7)	NE (NE, NE)	NE (NE, NE)	0.0003	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Decreased immunoglobulins (AMQ) - Narrow	2/109 (1.8)	NE (NE, NE)	29/267 (10.9)	16.03 (14.79, NE)	2.21 (0.51, 9.65)	0.2811	
Age group 1							0.9915
<35 years	0/50 (0.0)	NE (NE, NE)	12/123 (9.8)	16.03 (16.03, NE)	NE (NE, NE)	0.1860	
≥35 years	2/59 (3.4)	NE (NE, NE)	17/144 (11.8)	14.79 (7.74, NE)	1.28 (0.27, 6.05)	0.7535	
Age group 2							0.9298
<35 years	0/50 (0.0)	NE (NE, NE)	12/124 (9.7)	16.03 (16.03, NE)	NE (NE, NE)	0.1860	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	12/77 (15.6)	14.79 (5.08, NE)	NE (NE, NE)	0.2819	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	3/33 (9.1)	NE (5.80, NE)	0.64 (0.04, 10.23)	0.7497	
≥65 years	1/12 (8.3)	NE (NE, NE)	2/33 (6.1)	NE (7.74, NE)	0.34 (0.02, 5.56)	0.4297	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9877
Male	2/64 (3.1)	NE (NE, NE)	15/159 (9.4)	16.03 (8.30, NE)	1.13 (0.24, 5.41)	0.8808	
Female	0/45 (0.0)	NE (NE, NE)	14/108 (13.0)	14.79 (7.74, NE)	NE (NE, NE)	0.1772	
Region							0.4045
USA	1/13 (7.7)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	0.40 (0.03, 6.45)	0.5052	
Europe	1/68 (1.5)	NE (NE, NE)	20/177 (11.3)	NE (8.30, NE)	2.78 (0.35, 21.79)	0.3116	
Rest of the world	0/28 (0.0)	NE (NE, NE)	8/60 (13.3)	16.03 (NE, NE)	NE (NE, NE)	0.3594	
Prior salvage therapy							0.9904
Yes	0/63 (0.0)	NE (NE, NE)	18/161 (11.2)	16.03 (7.02, NE)	NE (NE, NE)	0.0981	
No	2/46 (4.3)	NE (NE, NE)	11/106 (10.4)	NE (14.79, NE)	0.78 (0.15, 4.03)	0.7655	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9999
0	2/55 (3.6)	NE (NE, NE)	13/112 (11.6)	16.03 (8.30, NE)	0.79 (0.15, 4.14)	0.7832	
1	0/34 (0.0)	NE (NE, NE)	11/91 (12.1)	NE (5.31, NE)	NE (NE, NE)	0.1851	
≥2	0/20 (0.0)	NE (NE, NE)	5/64 (7.8)	NE (7.18, NE)	NE (NE, NE)	0.4286	
Prior alloHSCT							0.9893
Yes	0/35 (0.0)	NE (NE, NE)	18/93 (19.4)	14.79 (7.02, NE)	NE (NE, NE)	0.1706	
No	2/74 (2.7)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	1.17 (0.25, 5.60)	0.8413	
Race							0.3321
Caucasian	1/90 (1.1)	NE (NE, NE)	24/226 (10.6)	16.03 (14.79, NE)	3.08 (0.40, 23.74)	0.2570	
Others	1/19 (5.3)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	1.39 (0.16, 12.37)	0.7766	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9902
<50%	0/27 (0.0)	NE (NE, NE)	13/73 (17.8)	14.79 (7.02, NE)	NE (NE, NE)	0.2777	
≥50%	2/77 (2.6)	NE (NE, NE)	13/168 (7.7)	NE (NE, NE)	1.42 (0.30, 6.74)	0.6573	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Haematopoietic cytopenias (SMQ) - Narrow	79/109 (72.5)	0.26 (0.23, 0.30)	160/267 (59.9)	1.15 (0.62, 2.10)	0.56 (0.42, 0.73)	<0.0001	
Age group 1							0.9443
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	72/123 (58.5)	1.64 (0.62, 2.59)	0.53 (0.35, 0.80)	0.0025	
≥35 years	45/59 (76.3)	0.26 (0.20, 0.30)	88/144 (61.1)	0.79 (0.46, 2.16)	0.58 (0.40, 0.84)	0.0033	
Age group 2							0.7235
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	73/124 (58.9)	1.64 (0.62, 2.59)	0.54 (0.35, 0.82)	0.0031	
35 - 54 years	18/25 (72.0)	0.26 (0.23, 0.56)	48/77 (62.3)	0.82 (0.33, 2.46)	0.68 (0.39, 1.18)	0.1541	
55 - 64 years	19/22 (86.4)	0.26 (0.10, 0.43)	20/33 (60.6)	0.52 (0.20, NE)	0.43 (0.22, 0.83)	0.0106	
≥65 years	8/12 (66.7)	0.23 (0.03, NE)	19/33 (57.6)	2.36 (0.20, 8.26)	0.63 (0.27, 1.49)	0.2791	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5701
Male	45/64 (70.3)	0.26 (0.20, 0.36)	96/159 (60.4)	1.31 (0.52, 2.03)	0.57 (0.40, 0.82)	0.0021	
Female	34/45 (75.6)	0.26 (0.20, 0.30)	64/108 (59.3)	0.98 (0.49, 3.11)	0.55 (0.36, 0.84)	0.0052	
Region							0.1404
USA	8/13 (61.5)	0.39 (0.20, NE)	23/30 (76.7)	0.48 (0.20, 1.15)	1.01 (0.45, 2.31)	0.9857	
Europe	47/68 (69.1)	0.26 (0.20, 0.33)	98/177 (55.4)	1.64 (0.62, 3.02)	0.59 (0.41, 0.84)	0.0029	
Rest of the world	24/28 (85.7)	0.23 (0.10, 0.30)	39/60 (65.0)	1.54 (0.33, 2.36)	0.32 (0.18, 0.57)	<0.0001	
Prior salvage therapy							0.0528
Yes	43/63 (68.3)	0.30 (0.23, 0.43)	101/161 (62.7)	1.08 (0.59, 1.93)	0.63 (0.44, 0.91)	0.0120	
No	36/46 (78.3)	0.23 (0.13, 0.26)	59/106 (55.7)	2.03 (0.39, 6.62)	0.46 (0.30, 0.71)	0.0003	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3433
0	42/55 (76.4)	0.26 (0.13, 0.26)	66/112 (58.9)	0.85 (0.39, 2.82)	0.50 (0.34, 0.75)	0.0007	
1	24/34 (70.6)	0.28 (0.20, 0.56)	55/91 (60.4)	1.64 (0.62, 2.89)	0.51 (0.31, 0.86)	0.0075	
≥2	13/20 (65.0)	0.39 (0.20, NE)	39/64 (60.9)	0.62 (0.33, 2.10)	0.76 (0.40, 1.43)	0.3722	
Prior alloHSCT							0.3349
Yes	29/35 (82.9)	0.26 (0.16, 0.36)	56/93 (60.2)	2.03 (0.26, 2.69)	0.45 (0.28, 0.73)	0.0006	
No	50/74 (67.6)	0.26 (0.20, 0.36)	104/174 (59.8)	0.98 (0.59, 1.93)	0.62 (0.44, 0.87)	0.0055	
Race							0.9441
Caucasian	64/90 (71.1)	0.26 (0.20, 0.30)	133/226 (58.8)	1.31 (0.59, 2.36)	0.58 (0.43, 0.79)	0.0003	
Others	15/19 (78.9)	0.26 (0.10, 0.43)	27/41 (65.9)	0.98 (0.39, 1.93)	0.42 (0.21, 0.82)	0.0101	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1867
<50%	20/27 (74.1)	0.26 (0.16, 0.36)	41/73 (56.2)	2.52 (1.15, 6.62)	0.39 (0.22, 0.69)	0.0009	
≥50%	56/77 (72.7)	0.26 (0.20, 0.36)	103/168 (61.3)	0.62 (0.39, 1.64)	0.64 (0.46, 0.89)	0.0059	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infections and infestations (SOC)	79/109 (72.5)	0.49 (0.39, 0.62)	172/267 (64.4)	1.31 (1.05, 1.90)	0.50 (0.38, 0.66)	<0.0001	
Age group 1							0.1392
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/123 (61.0)	1.28 (1.02, 2.72)	0.63 (0.41, 0.97)	0.0325	
≥35 years	48/59 (81.4)	0.43 (0.33, 0.56)	97/144 (67.4)	1.31 (0.75, 1.90)	0.42 (0.29, 0.61)	<0.0001	
Age group 2							0.2600
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/124 (60.5)	1.28 (1.02, 2.72)	0.63 (0.41, 0.96)	0.0320	
35 - 54 years	20/25 (80.0)	0.43 (0.30, 0.62)	54/77 (70.1)	1.08 (0.69, 2.49)	0.37 (0.21, 0.65)	0.0003	
55 - 64 years	17/22 (77.3)	0.41 (0.30, 0.79)	25/33 (75.8)	1.15 (0.46, 1.84)	0.55 (0.28, 1.07)	0.0714	
≥65 years	11/12 (91.7)	0.41 (0.10, 1.54)	18/33 (54.5)	3.08 (0.56, 5.54)	0.33 (0.15, 0.74)	0.0047	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7590
Male	46/64 (71.9)	0.49 (0.39, 0.72)	101/159 (63.5)	1.28 (0.79, 1.97)	0.51 (0.36, 0.74)	0.0002	
Female	33/45 (73.3)	0.49 (0.33, 0.69)	71/108 (65.7)	1.48 (0.95, 2.52)	0.49 (0.31, 0.75)	0.0010	
Region							0.8307
USA	8/13 (61.5)	1.21 (0.16, NE)	17/30 (56.7)	1.31 (0.72, NE)	0.64 (0.27, 1.52)	0.3130	
Europe	49/68 (72.1)	0.49 (0.36, 0.72)	112/177 (63.3)	1.80 (1.11, 2.69)	0.47 (0.33, 0.67)	<0.0001	
Rest of the world	22/28 (78.6)	0.46 (0.36, 0.49)	43/60 (71.7)	0.79 (0.49, 1.48)	0.50 (0.29, 0.87)	0.0131	
Prior salvage therapy							0.0360
Yes	42/63 (66.7)	0.49 (0.39, 1.11)	109/161 (67.7)	0.95 (0.69, 1.41)	0.67 (0.46, 0.96)	0.0298	
No	37/46 (80.4)	0.49 (0.33, 0.62)	63/106 (59.4)	2.75 (1.31, 3.31)	0.32 (0.21, 0.50)	<0.0001	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0618
0	40/55 (72.7)	0.49 (0.36, 0.72)	70/112 (62.5)	2.75 (1.28, 3.64)	0.38 (0.25, 0.58)	<0.0001	
1	27/34 (79.4)	0.46 (0.30, 0.66)	57/91 (62.6)	1.21 (0.69, 1.97)	0.42 (0.26, 0.69)	0.0003	
≥2	12/20 (60.0)	0.49 (0.33, NE)	45/64 (70.3)	0.72 (0.39, 1.28)	0.97 (0.50, 1.85)	0.9041	
Prior alloHSCT							0.5701
Yes	24/35 (68.6)	0.49 (0.36, 1.11)	66/93 (71.0)	1.31 (0.92, 2.00)	0.49 (0.30, 0.82)	0.0061	
No	55/74 (74.3)	0.49 (0.39, 0.62)	106/174 (60.9)	1.28 (0.75, 2.69)	0.49 (0.35, 0.68)	<0.0001	
Race							0.2441
Caucasian	66/90 (73.3)	0.49 (0.39, 0.62)	141/226 (62.4)	1.61 (1.15, 2.52)	0.47 (0.34, 0.64)	<0.0001	
Others	13/19 (68.4)	0.43 (0.20, 1.11)	31/41 (75.6)	0.72 (0.36, 1.02)	0.70 (0.36, 1.38)	0.2942	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0831
<50%	22/27 (81.5)	0.49 (0.33, 1.51)	45/73 (61.6)	3.21 (2.52, 4.10)	0.23 (0.13, 0.43)	<0.0001	
≥50%	54/77 (70.1)	0.49 (0.39, 0.59)	109/168 (64.9)	1.02 (0.69, 1.31)	0.60 (0.43, 0.84)	0.0031	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infusion reaction (AMQ) - Narrow	12/109 (11.0)	NE (NE, NE)	129/267 (48.3)	2.85 (1.41, NE)	5.25 (2.90, 9.49)	<0.0001	
Age group 1							0.3764
<35 years	7/50 (14.0)	NE (NE, NE)	58/123 (47.2)	6.23 (0.07, NE)	4.10 (1.87, 8.99)	<0.0001	
≥35 years	5/59 (8.5)	NE (NE, NE)	71/144 (49.3)	1.67 (0.07, NE)	6.79 (2.74, 16.83)	<0.0001	
Age group 2							0.7909
<35 years	7/50 (14.0)	NE (NE, NE)	58/124 (46.8)	6.23 (0.07, NE)	4.05 (1.85, 8.89)	<0.0001	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	40/77 (51.9)	1.44 (0.07, NE)	7.35 (1.77, 30.47)	0.0010	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	12/33 (36.4)	4.85 (2.92, NE)	7.75 (1.00, 60.32)	0.0198	
≥65 years	2/12 (16.7)	NE (0.07, NE)	19/33 (57.6)	0.07 (0.07, NE)	4.45 (1.03, 19.18)	0.0250	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4040
Male	8/64 (12.5)	NE (NE, NE)	72/159 (45.3)	2.92 (1.41, NE)	4.32 (2.08, 8.98)	<0.0001	
Female	4/45 (8.9)	NE (NE, NE)	57/108 (52.8)	1.44 (0.07, NE)	7.10 (2.57, 19.60)	<0.0001	
Region							0.0916
USA	1/13 (7.7)	NE (NE, NE)	13/30 (43.3)	NE (0.07, NE)	7.06 (0.92, 54.01)	0.0245	
Europe	3/68 (4.4)	NE (NE, NE)	78/177 (44.1)	NE (1.44, NE)	12.09 (3.81, 38.32)	<0.0001	
Rest of the world	8/28 (28.6)	NE (NE, NE)	38/60 (63.3)	0.07 (0.07, 2.82)	2.46 (1.14, 5.31)	0.0144	
Prior salvage therapy							0.4291
Yes	8/63 (12.7)	NE (NE, NE)	74/161 (46.0)	2.85 (1.41, NE)	4.22 (2.03, 8.76)	<0.0001	
No	4/46 (8.7)	NE (NE, NE)	55/106 (51.9)	1.44 (0.07, NE)	7.43 (2.69, 20.52)	<0.0001	

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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7331
0	7/55 (12.7)	NE (NE, NE)	61/112 (54.5)	1.41 (0.07, NE)	5.40 (2.47, 11.81)	<0.0001	
1	3/34 (8.8)	NE (NE, NE)	47/91 (51.6)	2.82 (0.07, 6.23)	7.10 (2.20, 22.88)	<0.0001	
≥2	2/20 (10.0)	NE (NE, NE)	21/64 (32.8)	NE (2.85, NE)	3.51 (0.82, 14.99)	0.0646	
Prior alloHSCT							0.4859
Yes	5/35 (14.3)	NE (NE, NE)	44/93 (47.3)	4.85 (0.07, NE)	3.94 (1.56, 9.96)	0.0013	
No	7/74 (9.5)	NE (NE, NE)	85/174 (48.9)	2.82 (0.07, NE)	6.17 (2.85, 13.36)	<0.0001	
Race							0.0422
Caucasian	6/90 (6.7)	NE (NE, NE)	102/226 (45.1)	4.85 (1.44, NE)	8.27 (3.63, 18.84)	<0.0001	
Others	6/19 (31.6)	NE (0.07, NE)	27/41 (65.9)	0.07 (0.07, 2.82)	2.22 (0.91, 5.42)	0.0596	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4553
<50%	3/27 (11.1)	NE (NE, NE)	45/73 (61.6)	0.07 (0.07, 2.85)	7.40 (2.29, 23.89)	<0.0001	
≥50%	9/77 (11.7)	NE (NE, NE)	76/168 (45.2)	2.92 (1.41, NE)	4.47 (2.24, 8.93)	<0.0001	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow	27/109 (24.8)	NE (3.02, NE)	58/267 (21.7)	NE (NE, NE)	0.80 (0.51, 1.27)	0.3407	
Age group 1							0.6817
<35 years	13/50 (26.0)	3.02 (3.02, NE)	26/123 (21.1)	NE (NE, NE)	0.72 (0.37, 1.41)	0.3286	
≥35 years	14/59 (23.7)	NE (NE, NE)	32/144 (22.2)	NE (NE, NE)	0.88 (0.47, 1.66)	0.6957	
Age group 2							0.0762
<35 years	13/50 (26.0)	3.02 (3.02, NE)	26/124 (21.0)	NE (NE, NE)	0.72 (0.36, 1.40)	0.3225	
35 - 54 years	5/25 (20.0)	NE (NE, NE)	21/77 (27.3)	NE (5.54, NE)	1.21 (0.45, 3.23)	0.7170	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	9/33 (27.3)	NE (NE, NE)	1.55 (0.48, 5.03)	0.4628	
≥65 years	5/12 (41.7)	NE (0.13, NE)	2/33 (6.1)	NE (NE, NE)	0.15 (0.03, 0.75)	0.0080	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5227
Male	16/64 (25.0)	NE (NE, NE)	39/159 (24.5)	NE (NE, NE)	0.94 (0.53, 1.68)	0.8363	
Female	11/45 (24.4)	NE (3.02, NE)	19/108 (17.6)	NE (NE, NE)	0.55 (0.26, 1.20)	0.1238	
Region							0.7237
USA	7/13 (53.8)	3.02 (0.13, NE)	14/30 (46.7)	1.44 (0.26, NE)	0.76 (0.30, 1.88)	0.5492	
Europe	11/68 (16.2)	NE (NE, NE)	29/177 (16.4)	NE (NE, NE)	1.00 (0.50, 2.02)	0.9985	
Rest of the world	9/28 (32.1)	NE (0.56, NE)	15/60 (25.0)	NE (NE, NE)	0.59 (0.25, 1.38)	0.2187	
Prior salvage therapy							0.7421
Yes	16/63 (25.4)	NE (NE, NE)	34/161 (21.1)	NE (NE, NE)	0.76 (0.42, 1.37)	0.3505	
No	11/46 (23.9)	NE (3.02, NE)	24/106 (22.6)	NE (NE, NE)	0.86 (0.42, 1.78)	0.6778	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5518
0	10/55 (18.2)	NE (3.02, NE)	22/112 (19.6)	NE (NE, NE)	1.05 (0.49, 2.23)	0.9129	
1	9/34 (26.5)	NE (NE, NE)	18/91 (19.8)	NE (NE, NE)	0.58 (0.26, 1.32)	0.1902	
≥2	8/20 (40.0)	NE (0.20, NE)	18/64 (28.1)	NE (NE, NE)	0.60 (0.26, 1.38)	0.2151	
Prior alloHSCT							0.4387
Yes	9/35 (25.7)	NE (NE, NE)	26/93 (28.0)	NE (NE, NE)	1.00 (0.46, 2.15)	0.9615	
No	18/74 (24.3)	NE (3.02, NE)	32/174 (18.4)	NE (NE, NE)	0.70 (0.39, 1.24)	0.2160	
Race							0.4870
Caucasian	24/90 (26.7)	NE (3.02, NE)	49/226 (21.7)	NE (NE, NE)	0.75 (0.46, 1.22)	0.2360	
Others	3/19 (15.8)	NE (NE, NE)	9/41 (22.0)	NE (NE, NE)	1.22 (0.33, 4.55)	0.7614	

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2757
<50%	5/27 (18.5)	NE (NE, NE)	20/73 (27.4)	NE (5.54, NE)	1.44 (0.54, 3.87)	0.4638	
≥50%	20/77 (26.0)	NE (NE, NE)	37/168 (22.0)	NE (NE, NE)	0.78 (0.45, 1.35)	0.3619	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Lymphopenia (AMQ) - Narrow	4/109 (3.7)	NE (NE, NE)	6/267 (2.2)	NE (NE, NE)	0.34 (0.08, 1.42)	0.1236	
Age group 1							0.4302
<35 years	1/50 (2.0)	-	3/123 (2.4)	-	-	-	
≥35 years	3/59 (5.1)	-	3/144 (2.1)	-	-	-	
Age group 2							0.7996
<35 years	1/50 (2.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	2/25 (8.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	1/22 (4.5)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8118
Male	3/64 (4.7)	-	4/159 (2.5)	-	-	-	
Female	1/45 (2.2)	-	2/108 (1.9)	-	-	-	
Region							0.6295
USA	1/13 (7.7)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	4/177 (2.3)	-	-	-	
Rest of the world	3/28 (10.7)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							0.4292
Yes	2/63 (3.2)	-	4/161 (2.5)	-	-	-	
No	2/46 (4.3)	-	2/106 (1.9)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7569
0	1/55 (1.8)	-	3/112 (2.7)	-	-	-	
1	2/34 (5.9)	-	2/91 (2.2)	-	-	-	
≥2	1/20 (5.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.6268
Yes	2/35 (5.7)	-	3/93 (3.2)	-	-	-	
No	2/74 (2.7)	-	3/174 (1.7)	-	-	-	
Race							0.9943
Caucasian	4/90 (4.4)	-	5/226 (2.2)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3748
<50%	1/27 (3.7)	-	4/73 (5.5)	-	-	-	
≥50%	3/77 (3.9)	-	2/168 (1.2)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Medication errors and product use issues (SMQ) - Broad	0/109 (0.0)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	NE (NE, NE)	0.0355	
Age group 1							0.9999
<35 years	0/50 (0.0)	-	7/123 (5.7)	-	-	-	
≥35 years	0/59 (0.0)	-	5/144 (3.5)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	7/124 (5.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	6/159 (3.8)	-	-	-	
Female	0/45 (0.0)	-	6/108 (5.6)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	7/177 (4.0)	-	-	-	
Rest of the world	0/28 (0.0)	-	5/60 (8.3)	-	-	-	
Prior salvage therapy							0.9999
Yes	0/63 (0.0)	-	5/161 (3.1)	-	-	-	
No	0/46 (0.0)	-	7/106 (6.6)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	9/112 (8.0)	-	-	-	
1	0/34 (0.0)	-	2/91 (2.2)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	3/93 (3.2)	-	-	-	
No	0/74 (0.0)	-	9/174 (5.2)	-	-	-	
Race							0.9998
Caucasian	0/90 (0.0)	-	7/226 (3.1)	-	-	-	
Others	0/19 (0.0)	-	5/41 (12.2)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9974
<50%	0/27 (0.0)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0242	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Neutropenia (AMQ) - Narrow	70/109 (64.2)	0.36 (0.26, 0.43)	111/267 (41.6)	4.79 (2.59, 6.69)	0.39 (0.28, 0.53)	<0.0001	
Age group 1							0.6599
<35 years	30/50 (60.0)	0.36 (0.26, 2.49)	51/123 (41.5)	5.02 (2.10, NE)	0.41 (0.26, 0.66)	0.0001	
≥35 years	40/59 (67.8)	0.36 (0.26, 0.46)	60/144 (41.7)	4.79 (2.36, NE)	0.37 (0.24, 0.56)	<0.0001	
Age group 2							0.9136
<35 years	30/50 (60.0)	0.36 (0.26, 2.49)	52/124 (41.9)	5.02 (2.10, NE)	0.42 (0.27, 0.67)	0.0002	
35 - 54 years	18/25 (72.0)	0.30 (0.23, 0.56)	33/77 (42.9)	4.79 (1.54, NE)	0.35 (0.19, 0.64)	0.0004	
55 - 64 years	16/22 (72.7)	0.38 (0.20, 0.59)	15/33 (45.5)	1.97 (0.49, NE)	0.38 (0.19, 0.79)	0.0084	
≥65 years	6/12 (50.0)	NE (0.10, NE)	11/33 (33.3)	4.95 (2.36, NE)	0.32 (0.10, 0.99)	0.0378	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3030
Male	41/64 (64.1)	0.36 (0.26, 0.59)	71/159 (44.7)	2.89 (1.97, 6.69)	0.41 (0.28, 0.62)	<0.0001	
Female	29/45 (64.4)	0.30 (0.23, 1.05)	40/108 (37.0)	6.69 (3.11, NE)	0.35 (0.21, 0.59)	<0.0001	
Region							0.7302
USA	9/13 (69.2)	0.33 (0.23, NE)	16/30 (53.3)	1.31 (0.39, NE)	0.54 (0.23, 1.25)	0.1408	
Europe	37/68 (54.4)	0.46 (0.30, NE)	59/177 (33.3)	8.26 (4.62, NE)	0.40 (0.26, 0.61)	<0.0001	
Rest of the world	24/28 (85.7)	0.26 (0.20, 0.36)	36/60 (60.0)	1.93 (0.79, 2.89)	0.26 (0.14, 0.47)	<0.0001	
Prior salvage therapy							0.0880
Yes	38/63 (60.3)	0.39 (0.30, 1.05)	70/161 (43.5)	3.02 (1.97, 6.69)	0.46 (0.31, 0.70)	0.0001	
No	32/46 (69.6)	0.26 (0.23, 0.43)	41/106 (38.7)	6.69 (4.79, NE)	0.31 (0.19, 0.50)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7045
0	36/55 (65.5)	0.30 (0.23, 0.43)	46/112 (41.1)	6.69 (2.59, NE)	0.37 (0.23, 0.59)	<0.0001	
1	22/34 (64.7)	0.38 (0.26, 1.05)	40/91 (44.0)	3.11 (1.93, NE)	0.37 (0.21, 0.64)	0.0002	
≥2	12/20 (60.0)	0.43 (0.26, NE)	25/64 (39.1)	2.79 (1.97, NE)	0.44 (0.22, 0.88)	0.0162	
Prior alloHSCT							0.0841
Yes	27/35 (77.1)	0.30 (0.23, 0.43)	38/93 (40.9)	4.79 (2.30, NE)	0.26 (0.15, 0.44)	<0.0001	
No	43/74 (58.1)	0.39 (0.30, NE)	73/174 (42.0)	4.62 (2.07, 8.26)	0.47 (0.32, 0.69)	0.0001	
Race							0.9589
Caucasian	55/90 (61.1)	0.36 (0.30, 0.95)	88/226 (38.9)	6.66 (2.89, NE)	0.39 (0.28, 0.56)	<0.0001	
Others	15/19 (78.9)	0.30 (0.13, 0.43)	23/41 (56.1)	1.41 (0.52, 5.02)	0.33 (0.16, 0.67)	0.0014	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3501
<50%	16/27 (59.3)	0.36 (0.26, NE)	27/73 (37.0)	6.69 (3.02, NE)	0.26 (0.13, 0.52)	<0.0001	
≥50%	51/77 (66.2)	0.33 (0.26, 0.43)	76/168 (45.2)	3.11 (1.64, 6.69)	0.48 (0.33, 0.69)	<0.0001	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-aesi-saf.sas
Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Tumour lysis syndrome (SMQ) - Narrow	1/109 (0.9)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	3.42 (0.43, 27.02)	0.2148	
Age group 1							0.9932
<35 years	0/50 (0.0)	-	4/123 (3.3)	-	-	-	
≥35 years	1/59 (1.7)	-	6/144 (4.2)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	4/124 (3.2)	-	-	-	
35 - 54 years	1/25 (4.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	0/22 (0.0)	-	3/33 (9.1)	-	-	-	
≥65 years	0/12 (0.0)	-	1/33 (3.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9941
Male	1/64 (1.6)	-	8/159 (5.0)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	5/177 (2.8)	-	-	-	
Rest of the world	1/28 (3.6)	-	3/60 (5.0)	-	-	-	
Prior salvage therapy							0.9932
Yes	1/63 (1.6)	-	6/161 (3.7)	-	-	-	
No	0/46 (0.0)	-	4/106 (3.8)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	5/112 (4.5)	-	-	-	
1	1/34 (2.9)	-	4/91 (4.4)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.9942
Yes	0/35 (0.0)	-	5/93 (5.4)	-	-	-	
No	1/74 (1.4)	-	5/174 (2.9)	-	-	-	
Race							0.9997
Caucasian	1/90 (1.1)	NE (NE, NE)	10/226 (4.4)	NE (NE, NE)	3.40 (0.43, 26.91)	0.2163	
Others	0/19 (0.0)	NE (NE, NE)	0/41 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.5. Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9957
<50%	0/27 (0.0)	-	1/73 (1.4)	-	-	-	
≥50%	1/77 (1.3)	-	5/168 (3.0)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-06-002-005-tte-sub-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Capillary leak syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow	2/109 (1.8)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	2.65 (0.61, 11.59)	0.1777	
Age group 1							0.6696
<35 years	1/50 (2.0)	NE (NE, NE)	7/123 (5.7)	NE (NE, NE)	1.23 (0.14, 10.89)	0.8533	
≥35 years	1/59 (1.7)	NE (NE, NE)	13/144 (9.0)	NE (NE, NE)	4.21 (0.54, 32.56)	0.1341	
Age group 2							0.8653
<35 years	1/50 (2.0)	-	8/124 (6.5)	-	-	-	
35 - 54 years	0/25 (0.0)	-	8/77 (10.4)	-	-	-	
55 - 64 years	1/22 (4.5)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9505
Male	1/64 (1.6)	NE (NE, NE)	9/159 (5.7)	NE (NE, NE)	2.51 (0.31, 20.11)	0.3693	
Female	1/45 (2.2)	NE (NE, NE)	11/108 (10.2)	NE (13.15, NE)	2.98 (0.37, 24.03)	0.2817	
Region							0.9338
USA	0/13 (0.0)	NE (NE, NE)	3/30 (10.0)	NE (NE, NE)	NE (NE, NE)	0.2854	
Europe	1/68 (1.5)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	2.59 (0.33, 20.57)	0.3492	
Rest of the world	1/28 (3.6)	NE (NE, NE)	6/60 (10.0)	NE (7.87, NE)	1.79 (0.20, 15.99)	0.5986	
Prior salvage therapy							0.9901
Yes	0/63 (0.0)	NE (NE, NE)	13/161 (8.1)	NE (13.15, NE)	NE (NE, NE)	0.1122	
No	2/46 (4.3)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	1.34 (0.28, 6.47)	0.7166	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	2/55 (3.6)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	1.74 (0.37, 8.23)	0.4786	
1	0/34 (0.0)	NE (NE, NE)	6/91 (6.6)	NE (8.85, NE)	NE (NE, NE)	0.3362	
≥2	0/20 (0.0)	NE (NE, NE)	6/64 (9.4)	NE (7.87, NE)	NE (NE, NE)	0.3359	
Prior alloHSCT							0.8875
Yes	1/35 (2.9)	NE (NE, NE)	11/93 (11.8)	NE (NE, NE)	2.21 (0.27, 17.89)	0.4456	
No	1/74 (1.4)	NE (NE, NE)	9/174 (5.2)	NE (8.85, NE)	2.92 (0.36, 23.46)	0.2913	
Race							0.4011
Caucasian	1/90 (1.1)	NE (NE, NE)	16/226 (7.1)	NE (NE, NE)	4.42 (0.58, 33.88)	0.1180	
Others	1/19 (5.3)	NE (NE, NE)	4/41 (9.8)	NE (8.85, NE)	0.92 (0.09, 9.21)	0.9449	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9907
<50%	0/27 (0.0)	NE (NE, NE)	6/73 (8.2)	NE (13.15, NE)	NE (NE, NE)	0.2213	
≥50%	1/77 (1.3)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	3.20 (0.40, 25.45)	0.2442	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Cytokine release syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	NE (NE, NE)	0.0541	
Age group 1							0.9998
<35 years	0/50 (0.0)	-	2/123 (1.6)	-	-	-	
≥35 years	0/59 (0.0)	-	8/144 (5.6)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	2/124 (1.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	4/77 (5.2)	-	-	-	
55 - 64 years	0/22 (0.0)	-	2/33 (6.1)	-	-	-	
≥65 years	0/12 (0.0)	-	2/33 (6.1)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	-	4/159 (2.5)	-	-	-	
Female	0/45 (0.0)	-	6/108 (5.6)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	6/177 (3.4)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	-	8/161 (5.0)	-	-	-	
No	0/46 (0.0)	-	2/106 (1.9)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	2/112 (1.8)	-	-	-	
1	0/34 (0.0)	-	6/91 (6.6)	-	-	-	
≥2	0/20 (0.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.9999
Yes	0/35 (0.0)	-	2/93 (2.2)	-	-	-	
No	0/74 (0.0)	-	8/174 (4.6)	-	-	-	
Race							>0.9999
Caucasian	0/90 (0.0)	-	9/226 (4.0)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9998
<50%	0/27 (0.0)	-	1/73 (1.4)	-	-	-	
≥50%	0/77 (0.0)	-	9/168 (5.4)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Decreased immunoglobulins (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Haematopoietic cytopenias (SMQ) - Narrow	17/109 (15.6)	NE (2.82, NE)	36/267 (13.5)	NE (NE, NE)	0.48 (0.26, 0.89)	0.0166	
Age group 1							0.8457
<35 years	8/50 (16.0)	NE (2.82, NE)	17/123 (13.8)	NE (11.05, NE)	0.50 (0.21, 1.22)	0.1205	
≥35 years	9/59 (15.3)	NE (1.87, NE)	19/144 (13.2)	NE (NE, NE)	0.45 (0.20, 1.06)	0.0614	
Age group 2							0.6341
<35 years	8/50 (16.0)	NE (2.82, NE)	17/124 (13.7)	NE (11.05, NE)	0.50 (0.21, 1.22)	0.1197	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	7/77 (9.1)	NE (14.07, NE)	0.70 (0.14, 3.55)	0.6714	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	7/33 (21.2)	NE (2.59, NE)	0.92 (0.23, 3.70)	0.9114	
≥65 years	4/12 (33.3)	NE (0.20, NE)	5/33 (15.2)	NE (4.59, NE)	0.13 (0.02, 0.71)	0.0059	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2220
Male	9/64 (14.1)	NE (2.82, NE)	24/159 (15.1)	NE (14.07, NE)	0.64 (0.29, 1.41)	0.2615	
Female	8/45 (17.8)	NE (1.77, NE)	12/108 (11.1)	NE (11.05, NE)	0.33 (0.12, 0.87)	0.0194	
Region							0.4710
USA	3/13 (23.1)	NE (1.28, NE)	9/30 (30.0)	NE (1.31, NE)	1.11 (0.30, 4.14)	0.8818	
Europe	8/68 (11.8)	NE (2.82, NE)	15/177 (8.5)	NE (NE, NE)	0.39 (0.16, 0.96)	0.0346	
Rest of the world	6/28 (21.4)	1.97 (1.77, NE)	12/60 (20.0)	14.07 (6.26, NE)	0.42 (0.14, 1.27)	0.1159	
Prior salvage therapy							0.0018
Yes	7/63 (11.1)	NE (1.84, NE)	30/161 (18.6)	14.07 (6.69, NE)	0.95 (0.40, 2.22)	0.8993	
No	10/46 (21.7)	2.82 (1.97, NE)	6/106 (5.7)	NE (NE, NE)	0.15 (0.05, 0.44)	<0.0001	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0730
0	10/55 (18.2)	NE (2.82, NE)	8/112 (7.1)	NE (NE, NE)	0.22 (0.08, 0.60)	0.0013	
1	3/34 (8.8)	NE (1.77, NE)	16/91 (17.6)	14.07 (11.05, NE)	1.01 (0.28, 3.65)	0.9906	
≥2	4/20 (20.0)	NE (1.84, NE)	12/64 (18.8)	NE (6.26, NE)	0.50 (0.15, 1.63)	0.2407	
Prior alloHSCT							0.0157
Yes	9/35 (25.7)	1.97 (1.28, NE)	11/93 (11.8)	NE (14.07, NE)	0.15 (0.05, 0.41)	<0.0001	
No	8/74 (10.8)	NE (NE, NE)	25/174 (14.4)	NE (11.05, NE)	0.89 (0.39, 2.03)	0.7890	
Race							0.4367
Caucasian	16/90 (17.8)	NE (2.82, NE)	32/226 (14.2)	NE (NE, NE)	0.45 (0.24, 0.86)	0.0124	
Others	1/19 (5.3)	NE (1.84, NE)	4/41 (9.8)	11.05 (NE, NE)	1.04 (0.11, 10.11)	0.9743	

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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6780
<50%	4/27 (14.8)	NE (NE, NE)	9/73 (12.3)	NE (NE, NE)	0.47 (0.14, 1.62)	0.2202	
≥50%	13/77 (16.9)	NE (1.97, NE)	26/168 (15.5)	NE (11.05, NE)	0.53 (0.26, 1.07)	0.0713	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infections and infestations (SOC)	33/109 (30.3)	NE (2.03, NE)	79/267 (29.6)	8.07 (5.87, 16.13)	0.51 (0.33, 0.80)	0.0023	
Age group 1							0.6650
<35 years	13/50 (26.0)	NE (2.03, NE)	35/123 (28.5)	7.57 (5.74, NE)	0.57 (0.29, 1.12)	0.0955	
≥35 years	20/59 (33.9)	NE (1.57, NE)	44/144 (30.6)	8.07 (5.54, 16.33)	0.49 (0.28, 0.86)	0.0122	
Age group 2							0.5965
<35 years	13/50 (26.0)	NE (2.03, NE)	35/124 (28.2)	7.57 (5.74, NE)	0.57 (0.29, 1.11)	0.0946	
35 - 54 years	9/25 (36.0)	1.87 (0.66, NE)	21/77 (27.3)	10.10 (5.05, NE)	0.31 (0.13, 0.72)	0.0046	
55 - 64 years	7/22 (31.8)	NE (0.62, NE)	11/33 (33.3)	8.07 (1.84, NE)	0.61 (0.22, 1.67)	0.3297	
≥65 years	4/12 (33.3)	NE (0.75, NE)	12/33 (36.4)	6.10 (4.79, NE)	0.80 (0.24, 2.68)	0.7208	

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Data cut-off date: 14MAR2017

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1848
Male	19/64 (29.7)	NE (2.03, NE)	52/159 (32.7)	6.10 (5.54, 10.10)	0.61 (0.35, 1.07)	0.0830	
Female	14/45 (31.1)	NE (1.87, NE)	27/108 (25.0)	14.75 (5.80, NE)	0.39 (0.19, 0.80)	0.0076	
Region							0.2188
USA	2/13 (15.4)	NE (1.21, NE)	7/30 (23.3)	5.74 (2.46, NE)	1.10 (0.22, 5.52)	0.9097	
Europe	18/68 (26.5)	NE (2.03, NE)	48/177 (27.1)	9.97 (7.25, 16.33)	0.54 (0.30, 0.96)	0.0340	
Rest of the world	13/28 (46.4)	1.11 (0.39, NE)	24/60 (40.0)	4.79 (2.56, NE)	0.36 (0.17, 0.77)	0.0059	
Prior salvage therapy							0.2640
Yes	17/63 (27.0)	NE (1.57, NE)	47/161 (29.2)	7.57 (4.79, NE)	0.68 (0.38, 1.20)	0.1795	
No	16/46 (34.8)	NE (1.87, NE)	32/106 (30.2)	9.97 (5.74, 16.33)	0.34 (0.17, 0.68)	0.0013	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3650
0	16/55 (29.1)	NE (2.03, NE)	33/112 (29.5)	9.97 (7.25, 16.33)	0.45 (0.23, 0.89)	0.0185	
1	13/34 (38.2)	1.57 (0.98, NE)	26/91 (28.6)	5.80 (4.59, NE)	0.37 (0.18, 0.75)	0.0044	
≥2	4/20 (20.0)	NE (1.21, NE)	20/64 (31.3)	6.07 (4.03, NE)	1.02 (0.34, 3.08)	0.9693	
Prior alloHSCT							0.1129
Yes	14/35 (40.0)	NE (0.56, NE)	33/93 (35.5)	7.57 (5.54, NE)	0.36 (0.18, 0.71)	0.0022	
No	19/74 (25.7)	NE (2.03, NE)	46/174 (26.4)	8.07 (5.74, NE)	0.63 (0.36, 1.10)	0.0998	
Race							0.3993
Caucasian	28/90 (31.1)	NE (1.87, NE)	66/226 (29.2)	9.97 (6.10, 16.33)	0.49 (0.31, 0.79)	0.0030	
Others	5/19 (26.3)	NE (0.89, NE)	13/41 (31.7)	4.79 (2.56, NE)	0.66 (0.22, 1.96)	0.4469	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3979
<50%	10/27 (37.0)	2.10 (1.57, NE)	22/73 (30.1)	8.07 (5.74, 16.13)	0.21 (0.08, 0.54)	0.0004	
≥50%	22/77 (28.6)	NE (2.03, NE)	46/168 (27.4)	7.57 (5.54, NE)	0.57 (0.33, 0.97)	0.0362	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infusion reaction (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	3/267 (1.1)	NE (NE, NE)	NE (NE, NE)	0.2674	
Age group 1							0.9987
<35 years	0/50 (0.0)	-	0/123 (0.0)	-	-	-	
≥35 years	0/59 (0.0)	-	3/144 (2.1)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	0/124 (0.0)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	2/33 (6.1)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9998
Male	0/64 (0.0)	-	1/159 (0.6)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	1/177 (0.6)	-	-	-	
Rest of the world	0/28 (0.0)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	2/161 (1.2)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	2/91 (2.2)	-	-	-	
≥2	0/20 (0.0)	-	0/64 (0.0)	-	-	-	
Prior alloHSCT							0.9987
Yes	0/35 (0.0)	-	0/93 (0.0)	-	-	-	
No	0/74 (0.0)	-	3/174 (1.7)	-	-	-	
Race							0.9999
Caucasian	0/90 (0.0)	-	2/226 (0.9)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9987
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	3/168 (1.8)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	3/267 (1.1)	NE (NE, NE)	NE (NE, NE)	0.2766	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	2/123 (1.6)	-	-	-	
≥35 years	0/59 (0.0)	-	1/144 (0.7)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	2/124 (1.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	2/159 (1.3)	-	-	-	
Female	0/45 (0.0)	-	1/108 (0.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	0/177 (0.0)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	2/161 (1.2)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	1/91 (1.1)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	1/93 (1.1)	-	-	-	
No	0/74 (0.0)	-	2/174 (1.1)	-	-	-	
Race							0.9989
Caucasian	0/90 (0.0)	-	3/226 (1.3)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9987
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	3/168 (1.8)	-	-	-	

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Data cut-off date: 14MAR2017

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Lymphopenia (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Medication errors and product use issues (SMQ) - Broad	0/109 (0.0)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	NE (NE, NE)	0.0355	
Age group 1							0.9999
<35 years	0/50 (0.0)	-	7/123 (5.7)	-	-	-	
≥35 years	0/59 (0.0)	-	5/144 (3.5)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	7/124 (5.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	6/159 (3.8)	-	-	-	
Female	0/45 (0.0)	-	6/108 (5.6)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	7/177 (4.0)	-	-	-	
Rest of the world	0/28 (0.0)	-	5/60 (8.3)	-	-	-	
Prior salvage therapy							0.9999
Yes	0/63 (0.0)	-	5/161 (3.1)	-	-	-	
No	0/46 (0.0)	-	7/106 (6.6)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	9/112 (8.0)	-	-	-	
1	0/34 (0.0)	-	2/91 (2.2)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	3/93 (3.2)	-	-	-	
No	0/74 (0.0)	-	9/174 (5.2)	-	-	-	
Race							0.9998
Caucasian	0/90 (0.0)	-	7/226 (3.1)	-	-	-	
Others	0/19 (0.0)	-	5/41 (12.2)	-	-	-	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9974
<50%	0/27 (0.0)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0242	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Neutropenia (AMQ) - Narrow	15/109 (13.8)	NE (2.82, NE)	29/267 (10.9)	NE (NE, NE)	0.44 (0.23, 0.86)	0.0136	
Age group 1							0.8586
<35 years	8/50 (16.0)	NE (1.97, NE)	14/123 (11.4)	NE (NE, NE)	0.41 (0.16, 1.03)	0.0502	
≥35 years	7/59 (11.9)	NE (NE, NE)	15/144 (10.4)	NE (NE, NE)	0.49 (0.19, 1.26)	0.1329	
Age group 2							0.9688
<35 years	8/50 (16.0)	NE (1.97, NE)	14/124 (11.3)	NE (NE, NE)	0.41 (0.16, 1.03)	0.0499	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	6/77 (7.8)	NE (14.07, NE)	0.58 (0.11, 3.07)	0.5186	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	5/33 (15.2)	NE (NE, NE)	0.72 (0.17, 3.13)	0.6638	
≥65 years	2/12 (16.7)	NE (1.87, NE)	4/33 (12.1)	NE (4.62, NE)	0.23 (0.03, 1.81)	0.1307	

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Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0144
Male	7/64 (10.9)	NE (2.82, NE)	23/159 (14.5)	NE (14.07, NE)	0.81 (0.34, 1.93)	0.6296	
Female	8/45 (17.8)	NE (1.77, NE)	6/108 (5.6)	NE (NE, NE)	0.15 (0.04, 0.52)	0.0006	
Region							0.5488
USA	2/13 (15.4)	NE (1.28, NE)	6/30 (20.0)	NE (2.30, NE)	1.10 (0.22, 5.51)	0.9101	
Europe	7/68 (10.3)	NE (2.82, NE)	12/177 (6.8)	NE (NE, NE)	0.34 (0.13, 0.92)	0.0277	
Rest of the world	6/28 (21.4)	1.97 (1.77, NE)	11/60 (18.3)	14.07 (6.26, NE)	0.42 (0.14, 1.27)	0.1159	
Prior salvage therapy							0.0014
Yes	5/63 (7.9)	NE (NE, NE)	24/161 (14.9)	14.07 (14.07, NE)	1.08 (0.40, 2.94)	0.8742	
No	10/46 (21.7)	2.82 (1.97, NE)	5/106 (4.7)	NE (NE, NE)	0.13 (0.04, 0.39)	<0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0515
0	10/55 (18.2)	NE (2.82, NE)	7/112 (6.3)	NE (NE, NE)	0.19 (0.07, 0.54)	0.0006	
1	2/34 (5.9)	NE (1.77, NE)	14/91 (15.4)	14.07 (14.07, NE)	1.35 (0.29, 6.24)	0.7013	
≥2	3/20 (15.0)	NE (NE, NE)	8/64 (12.5)	NE (6.26, NE)	0.47 (0.11, 1.93)	0.2842	
Prior alloHSCT							0.0162
Yes	9/35 (25.7)	1.97 (1.28, NE)	10/93 (10.8)	NE (NE, NE)	0.13 (0.04, 0.36)	<0.0001	
No	6/74 (8.1)	NE (NE, NE)	19/174 (10.9)	NE (NE, NE)	0.95 (0.37, 2.44)	0.9221	
Race							0.9888
Caucasian	15/90 (16.7)	NE (2.82, NE)	27/226 (11.9)	NE (NE, NE)	0.40 (0.20, 0.78)	0.0053	
Others	0/19 (0.0)	NE (NE, NE)	2/41 (4.9)	NE (NE, NE)	NE (NE, NE)	0.3828	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6635
<50%	4/27 (14.8)	NE (NE, NE)	8/73 (11.0)	NE (NE, NE)	0.40 (0.11, 1.43)	0.1448	
≥50%	11/77 (14.3)	NE (1.97, NE)	20/168 (11.9)	NE (NE, NE)	0.50 (0.23, 1.09)	0.0743	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Tumour lysis syndrome (SMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	3/267 (1.1)	NE (NE, NE)	NE (NE, NE)	0.3189	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	1/123 (0.8)	-	-	-	
≥35 years	0/59 (0.0)	-	2/144 (1.4)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	0/77 (0.0)	-	-	-	
55 - 64 years	0/22 (0.0)	-	2/33 (6.1)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9987
Male	0/64 (0.0)	-	3/159 (1.9)	-	-	-	
Female	0/45 (0.0)	-	0/108 (0.0)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	1/177 (0.6)	-	-	-	
Rest of the world	0/28 (0.0)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	2/161 (1.2)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	1/91 (1.1)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	1/93 (1.1)	-	-	-	
No	0/74 (0.0)	-	2/174 (1.1)	-	-	-	
Race							0.9990
Caucasian	0/90 (0.0)	-	3/226 (1.3)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.6. Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9990
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	2/168 (1.2)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-aesi-saf.sas
Output: t14-06-002-006-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Capillary leak syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	0/267 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central neuropsychiatric events due to direct neurotoxicities (AMQ) - Narrow	9/109 (8.3)	NE (NE, NE)	27/267 (10.1)	NE (NE, NE)	0.92 (0.42, 1.99)	0.8263	
Age group 1							0.4110
<35 years	5/50 (10.0)	NE (NE, NE)	11/123 (8.9)	NE (NE, NE)	0.53 (0.17, 1.61)	0.2527	
≥35 years	4/59 (6.8)	NE (NE, NE)	16/144 (11.1)	NE (NE, NE)	1.44 (0.48, 4.35)	0.5156	
Age group 2							0.9698
<35 years	5/50 (10.0)	NE (NE, NE)	12/124 (9.7)	NE (NE, NE)	0.60 (0.20, 1.79)	0.3545	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	9/77 (11.7)	NE (NE, NE)	1.22 (0.26, 5.68)	0.8009	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	2/33 (6.1)	13.15 (13.15, NE)	0.32 (0.03, 3.57)	0.3320	
≥65 years	0/12 (0.0)	NE (NE, NE)	4/33 (12.1)	NE (NE, NE)	NE (NE, NE)	0.2220	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7260
Male	5/64 (7.8)	NE (NE, NE)	13/159 (8.2)	NE (NE, NE)	0.85 (0.30, 2.39)	0.7522	
Female	4/45 (8.9)	NE (NE, NE)	14/108 (13.0)	NE (13.15, NE)	1.02 (0.32, 3.24)	0.9709	
Region							0.9636
USA	0/13 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	NE (NE, NE)	0.3674	
Europe	6/68 (8.8)	NE (NE, NE)	18/177 (10.2)	NE (NE, NE)	0.93 (0.37, 2.38)	0.8863	
Rest of the world	3/28 (10.7)	NE (NE, NE)	7/60 (11.7)	NE (7.87, NE)	0.56 (0.13, 2.51)	0.4462	
Prior salvage therapy							0.1058
Yes	4/63 (6.3)	NE (NE, NE)	20/161 (12.4)	13.15 (8.85, NE)	1.34 (0.45, 4.03)	0.5955	
No	5/46 (10.9)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	0.54 (0.17, 1.72)	0.2942	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5887
0	5/55 (9.1)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	0.88 (0.30, 2.59)	0.8229	
1	1/34 (2.9)	NE (NE, NE)	8/91 (8.8)	NE (8.85, NE)	2.01 (0.24, 16.81)	0.5119	
≥2	3/20 (15.0)	NE (1.11, NE)	9/64 (14.1)	NE (7.87, NE)	0.60 (0.15, 2.30)	0.4463	
Prior alloHSCT							0.5629
Yes	5/35 (14.3)	NE (NE, NE)	14/93 (15.1)	NE (13.15, NE)	0.75 (0.26, 2.15)	0.5902	
No	4/74 (5.4)	NE (NE, NE)	13/174 (7.5)	NE (NE, NE)	1.06 (0.34, 3.32)	0.9205	
Race							0.3031
Caucasian	6/90 (6.7)	NE (NE, NE)	23/226 (10.2)	NE (NE, NE)	1.25 (0.50, 3.11)	0.6276	
Others	3/19 (15.8)	NE (1.11, NE)	4/41 (9.8)	NE (8.85, NE)	0.27 (0.05, 1.43)	0.0998	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1611
<50%	3/27 (11.1)	NE (NE, NE)	5/73 (6.8)	NE (13.15, NE)	0.30 (0.06, 1.50)	0.1200	
≥50%	5/77 (6.5)	NE (NE, NE)	19/168 (11.3)	NE (NE, NE)	1.38 (0.51, 3.75)	0.5313	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Cytokine release syndrome (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	NE (NE, NE)	0.0327	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	5/123 (4.1)	-	-	-	
≥35 years	0/59 (0.0)	-	8/144 (5.6)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	5/124 (4.0)	-	-	-	
35 - 54 years	0/25 (0.0)	-	3/77 (3.9)	-	-	-	
55 - 64 years	0/22 (0.0)	-	2/33 (6.1)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9998
Male	0/64 (0.0)	-	5/159 (3.1)	-	-	-	
Female	0/45 (0.0)	-	8/108 (7.4)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	9/177 (5.1)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	-	9/161 (5.6)	-	-	-	
No	0/46 (0.0)	-	4/106 (3.8)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	4/112 (3.6)	-	-	-	
1	0/34 (0.0)	-	7/91 (7.7)	-	-	-	
≥2	0/20 (0.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.9998
Yes	0/35 (0.0)	NE (NE, NE)	2/93 (2.2)	NE (NE, NE)	NE (NE, NE)	0.4614	
No	0/74 (0.0)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	NE (NE, NE)	0.0418	
Race							0.9999
Caucasian	0/90 (0.0)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	NE (NE, NE)	0.0432	
Others	0/19 (0.0)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	NE (NE, NE)	0.4960	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9974
<50%	0/27 (0.0)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥50%	0/77 (0.0)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0226	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Decreased immunoglobulins (AMQ) - Narrow	0/109 (0.0)	NE (NE, NE)	7/267 (2.6)	NE (NE, NE)	NE (NE, NE)	0.4197	
Age group 1							0.9997
<35 years	0/50 (0.0)	-	6/123 (4.9)	-	-	-	
≥35 years	0/59 (0.0)	-	1/144 (0.7)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	6/124 (4.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	-	5/159 (3.1)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	5/177 (2.8)	-	-	-	
Rest of the world	0/28 (0.0)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							0.9997
Yes	0/63 (0.0)	-	6/161 (3.7)	-	-	-	
No	0/46 (0.0)	-	1/106 (0.9)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	1/112 (0.9)	-	-	-	
1	0/34 (0.0)	-	5/91 (5.5)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.9998
Yes	0/35 (0.0)	-	6/93 (6.5)	-	-	-	
No	0/74 (0.0)	-	1/174 (0.6)	-	-	-	
Race							>0.9999
Caucasian	0/90 (0.0)	-	6/226 (2.7)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9999
<50%	0/27 (0.0)	-	3/73 (4.1)	-	-	-	
≥50%	0/77 (0.0)	-	2/168 (1.2)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Haematopoietic cytopenias (SMQ) - Narrow	74/109 (67.9)	0.26 (0.26, 0.36)	142/267 (53.2)	2.07 (1.08, 3.11)	0.52 (0.39, 0.69)	<0.0001	
Age group 1							0.4216
<35 years	29/50 (58.0)	0.33 (0.26, NE)	62/123 (50.4)	2.52 (1.54, 4.43)	0.56 (0.36, 0.89)	0.0121	
≥35 years	45/59 (76.3)	0.26 (0.20, 0.30)	80/144 (55.6)	1.31 (0.52, 3.11)	0.49 (0.33, 0.71)	0.0001	
Age group 2							0.6867
<35 years	29/50 (58.0)	0.33 (0.26, NE)	62/124 (50.0)	2.52 (1.54, 4.43)	0.56 (0.36, 0.88)	0.0115	
35 - 54 years	18/25 (72.0)	0.26 (0.23, 0.56)	43/77 (55.8)	0.85 (0.52, 3.11)	0.57 (0.32, 0.99)	0.0419	
55 - 64 years	19/22 (86.4)	0.26 (0.10, 0.43)	19/33 (57.6)	1.18 (0.39, NE)	0.35 (0.18, 0.70)	0.0020	
≥65 years	8/12 (66.7)	0.23 (0.03, NE)	18/33 (54.5)	4.52 (0.23, 8.26)	0.53 (0.22, 1.27)	0.1373	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2653
Male	40/64 (62.5)	0.33 (0.26, 0.56)	84/159 (52.8)	2.07 (1.08, 3.87)	0.57 (0.39, 0.83)	0.0034	
Female	34/45 (75.6)	0.26 (0.20, 0.30)	58/108 (53.7)	2.10 (0.62, 4.62)	0.47 (0.30, 0.73)	0.0006	
Region							0.2612
USA	8/13 (61.5)	0.39 (0.20, NE)	20/30 (66.7)	0.51 (0.33, 1.31)	0.91 (0.40, 2.09)	0.8141	
Europe	44/68 (64.7)	0.26 (0.26, 0.43)	89/177 (50.3)	2.52 (0.92, 4.75)	0.55 (0.38, 0.80)	0.0012	
Rest of the world	22/28 (78.6)	0.26 (0.13, 0.36)	33/60 (55.0)	2.10 (0.79, 3.87)	0.31 (0.17, 0.55)	<0.0001	
Prior salvage therapy							0.0566
Yes	39/63 (61.9)	0.36 (0.26, 0.59)	89/161 (55.3)	1.93 (0.92, 3.02)	0.61 (0.41, 0.89)	0.0095	
No	35/46 (76.1)	0.26 (0.20, 0.30)	53/106 (50.0)	2.36 (0.62, NE)	0.42 (0.27, 0.65)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4478
0	39/55 (70.9)	0.26 (0.23, 0.30)	57/112 (50.9)	2.59 (0.75, 6.85)	0.46 (0.30, 0.70)	0.0002	
1	23/34 (67.6)	0.33 (0.20, 0.59)	50/91 (54.9)	1.93 (0.79, 3.57)	0.47 (0.27, 0.79)	0.0031	
≥2	12/20 (60.0)	0.39 (0.20, NE)	35/64 (54.7)	1.08 (0.52, 3.87)	0.67 (0.35, 1.31)	0.2254	
Prior alloHSCT							0.2237
Yes	27/35 (77.1)	0.26 (0.20, 0.39)	47/93 (50.5)	2.52 (1.18, 4.43)	0.43 (0.26, 0.70)	0.0005	
No	47/74 (63.5)	0.30 (0.23, 0.43)	95/174 (54.6)	1.54 (0.79, 4.52)	0.58 (0.41, 0.83)	0.0025	
Race							0.9542
Caucasian	61/90 (67.8)	0.26 (0.23, 0.36)	121/226 (53.5)	2.20 (0.92, 3.57)	0.53 (0.39, 0.73)	<0.0001	
Others	13/19 (68.4)	0.36 (0.26, 0.59)	21/41 (51.2)	1.64 (0.59, NE)	0.44 (0.21, 0.89)	0.0203	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0589
<50%	20/27 (74.1)	0.26 (0.16, 0.36)	35/73 (47.9)	4.43 (2.07, NE)	0.30 (0.17, 0.55)	<0.0001	
≥50%	52/77 (67.5)	0.30 (0.23, 0.43)	93/168 (55.4)	0.92 (0.52, 3.11)	0.62 (0.44, 0.88)	0.0052	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infections and infestations (SOC)	57/109 (52.3)	1.11 (0.62, 2.03)	93/267 (34.8)	7.25 (5.54, 16.13)	0.33 (0.23, 0.48)	<0.0001	
Age group 1							0.1820
<35 years	21/50 (42.0)	2.00 (0.62, NE)	42/123 (34.1)	6.07 (4.36, NE)	0.40 (0.23, 0.71)	0.0010	
≥35 years	36/59 (61.0)	0.66 (0.43, 1.51)	51/144 (35.4)	7.25 (5.05, NE)	0.30 (0.19, 0.47)	<0.0001	
Age group 2							0.6514
<35 years	21/50 (42.0)	2.00 (0.62, NE)	42/124 (33.9)	6.07 (4.36, NE)	0.40 (0.23, 0.71)	0.0010	
35 - 54 years	14/25 (56.0)	0.66 (0.36, NE)	26/77 (33.8)	7.25 (2.75, NE)	0.25 (0.13, 0.52)	<0.0001	
55 - 64 years	14/22 (63.6)	0.67 (0.30, NE)	13/33 (39.4)	5.80 (1.84, NE)	0.30 (0.13, 0.70)	0.0033	
≥65 years	8/12 (66.7)	0.62 (0.26, NE)	12/33 (36.4)	NE (1.48, NE)	0.40 (0.16, 1.02)	0.0465	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7934
Male	35/64 (54.7)	1.11 (0.52, 2.03)	59/159 (37.1)	6.10 (4.59, 10.10)	0.33 (0.21, 0.52)	<0.0001	
Female	22/45 (48.9)	1.34 (0.49, NE)	34/108 (31.5)	7.25 (4.79, NE)	0.35 (0.20, 0.62)	0.0002	
Region							0.2520
USA	5/13 (38.5)	NE (0.33, NE)	11/30 (36.7)	5.74 (1.48, NE)	0.62 (0.21, 1.86)	0.3896	
Europe	33/68 (48.5)	1.51 (0.62, NE)	56/177 (31.6)	7.57 (5.87, NE)	0.34 (0.22, 0.55)	<0.0001	
Rest of the world	19/28 (67.9)	0.49 (0.39, 0.69)	26/60 (43.3)	4.36 (2.10, NE)	0.21 (0.11, 0.42)	<0.0001	
Prior salvage therapy							0.1232
Yes	32/63 (50.8)	1.11 (0.49, NE)	63/161 (39.1)	5.80 (2.75, 16.13)	0.42 (0.27, 0.65)	<0.0001	
No	25/46 (54.3)	1.34 (0.49, 2.10)	30/106 (28.3)	10.10 (5.87, NE)	0.22 (0.12, 0.41)	<0.0001	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1291
0	28/55 (50.9)	1.34 (0.52, NE)	34/112 (30.4)	10.10 (6.10, NE)	0.26 (0.15, 0.46)	<0.0001	
1	22/34 (64.7)	0.59 (0.33, 1.11)	34/91 (37.4)	4.79 (2.69, 16.13)	0.27 (0.15, 0.47)	<0.0001	
≥2	7/20 (35.0)	NE (0.49, NE)	25/64 (39.1)	5.05 (1.61, NE)	0.70 (0.30, 1.68)	0.4250	
Prior alloHSCT							0.5074
Yes	19/35 (54.3)	0.72 (0.46, NE)	35/93 (37.6)	7.25 (5.05, NE)	0.28 (0.15, 0.52)	<0.0001	
No	38/74 (51.4)	1.34 (0.62, 2.10)	58/174 (33.3)	7.44 (4.36, NE)	0.36 (0.23, 0.55)	<0.0001	
Race							0.5493
Caucasian	47/90 (52.2)	1.34 (0.59, 2.10)	75/226 (33.2)	7.57 (5.80, NE)	0.33 (0.22, 0.49)	<0.0001	
Others	10/19 (52.6)	0.89 (0.33, NE)	18/41 (43.9)	3.38 (1.31, NE)	0.35 (0.15, 0.83)	0.0128	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5541
<50%	14/27 (51.9)	1.51 (0.43, NE)	25/73 (34.2)	7.25 (5.54, 16.13)	0.14 (0.06, 0.33)	<0.0001	
≥50%	41/77 (53.2)	0.89 (0.52, 2.03)	59/168 (35.1)	6.10 (4.30, NE)	0.38 (0.25, 0.58)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Infusion reaction (AMQ) - Narrow	1/109 (0.9)	NE (NE, NE)	17/267 (6.4)	NE (NE, NE)	6.38 (0.84, 48.21)	0.0384	
Age group 1							0.9904
<35 years	1/50 (2.0)	NE (NE, NE)	7/123 (5.7)	NE (NE, NE)	2.19 (0.26, 18.41)	0.4578	
≥35 years	0/59 (0.0)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)	NE (NE, NE)	0.0391	
Age group 2							>0.9999
<35 years	1/50 (2.0)	-	7/124 (5.6)	-	-	-	
35 - 54 years	0/25 (0.0)	-	6/77 (7.8)	-	-	-	
55 - 64 years	0/22 (0.0)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9919
Male	1/64 (1.6)	NE (NE, NE)	6/159 (3.8)	NE (NE, NE)	1.77 (0.20, 15.40)	0.5973	
Female	0/45 (0.0)	NE (NE, NE)	11/108 (10.2)	NE (NE, NE)	NE (NE, NE)	0.0274	
Region							0.9999
USA	0/13 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	NE (NE, NE)	0.3461	
Europe	0/68 (0.0)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	NE (NE, NE)	0.0463	
Rest of the world	1/28 (3.6)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	1.41 (0.15, 13.53)	0.7657	
Prior salvage therapy							0.9916
Yes	1/63 (1.6)	NE (NE, NE)	9/161 (5.6)	NE (NE, NE)	2.93 (0.36, 23.52)	0.2884	
No	0/46 (0.0)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	NE (NE, NE)	0.0573	

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Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	8/112 (7.1)	-	-	-	
1	0/34 (0.0)	-	5/91 (5.5)	-	-	-	
≥2	1/20 (5.0)	-	4/64 (6.3)	-	-	-	
Prior alloHSCT							0.9888
Yes	1/35 (2.9)	NE (NE, NE)	3/93 (3.2)	NE (NE, NE)	0.76 (0.07, 8.34)	0.8201	
No	0/74 (0.0)	NE (NE, NE)	14/174 (8.0)	NE (NE, NE)	NE (NE, NE)	0.0152	
Race							0.9919
Caucasian	1/90 (1.1)	NE (NE, NE)	13/226 (5.8)	NE (NE, NE)	4.88 (0.63, 37.56)	0.0903	
Others	0/19 (0.0)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	NE (NE, NE)	0.2220	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9909
<50%	0/27 (0.0)	NE (NE, NE)	3/73 (4.1)	NE (NE, NE)	NE (NE, NE)	0.3813	
≥50%	1/77 (1.3)	NE (NE, NE)	13/168 (7.7)	NE (NE, NE)	6.16 (0.81, 47.07)	0.0442	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow	16/109 (14.7)	NE (3.02, NE)	34/267 (12.7)	NE (NE, NE)	0.80 (0.44, 1.46)	0.4694	
Age group 1							0.1182
<35 years	10/50 (20.0)	NE (3.02, NE)	14/123 (11.4)	NE (NE, NE)	0.48 (0.21, 1.10)	0.0761	
≥35 years	6/59 (10.2)	NE (NE, NE)	20/144 (13.9)	NE (NE, NE)	1.37 (0.55, 3.43)	0.4971	
Age group 2							0.1310
<35 years	10/50 (20.0)	NE (3.02, NE)	14/124 (11.3)	NE (NE, NE)	0.48 (0.21, 1.10)	0.0750	
35 - 54 years	3/25 (12.0)	NE (NE, NE)	12/77 (15.6)	NE (NE, NE)	1.20 (0.34, 4.27)	0.7806	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	7/33 (21.2)	NE (NE, NE)	4.97 (0.61, 40.43)	0.0943	
≥65 years	2/12 (16.7)	NE (0.95, NE)	1/33 (3.0)	NE (NE, NE)	0.21 (0.02, 2.37)	0.1666	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8047
Male	11/64 (17.2)	NE (NE, NE)	25/159 (15.7)	NE (NE, NE)	0.82 (0.40, 1.68)	0.5929	
Female	5/45 (11.1)	NE (3.02, NE)	9/108 (8.3)	NE (NE, NE)	0.72 (0.24, 2.19)	0.5582	
Region							0.9846
USA	4/13 (30.8)	3.02 (0.95, NE)	8/30 (26.7)	NE (2.46, NE)	0.79 (0.24, 2.64)	0.7064	
Europe	8/68 (11.8)	NE (NE, NE)	17/177 (9.6)	NE (NE, NE)	0.81 (0.35, 1.89)	0.6266	
Rest of the world	4/28 (14.3)	NE (NE, NE)	9/60 (15.0)	NE (NE, NE)	1.01 (0.31, 3.28)	0.9857	
Prior salvage therapy							0.3356
Yes	11/63 (17.5)	NE (NE, NE)	20/161 (12.4)	NE (NE, NE)	0.64 (0.30, 1.33)	0.2259	
No	5/46 (10.9)	NE (3.02, NE)	14/106 (13.2)	NE (NE, NE)	1.17 (0.42, 3.28)	0.7667	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.5953
0	6/55 (10.9)	NE (3.02, NE)	14/112 (12.5)	NE (NE, NE)	1.10 (0.42, 2.87)	0.8572	
1	5/34 (14.7)	NE (NE, NE)	8/91 (8.8)	NE (NE, NE)	0.53 (0.17, 1.64)	0.2650	
≥2	5/20 (25.0)	NE (0.56, NE)	12/64 (18.8)	NE (NE, NE)	0.66 (0.23, 1.90)	0.4397	
Prior alloHSCT							0.8974
Yes	6/35 (17.1)	NE (NE, NE)	15/93 (16.1)	NE (NE, NE)	0.87 (0.34, 2.27)	0.7728	
No	10/74 (13.5)	NE (3.02, NE)	19/174 (10.9)	NE (NE, NE)	0.75 (0.35, 1.62)	0.4585	
Race							0.9810
Caucasian	14/90 (15.6)	NE (3.02, NE)	30/226 (13.3)	NE (NE, NE)	0.81 (0.43, 1.54)	0.5183	
Others	2/19 (10.5)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.69 (0.12, 3.97)	0.6795	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1409
<50%	1/27 (3.7)	NE (NE, NE)	10/73 (13.7)	NE (NE, NE)	3.62 (0.46, 28.41)	0.1905	
≥50%	14/77 (18.2)	NE (NE, NE)	23/168 (13.7)	NE (NE, NE)	0.71 (0.36, 1.38)	0.3051	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Lymphopenia (AMQ) - Narrow	4/109 (3.7)	NE (NE, NE)	5/267 (1.9)	NE (NE, NE)	0.30 (0.07, 1.36)	0.0980	
Age group 1							0.6551
<35 years	1/50 (2.0)	-	2/123 (1.6)	-	-	-	
≥35 years	3/59 (5.1)	-	3/144 (2.1)	-	-	-	
Age group 2							0.8914
<35 years	1/50 (2.0)	-	2/124 (1.6)	-	-	-	
35 - 54 years	2/25 (8.0)	-	2/77 (2.6)	-	-	-	
55 - 64 years	1/22 (4.5)	-	1/33 (3.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6326
Male	3/64 (4.7)	-	3/159 (1.9)	-	-	-	
Female	1/45 (2.2)	-	2/108 (1.9)	-	-	-	
Region							0.6322
USA	1/13 (7.7)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	3/177 (1.7)	-	-	-	
Rest of the world	3/28 (10.7)	-	1/60 (1.7)	-	-	-	
Prior salvage therapy							0.5905
Yes	2/63 (3.2)	-	3/161 (1.9)	-	-	-	
No	2/46 (4.3)	-	2/106 (1.9)	-	-	-	

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[a] p-values were calculated using the unstratified log-rank test.
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Data cut-off date: 14MAR2017

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Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9125
0	1/55 (1.8)	-	2/112 (1.8)	-	-	-	
1	2/34 (5.9)	-	2/91 (2.2)	-	-	-	
≥2	1/20 (5.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.8704
Yes	2/35 (5.7)	-	3/93 (3.2)	-	-	-	
No	2/74 (2.7)	-	2/174 (1.1)	-	-	-	
Race							0.9944
Caucasian	4/90 (4.4)	-	4/226 (1.8)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4695
<50%	1/27 (3.7)	-	3/73 (4.1)	-	-	-	
≥50%	3/77 (3.9)	-	2/168 (1.2)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Medication errors and product use issues (SMQ) - Broad	0/109 (0.0)	NE (NE, NE)	4/267 (1.5)	NE (NE, NE)	NE (NE, NE)	0.2826	
Age group 1							0.9998
<35 years	0/50 (0.0)	-	1/123 (0.8)	-	-	-	
≥35 years	0/59 (0.0)	-	3/144 (2.1)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	0/25 (0.0)	-	0/77 (0.0)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	3/33 (9.1)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	-	2/159 (1.3)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	0/30 (0.0)	-	-	-	
Europe	0/68 (0.0)	-	4/177 (2.3)	-	-	-	
Rest of the world	0/28 (0.0)	-	0/60 (0.0)	-	-	-	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	-	1/161 (0.6)	-	-	-	
No	0/46 (0.0)	-	3/106 (2.8)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	4/112 (3.6)	-	-	-	
1	0/34 (0.0)	-	0/91 (0.0)	-	-	-	
≥2	0/20 (0.0)	-	0/64 (0.0)	-	-	-	
Prior alloHSCT							0.9986
Yes	0/35 (0.0)	-	0/93 (0.0)	-	-	-	
No	0/74 (0.0)	-	4/174 (2.3)	-	-	-	
Race							0.9988
Caucasian	0/90 (0.0)	-	4/226 (1.8)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9986
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	0/77 (0.0)	-	4/168 (2.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Neutropenia (AMQ) - Narrow	63/109 (57.8)	0.43 (0.30, 0.95)	101/267 (37.8)	4.95 (3.87, NE)	0.40 (0.29, 0.55)	<0.0001	
Age group 1							0.4265
<35 years	24/50 (48.0)	1.05 (0.30, NE)	43/123 (35.0)	6.69 (2.59, NE)	0.46 (0.28, 0.77)	0.0025	
≥35 years	39/59 (66.1)	0.36 (0.26, 0.56)	58/144 (40.3)	4.75 (2.89, NE)	0.35 (0.23, 0.54)	<0.0001	
Age group 2							0.8036
<35 years	24/50 (48.0)	1.05 (0.30, NE)	43/124 (34.7)	6.69 (2.59, NE)	0.46 (0.27, 0.77)	0.0025	
35 - 54 years	18/25 (72.0)	0.30 (0.23, 0.56)	32/77 (41.6)	6.69 (1.54, NE)	0.33 (0.18, 0.61)	0.0002	
55 - 64 years	15/22 (68.2)	0.39 (0.20, 0.59)	15/33 (45.5)	2.20 (0.49, NE)	0.41 (0.20, 0.87)	0.0173	
≥65 years	6/12 (50.0)	NE (0.10, NE)	11/33 (33.3)	4.95 (4.59, NE)	0.27 (0.08, 0.88)	0.0202	

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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1934
Male	35/64 (54.7)	0.46 (0.33, NE)	64/159 (40.3)	4.59 (2.36, 8.26)	0.44 (0.29, 0.67)	0.0001	
Female	28/45 (62.2)	0.30 (0.26, 1.05)	37/108 (34.3)	NE (3.11, NE)	0.35 (0.21, 0.59)	<0.0001	
Region							0.6886
USA	9/13 (69.2)	0.33 (0.23, NE)	14/30 (46.7)	1.31 (0.46, NE)	0.42 (0.18, 0.99)	0.0428	
Europe	32/68 (47.1)	NE (0.36, NE)	57/177 (32.2)	8.26 (4.75, NE)	0.47 (0.30, 0.73)	0.0006	
Rest of the world	22/28 (78.6)	0.30 (0.20, 0.36)	30/60 (50.0)	2.36 (1.41, 4.43)	0.25 (0.13, 0.45)	<0.0001	
Prior salvage therapy							0.1349
Yes	34/63 (54.0)	0.56 (0.33, NE)	64/161 (39.8)	4.43 (2.52, 6.69)	0.46 (0.30, 0.71)	0.0003	
No	29/46 (63.0)	0.30 (0.26, 0.59)	37/106 (34.9)	8.26 (4.95, NE)	0.33 (0.20, 0.55)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7114
0	32/55 (58.2)	0.36 (0.26, NE)	40/112 (35.7)	6.69 (4.75, NE)	0.36 (0.22, 0.59)	<0.0001	
1	20/34 (58.8)	0.43 (0.26, NE)	38/91 (41.8)	3.11 (1.93, NE)	0.39 (0.22, 0.70)	0.0009	
≥2	11/20 (55.0)	0.43 (0.26, NE)	23/64 (35.9)	3.87 (2.07, NE)	0.44 (0.21, 0.91)	0.0220	
Prior alloHSCT							0.0555
Yes	24/35 (68.6)	0.30 (0.23, 0.56)	32/93 (34.4)	6.69 (2.89, NE)	0.26 (0.15, 0.47)	<0.0001	
No	39/74 (52.7)	0.46 (0.33, NE)	69/174 (39.7)	4.75 (3.02, NE)	0.49 (0.33, 0.73)	0.0004	
Race							0.6606
Caucasian	50/90 (55.6)	0.43 (0.30, NE)	84/226 (37.2)	4.95 (3.87, NE)	0.41 (0.29, 0.60)	<0.0001	
Others	13/19 (68.4)	0.36 (0.26, 0.59)	17/41 (41.5)	1.93 (0.79, NE)	0.33 (0.16, 0.70)	0.0025	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3542
<50%	15/27 (55.6)	0.46 (0.26, NE)	25/73 (34.2)	NE (4.43, NE)	0.26 (0.13, 0.53)	<0.0001	
≥50%	46/77 (59.7)	0.39 (0.26, 0.95)	68/168 (40.5)	4.62 (2.10, NE)	0.48 (0.33, 0.70)	0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Tumour lysis syndrome (SMQ) - Narrow	1/109 (0.9)	NE (NE, NE)	8/267 (3.0)	NE (NE, NE)	3.00 (0.37, 24.05)	0.2763	
Age group 1							0.9934
<35 years	0/50 (0.0)	-	4/123 (3.3)	-	-	-	
≥35 years	1/59 (1.7)	-	4/144 (2.8)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	4/124 (3.2)	-	-	-	
35 - 54 years	1/25 (4.0)	-	0/77 (0.0)	-	-	-	
55 - 64 years	0/22 (0.0)	-	3/33 (9.1)	-	-	-	
≥65 years	0/12 (0.0)	-	1/33 (3.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9948
Male	1/64 (1.6)	-	7/159 (4.4)	-	-	-	
Female	0/45 (0.0)	-	1/108 (0.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	2/30 (6.7)	-	-	-	
Europe	0/68 (0.0)	-	4/177 (2.3)	-	-	-	
Rest of the world	1/28 (3.6)	-	2/60 (3.3)	-	-	-	
Prior salvage therapy							0.9935
Yes	1/63 (1.6)	-	5/161 (3.1)	-	-	-	
No	0/46 (0.0)	-	3/106 (2.8)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	4/112 (3.6)	-	-	-	
1	1/34 (2.9)	-	3/91 (3.3)	-	-	-	
≥2	0/20 (0.0)	-	1/64 (1.6)	-	-	-	
Prior alloHSCT							0.9945
Yes	0/35 (0.0)	-	3/93 (3.2)	-	-	-	
No	1/74 (1.4)	-	5/174 (2.9)	-	-	-	
Race							0.9998
Caucasian	1/90 (1.1)	-	8/226 (3.5)	-	-	-	
Others	0/19 (0.0)	-	0/41 (0.0)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.7. Subgroup Analysis of Time to First Onset of Prior Defined Severe (Grade ≥ 3) Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95 CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9999
<50%	0/27 (0.0)	-	0/73 (0.0)	-	-	-	
≥50%	1/77 (1.3)	-	5/168 (3.0)	-	-	-	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-aesi-saf.sas
Output: t14-06-002-007-tte-sub-sev-teae-aesi-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.4536
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	123/123 (100.0)	0.07 (NE, NE)	0.91 (0.65, 1.27)	0.5535	
≥35 years	59/59 (100.0)	0.07 (0.03, 0.07)	140/144 (97.2)	0.07 (0.03, 0.07)	1.09 (0.80, 1.48)	0.7769	
Age group 2							0.8972
<35 years	49/50 (98.0)	0.07 (0.03, 0.07)	124/124 (100.0)	0.07 (NE, NE)	0.92 (0.66, 1.28)	0.5805	
35 - 54 years	25/25 (100.0)	0.07 (0.03, 0.10)	76/77 (98.7)	0.07 (0.03, 0.07)	1.10 (0.70, 1.74)	0.8750	
55 - 64 years	22/22 (100.0)	0.07 (0.03, 0.10)	32/33 (97.0)	0.03 (0.03, 0.07)	1.09 (0.63, 1.90)	0.8594	
≥65 years	12/12 (100.0)	0.05 (0.03, 0.20)	31/33 (93.9)	0.07 (0.03, 0.07)	0.96 (0.49, 1.88)	0.7941	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2493
Male	63/64 (98.4)	0.07 (0.03, 0.07)	156/159 (98.1)	0.07 (NE, NE)	0.90 (0.67, 1.21)	0.4162	
Female	45/45 (100.0)	0.07 (0.03, 0.07)	107/108 (99.1)	0.07 (0.03, 0.07)	1.22 (0.86, 1.74)	0.3363	
Region							0.3482
USA	12/13 (92.3)	0.07 (0.03, 0.16)	30/30 (100.0)	0.07 (0.03, 0.07)	1.54 (0.78, 3.03)	0.1887	
Europe	68/68 (100.0)	0.07 (0.03, 0.07)	174/177 (98.3)	0.07 (NE, NE)	0.91 (0.69, 1.21)	0.3724	
Rest of the world	28/28 (100.0)	0.07 (0.03, 0.07)	59/60 (98.3)	0.05 (0.03, 0.07)	1.09 (0.69, 1.72)	0.7975	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1701
Yes	62/63 (98.4)	0.07 (0.07, 0.10)	159/161 (98.8)	0.07 (NE, NE)	1.13 (0.84, 1.52)	0.5362	
No	46/46 (100.0)	0.07 (0.03, 0.07)	104/106 (98.1)	0.07 (NE, NE)	0.84 (0.60, 1.20)	0.2717	
Number of salvage therapies							0.1573
0	55/55 (100.0)	0.03 (0.03, 0.07)	110/112 (98.2)	0.07 (NE, NE)	0.81 (0.59, 1.12)	0.1401	
1	33/34 (97.1)	0.07 (0.07, 0.10)	89/91 (97.8)	0.07 (0.03, 0.07)	1.13 (0.76, 1.69)	0.5886	
≥2	20/20 (100.0)	0.10 (0.07, 0.13)	64/64 (100.0)	0.07 (0.03, 0.07)	1.36 (0.81, 2.29)	0.2734	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.8. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.8878
Yes	35/35 (100.0)	0.07 (0.03, 0.07)	92/93 (98.9)	0.07 (0.03, 0.07)	0.95 (0.64, 1.42)	0.5578	
No	73/74 (98.6)	0.07 (NE, NE)	171/174 (98.3)	0.07 (NE, NE)	1.01 (0.77, 1.33)	0.9247	
Race							0.8263
Caucasian	90/90 (100.0)	0.07 (0.03, 0.07)	222/226 (98.2)	0.07 (NE, NE)	0.99 (0.77, 1.26)	0.6685	
Others	18/19 (94.7)	0.07 (0.03, 0.07)	41/41 (100.0)	0.07 (0.03, 0.07)	1.04 (0.59, 1.81)	0.7449	
Central laboratory baseline bone marrow blasts							0.3812
<50%	27/27 (100.0)	0.07 (0.03, 0.07)	70/73 (95.9)	0.07 (0.03, 0.07)	0.96 (0.61, 1.50)	0.7252	
≥50%	76/77 (98.7)	0.07 (NE, NE)	168/168 (100.0)	0.07 (NE, NE)	1.14 (0.87, 1.50)	0.4141	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-edp-saf.sas
Output: t14-06-002-008-tte-sub-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.7394
<35 years	21/50 (42.0)	2.82 (1.02, NE)	74/123 (60.2)	1.48 (1.02, 3.87)	1.12 (0.68, 1.83)	0.6555	
≥35 years	28/59 (47.5)	1.84 (0.69, NE)	93/144 (64.6)	1.57 (1.18, 2.56)	0.96 (0.62, 1.49)	0.8752	
Age group 2							0.3847
<35 years	21/50 (42.0)	2.82 (1.02, NE)	75/124 (60.5)	1.48 (1.02, 3.87)	1.13 (0.69, 1.85)	0.6125	
35 - 54 years	12/25 (48.0)	1.87 (0.39, NE)	41/77 (53.2)	2.56 (1.38, 5.41)	0.64 (0.33, 1.24)	0.1891	
55 - 64 years	10/22 (45.5)	1.57 (0.43, NE)	26/33 (78.8)	1.51 (0.95, 3.70)	1.03 (0.48, 2.22)	0.9502	
≥65 years	6/12 (50.0)	1.85 (0.20, NE)	25/33 (75.8)	0.49 (0.23, 2.36)	1.49 (0.60, 3.72)	0.4021	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
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Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3141
Male	27/64 (42.2)	2.82 (1.11, NE)	100/159 (62.9)	1.48 (1.08, 3.08)	1.17 (0.76, 1.80)	0.4820	
Female	22/45 (48.9)	1.28 (0.52, NE)	67/108 (62.0)	1.70 (1.18, 2.92)	0.86 (0.52, 1.42)	0.5665	
Region							0.2033
USA	4/13 (30.8)	1.84 (0.89, NE)	22/30 (73.3)	1.08 (0.46, 2.92)	2.36 (0.80, 6.91)	0.1102	
Europe	28/68 (41.2)	2.03 (1.57, NE)	98/177 (55.4)	2.59 (1.51, 4.59)	0.95 (0.62, 1.47)	0.8315	
Rest of the world	17/28 (60.7)	0.46 (0.33, NE)	47/60 (78.3)	0.92 (0.56, 1.31)	0.94 (0.53, 1.65)	0.8316	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.1804
Yes	27/63 (42.9)	1.84 (1.02, NE)	105/161 (65.2)	1.31 (0.98, 1.64)	1.23 (0.80, 1.89)	0.3462	
No	22/46 (47.8)	1.87 (0.52, NE)	62/106 (58.5)	2.56 (1.44, 5.54)	0.78 (0.47, 1.30)	0.3424	
Number of salvage therapies							0.8204
0	24/55 (43.6)	2.82 (0.75, NE)	63/112 (56.3)	3.08 (1.44, 5.54)	0.91 (0.56, 1.48)	0.7087	
1	15/34 (44.1)	1.57 (0.62, NE)	61/91 (67.0)	1.15 (0.75, 1.64)	1.14 (0.64, 2.03)	0.6535	
≥2	10/20 (50.0)	1.84 (0.39, NE)	43/64 (67.2)	1.28 (0.98, 2.52)	0.96 (0.47, 1.93)	0.8967	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.9. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.0061
Yes	22/35 (62.9)	0.92 (0.39, 2.82)	60/93 (64.5)	1.74 (1.18, 4.59)	0.55 (0.33, 0.92)	0.0209	
No	27/74 (36.5)	2.03 (1.84, NE)	107/174 (61.5)	1.48 (1.05, 2.46)	1.43 (0.93, 2.20)	0.0978	
Race							0.6354
Caucasian	40/90 (44.4)	1.87 (1.02, NE)	140/226 (61.9)	1.70 (1.38, 2.92)	1.01 (0.70, 1.44)	0.9692	
Others	9/19 (47.4)	1.84 (0.43, NE)	27/41 (65.9)	1.05 (0.72, 2.56)	1.28 (0.59, 2.74)	0.5329	
Central laboratory baseline bone marrow blasts							0.1369
<50%	15/27 (55.6)	1.87 (0.52, NE)	45/73 (61.6)	3.28 (1.44, 5.74)	0.58 (0.31, 1.08)	0.0840	
≥50%	32/77 (41.6)	2.82 (1.11, NE)	106/168 (63.1)	1.41 (1.05, 1.87)	1.23 (0.83, 1.85)	0.3028	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-edp-saf.sas
Output: t14-06-002-009-tte-sub-ser-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.6965
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	102/123 (82.9)	0.36 (0.23, 0.59)	0.63 (0.44, 0.90)	0.0098	
≥35 years	55/59 (93.2)	0.23 (0.13, 0.26)	129/144 (89.6)	0.16 (0.10, 0.33)	0.72 (0.52, 1.00)	0.0376	
Age group 2							0.8483
<35 years	45/50 (90.0)	0.25 (0.13, 0.33)	103/124 (83.1)	0.34 (0.20, 0.59)	0.63 (0.44, 0.91)	0.0111	
35 - 54 years	24/25 (96.0)	0.23 (0.13, 0.26)	69/77 (89.6)	0.26 (0.13, 0.43)	0.61 (0.38, 1.01)	0.0440	
55 - 64 years	21/22 (95.5)	0.21 (0.10, 0.26)	29/33 (87.9)	0.10 (0.07, 0.46)	0.68 (0.37, 1.24)	0.1644	
≥65 years	10/12 (83.3)	0.23 (0.03, 0.56)	30/33 (90.9)	0.13 (0.07, 0.33)	0.97 (0.47, 2.02)	0.9315	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8112
Male	56/64 (87.5)	0.21 (0.13, 0.30)	135/159 (84.9)	0.33 (0.23, 0.46)	0.68 (0.49, 0.93)	0.0156	
Female	44/45 (97.8)	0.23 (0.16, 0.26)	96/108 (88.9)	0.13 (0.10, 0.30)	0.68 (0.47, 1.00)	0.0333	
Region							0.0941
USA	10/13 (76.9)	0.26 (0.07, 0.89)	28/30 (93.3)	0.13 (0.07, 0.33)	1.42 (0.69, 2.94)	0.3534	
Europe	63/68 (92.6)	0.23 (0.16, 0.26)	147/177 (83.1)	0.30 (0.16, 0.39)	0.64 (0.47, 0.87)	0.0028	
Rest of the world	27/28 (96.4)	0.16 (0.07, 0.26)	56/60 (93.3)	0.38 (0.13, 0.56)	0.55 (0.34, 0.89)	0.0130	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior salvage therapy							0.4910
Yes	58/63 (92.1)	0.23 (0.16, 0.26)	143/161 (88.8)	0.30 (0.16, 0.39)	0.70 (0.51, 0.96)	0.0186	
No	42/46 (91.3)	0.23 (0.10, 0.26)	88/106 (83.0)	0.26 (0.13, 0.43)	0.65 (0.45, 0.95)	0.0241	
Number of salvage therapies							0.7257
0	50/55 (90.9)	0.23 (0.13, 0.26)	92/112 (82.1)	0.26 (0.13, 0.39)	0.68 (0.47, 0.96)	0.0284	
1	31/34 (91.2)	0.20 (0.10, 0.26)	81/91 (89.0)	0.33 (0.16, 0.46)	0.60 (0.39, 0.93)	0.0184	
≥2	19/20 (95.0)	0.25 (0.10, 0.43)	58/64 (90.6)	0.23 (0.07, 0.36)	0.75 (0.44, 1.29)	0.2124	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.10. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.6028
Yes	35/35 (100.0)	0.23 (0.16, 0.26)	81/93 (87.1)	0.20 (0.13, 0.36)	0.60 (0.39, 0.91)	0.0113	
No	65/74 (87.8)	0.21 (0.13, 0.26)	150/174 (86.2)	0.33 (0.16, 0.43)	0.71 (0.53, 0.96)	0.0217	
Race							0.3064
Caucasian	83/90 (92.2)	0.21 (0.16, 0.26)	194/226 (85.8)	0.26 (0.16, 0.36)	0.66 (0.50, 0.86)	0.0013	
Others	17/19 (89.5)	0.26 (0.10, 0.43)	37/41 (90.2)	0.39 (0.10, 0.59)	0.80 (0.44, 1.43)	0.4404	
Central laboratory baseline bone marrow blasts							0.0619
<50%	24/27 (88.9)	0.23 (0.10, 0.26)	58/73 (79.5)	0.66 (0.33, 1.44)	0.46 (0.28, 0.77)	0.0018	
≥50%	71/77 (92.2)	0.20 (0.16, 0.26)	151/168 (89.9)	0.18 (0.10, 0.33)	0.81 (0.61, 1.08)	0.1172	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-edp-saf.sas
Output: t14-06-002-010-tte-sub-sev-teae-edp-saf.rtf (Date generated: 22JUN2025:22:28) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Blood and lymphatic system disorders							
Overall	83/109 (76.1)	0.26 (0.20, 0.30)	182/267 (68.2)	0.52 (0.39, 0.82)	0.62 (0.48, 0.81)	0.0004	
Age group 1							0.4868
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	83/123 (67.5)	0.82 (0.39, 1.74)	0.66 (0.44, 1.00)	0.0470	
≥35 years	49/59 (83.1)	0.23 (0.13, 0.26)	99/144 (68.8)	0.46 (0.30, 0.72)	0.59 (0.42, 0.85)	0.0031	
Age group 2							0.8037
<35 years	34/50 (68.0)	0.26 (0.20, 0.43)	84/124 (67.7)	0.82 (0.39, 1.74)	0.67 (0.45, 1.01)	0.0542	
35 - 54 years	22/25 (88.0)	0.26 (0.13, 0.30)	53/77 (68.8)	0.52 (0.26, 0.79)	0.54 (0.32, 0.90)	0.0164	
55 - 64 years	20/22 (90.9)	0.20 (0.07, 0.30)	26/33 (78.8)	0.33 (0.07, 0.52)	0.62 (0.34, 1.14)	0.1110	
≥65 years	7/12 (58.3)	0.30 (0.03, NE)	19/33 (57.6)	2.36 (0.33, 4.95)	0.67 (0.27, 1.66)	0.3802	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3454
Male	45/64 (70.3)	0.30 (0.16, 0.36)	109/159 (68.6)	0.59 (0.39, 1.15)	0.69 (0.48, 0.98)	0.0376	
Female	38/45 (84.4)	0.23 (0.20, 0.26)	73/108 (67.6)	0.52 (0.30, 0.92)	0.55 (0.37, 0.83)	0.0037	
Region							0.2229
USA	8/13 (61.5)	0.33 (0.13, NE)	25/30 (83.3)	0.49 (0.20, 0.98)	1.05 (0.47, 2.37)	0.8965	
Europe	52/68 (76.5)	0.26 (0.16, 0.30)	113/177 (63.8)	0.56 (0.39, 1.44)	0.61 (0.43, 0.85)	0.0028	
Rest of the world	23/28 (82.1)	0.23 (0.16, 0.36)	44/60 (73.3)	0.39 (0.26, 1.90)	0.50 (0.29, 0.85)	0.0091	
Prior salvage therapy							0.0981
Yes	45/63 (71.4)	0.30 (0.20, 0.43)	112/161 (69.6)	0.56 (0.33, 0.92)	0.72 (0.50, 1.02)	0.0565	
No	38/46 (82.6)	0.23 (0.10, 0.26)	70/106 (66.0)	0.52 (0.26, 1.87)	0.52 (0.34, 0.78)	0.0014	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3063
0	44/55 (80.0)	0.23 (0.13, 0.26)	76/112 (67.9)	0.59 (0.30, 1.38)	0.56 (0.38, 0.82)	0.0029	
1	25/34 (73.5)	0.26 (0.16, 0.56)	60/91 (65.9)	0.79 (0.46, 1.74)	0.58 (0.36, 0.95)	0.0233	
≥2	14/20 (70.0)	0.39 (0.20, 0.52)	46/64 (71.9)	0.46 (0.26, 0.75)	0.89 (0.49, 1.63)	0.6626	
Prior alloHSCT							0.9776
Yes	29/35 (82.9)	0.26 (0.20, 0.36)	67/93 (72.0)	0.39 (0.26, 0.92)	0.62 (0.39, 0.97)	0.0303	
No	54/74 (73.0)	0.26 (0.16, 0.33)	115/174 (66.1)	0.69 (0.46, 1.15)	0.62 (0.45, 0.87)	0.0050	
Race							0.9573
Caucasian	69/90 (76.7)	0.23 (0.20, 0.30)	154/226 (68.1)	0.52 (0.33, 0.85)	0.63 (0.47, 0.85)	0.0016	
Others	14/19 (73.7)	0.33 (0.10, 0.56)	28/41 (68.3)	0.75 (0.30, 1.90)	0.54 (0.28, 1.06)	0.0723	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4657
<50%	20/27 (74.1)	0.26 (0.10, 0.56)	47/73 (64.4)	1.15 (0.33, 2.59)	0.56 (0.33, 0.97)	0.0354	
≥50%	58/77 (75.3)	0.26 (0.20, 0.33)	115/168 (68.5)	0.52 (0.33, 0.72)	0.68 (0.49, 0.94)	0.0163	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Anaemia							
Overall	46/109 (42.2)	1.93 (0.79, NE)	68/267 (25.5)	NE (NE, NE)	0.52 (0.36, 0.76)	0.0006	
Age group 1							0.3134
<35 years	21/50 (42.0)	1.93 (0.43, NE)	26/123 (21.1)	NE (11.90, NE)	0.39 (0.22, 0.70)	0.0010	
≥35 years	25/59 (42.4)	NE (0.46, NE)	42/144 (29.2)	NE (NE, NE)	0.65 (0.39, 1.06)	0.0798	
Age group 2							0.7027
<35 years	21/50 (42.0)	1.93 (0.43, NE)	26/124 (21.0)	NE (11.90, NE)	0.39 (0.21, 0.70)	0.0010	
35 - 54 years	10/25 (40.0)	NE (0.36, NE)	24/77 (31.2)	NE (NE, NE)	0.75 (0.36, 1.56)	0.4310	
55 - 64 years	11/22 (50.0)	0.79 (0.10, NE)	10/33 (30.3)	NE (NE, NE)	0.60 (0.25, 1.40)	0.2126	
≥65 years	4/12 (33.3)	NE (0.10, NE)	8/33 (24.2)	NE (NE, NE)	0.65 (0.20, 2.17)	0.4911	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4349
Male	25/64 (39.1)	NE (0.79, NE)	34/159 (21.4)	NE (11.90, NE)	0.44 (0.26, 0.74)	0.0016	
Female	21/45 (46.7)	1.93 (0.36, NE)	34/108 (31.5)	NE (NE, NE)	0.64 (0.37, 1.11)	0.1087	
Region							0.3500
USA	6/13 (46.2)	NE (0.13, NE)	7/30 (23.3)	NE (NE, NE)	0.45 (0.15, 1.36)	0.1465	
Europe	27/68 (39.7)	NE (0.79, NE)	50/177 (28.2)	NE (11.90, NE)	0.63 (0.39, 1.00)	0.0492	
Rest of the world	13/28 (46.4)	1.08 (0.33, NE)	11/60 (18.3)	NE (NE, NE)	0.33 (0.14, 0.73)	0.0039	
Prior salvage therapy							0.4969
Yes	23/63 (36.5)	1.93 (1.08, NE)	38/161 (23.6)	NE (11.90, NE)	0.56 (0.33, 0.95)	0.0270	
No	23/46 (50.0)	0.66 (0.26, NE)	30/106 (28.3)	NE (NE, NE)	0.48 (0.28, 0.83)	0.0070	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9834
0	25/55 (45.5)	NE (0.33, NE)	33/112 (29.5)	NE (NE, NE)	0.56 (0.33, 0.94)	0.0263	
1	14/34 (41.2)	1.15 (0.79, NE)	21/91 (23.1)	NE (NE, NE)	0.51 (0.26, 1.01)	0.0480	
≥2	7/20 (35.0)	1.93 (0.43, NE)	14/64 (21.9)	11.90 (11.90, NE)	0.53 (0.21, 1.32)	0.1606	
Prior alloHSCT							0.6501
Yes	17/35 (48.6)	1.08 (0.36, NE)	25/93 (26.9)	NE (11.90, NE)	0.47 (0.25, 0.87)	0.0133	
No	29/74 (39.2)	NE (0.79, NE)	43/174 (24.7)	NE (NE, NE)	0.56 (0.35, 0.90)	0.0143	
Race							0.9689
Caucasian	41/90 (45.6)	1.93 (0.46, NE)	62/226 (27.4)	NE (11.90, NE)	0.52 (0.35, 0.77)	0.0009	
Others	5/19 (26.3)	NE (1.15, NE)	6/41 (14.6)	NE (NE, NE)	0.50 (0.15, 1.64)	0.2400	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3645
<50%	16/27 (59.3)	0.79 (0.23, NE)	20/73 (27.4)	NE (NE, NE)	0.38 (0.20, 0.75)	0.0032	
≥50%	28/77 (36.4)	NE (1.08, NE)	38/168 (22.6)	NE (NE, NE)	0.56 (0.34, 0.91)	0.0168	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Febrile neutropenia							
Overall	43/109 (39.4)	2.82 (1.77, NE)	65/267 (24.3)	NE (NE, NE)	0.48 (0.32, 0.71)	0.0002	
Age group 1							0.9784
<35 years	20/50 (40.0)	2.49 (0.95, NE)	31/123 (25.2)	NE (6.69, NE)	0.43 (0.24, 0.77)	0.0038	
≥35 years	23/59 (39.0)	NE (0.59, NE)	34/144 (23.6)	NE (NE, NE)	0.53 (0.31, 0.91)	0.0183	
Age group 2							0.8301
<35 years	20/50 (40.0)	2.49 (0.95, NE)	32/124 (25.8)	NE (6.69, NE)	0.45 (0.25, 0.80)	0.0056	
35 - 54 years	11/25 (44.0)	NE (0.33, NE)	17/77 (22.1)	NE (NE, NE)	0.45 (0.21, 0.97)	0.0354	
55 - 64 years	9/22 (40.9)	NE (0.43, NE)	10/33 (30.3)	NE (1.31, NE)	0.67 (0.27, 1.66)	0.3910	
≥65 years	3/12 (25.0)	NE (0.33, NE)	6/33 (18.2)	NE (4.59, NE)	0.49 (0.11, 2.18)	0.3395	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8821
Male	28/64 (43.8)	2.49 (0.56, NE)	44/159 (27.7)	NE (6.69, NE)	0.46 (0.29, 0.75)	0.0014	
Female	15/45 (33.3)	NE (1.77, NE)	21/108 (19.4)	NE (NE, NE)	0.51 (0.26, 0.99)	0.0459	
Region							0.5254
USA	6/13 (46.2)	NE (0.33, NE)	14/30 (46.7)	2.30 (0.52, NE)	0.75 (0.28, 1.97)	0.5646	
Europe	22/68 (32.4)	NE (2.49, NE)	31/177 (17.5)	NE (NE, NE)	0.44 (0.25, 0.77)	0.0028	
Rest of the world	15/28 (53.6)	0.56 (0.36, NE)	20/60 (33.3)	NE (3.87, NE)	0.43 (0.21, 0.87)	0.0166	
Prior salvage therapy							0.0577
Yes	23/63 (36.5)	2.49 (1.77, NE)	46/161 (28.6)	NE (6.69, NE)	0.61 (0.37, 1.02)	0.0542	
No	20/46 (43.5)	2.82 (0.43, NE)	19/106 (17.9)	NE (NE, NE)	0.32 (0.17, 0.61)	0.0003	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4939
0	21/55 (38.2)	NE (0.59, NE)	21/112 (18.8)	NE (NE, NE)	0.39 (0.21, 0.72)	0.0019	
1	13/34 (38.2)	1.77 (0.56, NE)	27/91 (29.7)	NE (4.59, NE)	0.61 (0.31, 1.20)	0.1478	
≥2	9/20 (45.0)	2.49 (0.39, NE)	17/64 (26.6)	NE (3.87, NE)	0.40 (0.17, 0.94)	0.0282	
Prior alloHSCT							0.1323
Yes	17/35 (48.6)	1.77 (0.43, 2.82)	20/93 (21.5)	NE (NE, NE)	0.27 (0.14, 0.54)	<0.0001	
No	26/74 (35.1)	NE (NE, NE)	45/174 (25.9)	NE (NE, NE)	0.62 (0.38, 1.01)	0.0515	
Race							0.3215
Caucasian	32/90 (35.6)	2.82 (1.77, NE)	53/226 (23.5)	NE (NE, NE)	0.52 (0.33, 0.81)	0.0035	
Others	11/19 (57.9)	0.56 (0.30, NE)	12/41 (29.3)	NE (1.64, NE)	0.34 (0.15, 0.79)	0.0092	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0878
<50%	10/27 (37.0)	NE (0.43, NE)	11/73 (15.1)	NE (NE, NE)	0.27 (0.11, 0.67)	0.0027	
≥50%	32/77 (41.6)	2.49 (0.59, NE)	51/168 (30.4)	NE (6.26, NE)	0.60 (0.38, 0.95)	0.0253	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutropenia							
Overall	33/109 (30.3)	NE (2.30, NE)	53/267 (19.9)	NE (8.26, NE)	0.41 (0.26, 0.65)	<0.0001	
Age group 1							0.7430
<35 years	15/50 (30.0)	NE (2.30, NE)	26/123 (21.1)	NE (5.02, NE)	0.45 (0.23, 0.87)	0.0146	
≥35 years	18/59 (30.5)	NE (NE, NE)	27/144 (18.8)	NE (6.69, NE)	0.38 (0.20, 0.72)	0.0020	
Age group 2							0.7612
<35 years	15/50 (30.0)	NE (2.30, NE)	26/124 (21.0)	NE (5.02, NE)	0.45 (0.23, 0.86)	0.0143	
35 - 54 years	8/25 (32.0)	NE (0.52, NE)	17/77 (22.1)	NE (4.79, NE)	0.40 (0.16, 0.96)	0.0357	
55 - 64 years	8/22 (36.4)	NE (0.26, NE)	5/33 (15.2)	NE (NE, NE)	0.32 (0.10, 1.00)	0.0395	
≥65 years	2/12 (16.7)	NE (0.36, NE)	5/33 (15.2)	8.26 (4.95, NE)	0.39 (0.05, 2.74)	0.3235	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0476
Male	14/64 (21.9)	NE (2.30, NE)	31/159 (19.5)	NE (8.26, NE)	0.61 (0.32, 1.17)	0.1392	
Female	19/45 (42.2)	NE (0.30, NE)	22/108 (20.4)	NE (6.69, NE)	0.26 (0.13, 0.51)	<0.0001	
Region							0.4394
USA	1/13 (7.7)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)	1.80 (0.20, 16.11)	0.5889	
Europe	20/68 (29.4)	NE (2.30, NE)	33/177 (18.6)	NE (8.26, NE)	0.42 (0.24, 0.75)	0.0026	
Rest of the world	12/28 (42.9)	NE (0.23, NE)	16/60 (26.7)	NE (3.11, NE)	0.24 (0.10, 0.57)	0.0006	
Prior salvage therapy							0.5799
Yes	14/63 (22.2)	NE (NE, NE)	25/161 (15.5)	NE (NE, NE)	0.43 (0.22, 0.84)	0.0117	
No	19/46 (41.3)	NE (0.26, NE)	28/106 (26.4)	NE (6.69, NE)	0.41 (0.22, 0.76)	0.0035	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6377
0	20/55 (36.4)	NE (2.30, NE)	29/112 (25.9)	NE (6.69, NE)	0.47 (0.26, 0.86)	0.0127	
1	9/34 (26.5)	NE (NE, NE)	13/91 (14.3)	NE (5.02, NE)	0.26 (0.10, 0.69)	0.0037	
≥2	4/20 (20.0)	NE (NE, NE)	11/64 (17.2)	NE (3.61, NE)	0.58 (0.18, 1.85)	0.3479	
Prior alloHSCT							0.2583
Yes	15/35 (42.9)	NE (0.26, NE)	22/93 (23.7)	NE (4.79, NE)	0.27 (0.13, 0.56)	0.0002	
No	18/74 (24.3)	NE (NE, NE)	31/174 (17.8)	NE (8.26, NE)	0.51 (0.28, 0.93)	0.0265	
Race							0.2955
Caucasian	29/90 (32.2)	NE (2.30, NE)	43/226 (19.0)	NE (8.26, NE)	0.36 (0.22, 0.60)	<0.0001	
Others	4/19 (21.1)	NE (NE, NE)	10/41 (24.4)	NE (4.79, NE)	0.79 (0.24, 2.63)	0.6954	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5179
<50%	6/27 (22.2)	NE (NE, NE)	16/73 (21.9)	NE (6.69, NE)	0.57 (0.21, 1.52)	0.2594	
≥50%	25/77 (32.5)	NE (2.30, NE)	34/168 (20.2)	NE (5.02, NE)	0.42 (0.25, 0.72)	0.0013	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Thrombocytopenia							
Overall	32/109 (29.4)	NE (NE, NE)	48/267 (18.0)	NE (NE, NE)	0.51 (0.33, 0.81)	0.0035	
Age group 1							0.6414
<35 years	16/50 (32.0)	NE (2.03, NE)	23/123 (18.7)	NE (16.26, NE)	0.41 (0.21, 0.79)	0.0065	
≥35 years	16/59 (27.1)	NE (NE, NE)	25/144 (17.4)	NE (NE, NE)	0.63 (0.34, 1.18)	0.1488	
Age group 2							0.9405
<35 years	16/50 (32.0)	NE (2.03, NE)	23/124 (18.5)	NE (16.26, NE)	0.41 (0.21, 0.79)	0.0062	
35 - 54 years	6/25 (24.0)	NE (NE, NE)	14/77 (18.2)	NE (NE, NE)	0.73 (0.28, 1.90)	0.5182	
55 - 64 years	7/22 (31.8)	NE (0.36, NE)	6/33 (18.2)	NE (NE, NE)	0.55 (0.19, 1.65)	0.2829	
≥65 years	3/12 (25.0)	NE (0.16, NE)	5/33 (15.2)	NE (NE, NE)	0.62 (0.15, 2.61)	0.5047	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8888
Male	18/64 (28.1)	NE (NE, NE)	29/159 (18.2)	NE (16.26, NE)	0.53 (0.29, 0.96)	0.0326	
Female	14/45 (31.1)	NE (2.03, NE)	19/108 (17.6)	NE (NE, NE)	0.50 (0.25, 1.01)	0.0492	
Region							0.1404
USA	1/13 (7.7)	NE (2.03, NE)	5/30 (16.7)	NE (NE, NE)	2.09 (0.24, 18.00)	0.4961	
Europe	25/68 (36.8)	NE (NE, NE)	40/177 (22.6)	NE (16.26, NE)	0.51 (0.31, 0.85)	0.0082	
Rest of the world	6/28 (21.4)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.21 (0.05, 0.85)	0.0154	
Prior salvage therapy							0.6486
Yes	15/63 (23.8)	NE (NE, NE)	25/161 (15.5)	NE (16.26, NE)	0.56 (0.29, 1.08)	0.0773	
No	17/46 (37.0)	NE (0.39, NE)	23/106 (21.7)	NE (NE, NE)	0.48 (0.25, 0.90)	0.0204	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3660
0	21/55 (38.2)	NE (0.39, NE)	23/112 (20.5)	NE (NE, NE)	0.42 (0.23, 0.77)	0.0043	
1	8/34 (23.5)	NE (NE, NE)	13/91 (14.3)	16.26 (16.26, NE)	0.51 (0.20, 1.27)	0.1375	
≥2	3/20 (15.0)	NE (NE, NE)	12/64 (18.8)	NE (NE, NE)	1.15 (0.32, 4.07)	0.8326	
Prior alloHSCT							0.4392
Yes	10/35 (28.6)	NE (NE, NE)	21/93 (22.6)	NE (16.26, NE)	0.63 (0.29, 1.38)	0.2394	
No	22/74 (29.7)	NE (2.03, NE)	27/174 (15.5)	NE (NE, NE)	0.46 (0.26, 0.81)	0.0060	
Race							0.8500
Caucasian	30/90 (33.3)	NE (2.03, NE)	45/226 (19.9)	NE (NE, NE)	0.50 (0.31, 0.80)	0.0032	
Others	2/19 (10.5)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.63 (0.11, 3.78)	0.6115	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1726
<50%	14/27 (51.9)	0.39 (0.26, NE)	16/73 (21.9)	NE (16.26, NE)	0.26 (0.12, 0.56)	0.0003	
≥50%	17/77 (22.1)	NE (NE, NE)	26/168 (15.5)	NE (NE, NE)	0.67 (0.36, 1.23)	0.1927	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Leukopenia							
Overall	5/109 (4.6)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.77 (0.26, 2.26)	0.6352	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Cardiac disorders							
Overall	26/109 (23.9)	NE (2.26, NE)	49/267 (18.4)	NE (NE, NE)	0.64 (0.39, 1.03)	0.0630	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Tachycardia							
Overall	10/109 (9.2)	NE (2.82, NE)	18/267 (6.7)	NE (NE, NE)	0.61 (0.28, 1.34)	0.2118	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sinus tachycardia							
Overall	6/109 (5.5)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.94 (0.36, 2.44)	0.9006	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Ear and labyrinth disorders							
Overall	4/109 (3.7)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	1.13 (0.36, 3.51)	0.8363	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Eye disorders							
Overall	15/109 (13.8)	NE (NE, NE)	27/267 (10.1)	NE (NE, NE)	0.52 (0.27, 1.00)	0.0469	
Age group 1							0.2177
<35 years	7/50 (14.0)	NE (NE, NE)	8/123 (6.5)	NE (NE, NE)	0.33 (0.12, 0.97)	0.0342	
≥35 years	8/59 (13.6)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)	0.68 (0.28, 1.61)	0.3788	
Age group 2							0.3714
<35 years	7/50 (14.0)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)	0.39 (0.14, 1.08)	0.0610	
35 - 54 years	5/25 (20.0)	NE (1.05, NE)	9/77 (11.7)	NE (NE, NE)	0.28 (0.09, 0.93)	0.0278	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	6/33 (18.2)	8.10 (8.10, NE)	1.73 (0.33, 8.90)	0.5064	
≥65 years	1/12 (8.3)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	0.90 (0.08, 9.92)	0.9288	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3503
Male	11/64 (17.2)	NE (NE, NE)	16/159 (10.1)	NE (NE, NE)	0.49 (0.23, 1.07)	0.0694	
Female	4/45 (8.9)	NE (NE, NE)	11/108 (10.2)	NE (8.72, NE)	0.50 (0.14, 1.84)	0.2880	
Region							0.8225
USA	1/13 (7.7)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	0.84 (0.08, 9.32)	0.8890	
Europe	7/68 (10.3)	NE (NE, NE)	15/177 (8.5)	NE (NE, NE)	0.60 (0.23, 1.52)	0.2745	
Rest of the world	7/28 (25.0)	NE (NE, NE)	10/60 (16.7)	NE (5.77, NE)	0.37 (0.13, 1.09)	0.0603	
Prior salvage therapy							0.9625
Yes	9/63 (14.3)	NE (NE, NE)	16/161 (9.9)	NE (NE, NE)	0.49 (0.21, 1.13)	0.0885	
No	6/46 (13.0)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	0.57 (0.20, 1.63)	0.2867	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1441
0	8/55 (14.5)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	0.56 (0.22, 1.42)	0.2159	
1	6/34 (17.6)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)	0.14 (0.03, 0.57)	0.0015	
≥2	1/20 (5.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)	2.57 (0.32, 20.41)	0.3534	
Prior alloHSCT							0.3548
Yes	3/35 (8.6)	NE (NE, NE)	11/93 (11.8)	NE (NE, NE)	0.75 (0.19, 2.97)	0.6818	
No	12/74 (16.2)	NE (NE, NE)	16/174 (9.2)	NE (NE, NE)	0.46 (0.22, 0.99)	0.0423	
Race							0.9477
Caucasian	11/90 (12.2)	NE (NE, NE)	20/226 (8.8)	NE (NE, NE)	0.53 (0.25, 1.15)	0.1053	
Others	4/19 (21.1)	NE (NE, NE)	7/41 (17.1)	NE (5.77, NE)	0.46 (0.12, 1.72)	0.2365	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9486
<50%	3/27 (11.1)	NE (NE, NE)	6/73 (8.2)	NE (8.72, NE)	0.28 (0.05, 1.50)	0.1149	
≥50%	11/77 (14.3)	NE (NE, NE)	15/168 (8.9)	NE (NE, NE)	0.50 (0.23, 1.12)	0.0874	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Gastrointestinal disorders							
Overall	88/109 (80.7)	0.23 (0.10, 0.26)	154/267 (57.7)	1.21 (0.95, 2.13)	0.37 (0.28, 0.49)	<0.0001	
Age group 1							0.2979
<35 years	40/50 (80.0)	0.16 (0.10, 0.26)	68/123 (55.3)	1.74 (0.98, 3.08)	0.30 (0.20, 0.46)	<0.0001	
≥35 years	48/59 (81.4)	0.23 (0.13, 0.30)	86/144 (59.7)	0.95 (0.59, 2.39)	0.44 (0.31, 0.64)	<0.0001	
Age group 2							0.1032
<35 years	40/50 (80.0)	0.16 (0.10, 0.26)	69/124 (55.6)	1.48 (0.98, 3.08)	0.31 (0.21, 0.47)	<0.0001	
35 - 54 years	21/25 (84.0)	0.23 (0.10, 0.30)	48/77 (62.3)	0.95 (0.46, 2.62)	0.35 (0.21, 0.61)	0.0001	
55 - 64 years	17/22 (77.3)	0.30 (0.10, 0.82)	24/33 (72.7)	0.56 (0.13, 1.08)	0.78 (0.41, 1.47)	0.4331	
≥65 years	10/12 (83.3)	0.20 (0.03, 1.57)	13/33 (39.4)	7.48 (0.59, NE)	0.26 (0.11, 0.61)	0.0010	

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Adverse events coded using MedDRA version 20.0.
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Data cut-off date: 14MAR2017

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Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0380
Male	48/64 (75.0)	0.26 (0.16, 0.46)	90/159 (56.6)	1.18 (0.72, 2.39)	0.46 (0.32, 0.66)	<0.0001	
Female	40/45 (88.9)	0.10 (0.10, 0.23)	64/108 (59.3)	1.61 (0.62, 2.98)	0.27 (0.17, 0.41)	<0.0001	
Region							0.3543
USA	11/13 (84.6)	0.23 (0.07, 0.33)	19/30 (63.3)	0.98 (0.49, 1.31)	0.36 (0.16, 0.77)	0.0068	
Europe	54/68 (79.4)	0.23 (0.10, 0.26)	91/177 (51.4)	2.59 (1.15, 6.62)	0.32 (0.23, 0.46)	<0.0001	
Rest of the world	23/28 (82.1)	0.15 (0.07, 0.23)	44/60 (73.3)	0.46 (0.20, 0.95)	0.54 (0.32, 0.91)	0.0210	
Prior salvage therapy							0.0192
Yes	46/63 (73.0)	0.26 (0.20, 0.46)	91/161 (56.5)	1.15 (0.72, 2.13)	0.48 (0.33, 0.69)	<0.0001	
No	42/46 (91.3)	0.10 (0.07, 0.23)	63/106 (59.4)	1.74 (0.59, 2.89)	0.26 (0.17, 0.39)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0114
0	51/55 (92.7)	0.10 (0.07, 0.20)	68/112 (60.7)	1.74 (0.62, 2.98)	0.25 (0.17, 0.37)	<0.0001	
1	23/34 (67.6)	0.30 (0.23, 2.16)	47/91 (51.6)	1.61 (0.62, NE)	0.53 (0.32, 0.88)	0.0126	
≥2	14/20 (70.0)	0.46 (0.10, NE)	39/64 (60.9)	1.08 (0.39, 1.38)	0.56 (0.30, 1.04)	0.0616	
Prior alloHSCT							0.0633
Yes	33/35 (94.3)	0.10 (0.07, 0.20)	61/93 (65.6)	1.11 (0.62, 2.13)	0.23 (0.14, 0.36)	<0.0001	
No	55/74 (74.3)	0.26 (0.16, 0.30)	93/174 (53.4)	1.28 (0.72, 2.95)	0.45 (0.32, 0.63)	<0.0001	
Race							0.8251
Caucasian	73/90 (81.1)	0.23 (0.13, 0.26)	127/226 (56.2)	1.48 (0.95, 2.62)	0.37 (0.27, 0.49)	<0.0001	
Others	15/19 (78.9)	0.10 (0.07, 0.23)	27/41 (65.9)	0.69 (0.39, 1.61)	0.43 (0.23, 0.83)	0.0121	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0022
<50%	25/27 (92.6)	0.10 (0.07, 0.30)	35/73 (47.9)	2.98 (2.59, 11.28)	0.17 (0.10, 0.30)	<0.0001	
≥50%	58/77 (75.3)	0.23 (0.13, 0.26)	108/168 (64.3)	0.72 (0.43, 1.15)	0.55 (0.39, 0.76)	0.0003	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Diarrhoea							
Overall	38/109 (34.9)	NE (1.67, NE)	59/267 (22.1)	NE (13.41, NE)	0.40 (0.26, 0.61)	<0.0001	
Age group 1							0.0274
<35 years	19/50 (38.0)	NE (0.49, NE)	19/123 (15.4)	NE (13.41, NE)	0.24 (0.12, 0.46)	<0.0001	
≥35 years	19/59 (32.2)	NE (1.51, NE)	40/144 (27.8)	NE (5.48, NE)	0.58 (0.33, 1.01)	0.0533	
Age group 2							0.1119
<35 years	19/50 (38.0)	NE (0.49, NE)	19/124 (15.3)	NE (13.41, NE)	0.24 (0.12, 0.46)	<0.0001	
35 - 54 years	7/25 (28.0)	NE (0.66, NE)	24/77 (31.2)	NE (2.98, NE)	0.66 (0.28, 1.56)	0.3472	
55 - 64 years	9/22 (40.9)	2.16 (0.33, NE)	12/33 (36.4)	11.28 (1.54, NE)	0.60 (0.24, 1.48)	0.2597	
≥65 years	3/12 (25.0)	NE (0.23, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.11, 2.16)	0.3387	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6078
Male	22/64 (34.4)	NE (1.67, NE)	35/159 (22.0)	NE (13.41, NE)	0.45 (0.26, 0.78)	0.0037	
Female	16/45 (35.6)	NE (1.21, NE)	24/108 (22.2)	NE (11.28, NE)	0.31 (0.16, 0.61)	0.0004	
Region							0.1250
USA	6/13 (46.2)	1.51 (0.23, NE)	8/30 (26.7)	NE (1.21, NE)	0.43 (0.15, 1.25)	0.1102	
Europe	19/68 (27.9)	NE (2.16, NE)	39/177 (22.0)	NE (11.28, NE)	0.52 (0.29, 0.92)	0.0222	
Rest of the world	13/28 (46.4)	1.21 (0.30, NE)	12/60 (20.0)	NE (3.38, NE)	0.16 (0.06, 0.40)	<0.0001	
Prior salvage therapy							0.1788
Yes	18/63 (28.6)	NE (2.16, NE)	36/161 (22.4)	13.41 (11.28, NE)	0.49 (0.28, 0.88)	0.0158	
No	20/46 (43.5)	1.67 (0.43, NE)	23/106 (21.7)	NE (NE, NE)	0.30 (0.16, 0.57)	0.0001	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0972
0	22/55 (40.0)	NE (1.21, NE)	20/112 (17.9)	NE (NE, NE)	0.25 (0.13, 0.48)	<0.0001	
1	12/34 (35.3)	2.16 (0.66, NE)	23/91 (25.3)	11.28 (3.38, NE)	0.40 (0.19, 0.84)	0.0117	
≥2	4/20 (20.0)	NE (NE, NE)	16/64 (25.0)	NE (3.02, NE)	0.99 (0.33, 2.96)	0.9812	
Prior alloHSCT							0.0418
Yes	20/35 (57.1)	0.66 (0.30, NE)	25/93 (26.9)	13.41 (5.48, NE)	0.21 (0.11, 0.41)	<0.0001	
No	18/74 (24.3)	NE (NE, NE)	34/174 (19.5)	NE (NE, NE)	0.59 (0.33, 1.05)	0.0697	
Race							0.9706
Caucasian	32/90 (35.6)	NE (1.67, NE)	50/226 (22.1)	NE (11.28, NE)	0.40 (0.25, 0.63)	<0.0001	
Others	6/19 (31.6)	NE (0.56, NE)	9/41 (22.0)	NE (3.02, NE)	0.39 (0.13, 1.13)	0.0728	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1156
<50%	12/27 (44.4)	2.16 (0.39, NE)	17/73 (23.3)	13.41 (5.90, NE)	0.11 (0.04, 0.30)	<0.0001	
≥50%	23/77 (29.9)	NE (1.51, NE)	38/168 (22.6)	NE (NE, NE)	0.59 (0.35, 0.99)	0.0462	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Nausea							
Overall	46/109 (42.2)	1.61 (1.02, NE)	51/267 (19.1)	NE (NE, NE)	0.28 (0.19, 0.43)	<0.0001	
Age group 1							0.0036
<35 years	28/50 (56.0)	1.02 (0.30, 1.61)	19/123 (15.4)	NE (NE, NE)	0.14 (0.08, 0.26)	<0.0001	
≥35 years	18/59 (30.5)	NE (1.51, NE)	32/144 (22.2)	NE (NE, NE)	0.53 (0.29, 0.96)	0.0320	
Age group 2							0.0090
<35 years	28/50 (56.0)	1.02 (0.30, 1.61)	20/124 (16.1)	NE (NE, NE)	0.15 (0.08, 0.28)	<0.0001	
35 - 54 years	10/25 (40.0)	NE (0.23, NE)	17/77 (22.1)	NE (NE, NE)	0.26 (0.11, 0.61)	0.0009	
55 - 64 years	5/22 (22.7)	NE (1.51, NE)	11/33 (33.3)	6.13 (5.41, NE)	1.24 (0.41, 3.70)	0.7106	
≥65 years	3/12 (25.0)	NE (0.30, NE)	3/33 (9.1)	NE (NE, NE)	0.39 (0.08, 1.93)	0.2324	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4831
Male	24/64 (37.5)	NE (1.02, NE)	28/159 (17.6)	NE (NE, NE)	0.31 (0.18, 0.54)	<0.0001	
Female	22/45 (48.9)	1.51 (0.23, NE)	23/108 (21.3)	NE (NE, NE)	0.25 (0.13, 0.46)	<0.0001	
Region							0.0167
USA	4/13 (30.8)	NE (0.66, NE)	7/30 (23.3)	5.41 (2.98, NE)	0.50 (0.14, 1.78)	0.2701	
Europe	29/68 (42.6)	1.77 (0.85, NE)	20/177 (11.3)	NE (NE, NE)	0.17 (0.09, 0.30)	<0.0001	
Rest of the world	13/28 (46.4)	1.31 (0.16, NE)	24/60 (40.0)	NE (1.44, NE)	0.49 (0.24, 1.00)	0.0455	
Prior salvage therapy							0.5531
Yes	26/63 (41.3)	1.77 (0.79, NE)	31/161 (19.3)	NE (NE, NE)	0.30 (0.18, 0.52)	<0.0001	
No	20/46 (43.5)	1.51 (0.66, NE)	20/106 (18.9)	NE (NE, NE)	0.25 (0.13, 0.49)	<0.0001	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4245
0	27/55 (49.1)	1.31 (0.56, NE)	22/112 (19.6)	NE (NE, NE)	0.22 (0.12, 0.40)	<0.0001	
1	11/34 (32.4)	NE (0.89, NE)	17/91 (18.7)	NE (NE, NE)	0.44 (0.20, 0.95)	0.0328	
≥2	8/20 (40.0)	1.51 (0.46, NE)	12/64 (18.8)	NE (2.98, NE)	0.27 (0.11, 0.68)	0.0031	
Prior alloHSCT							0.0454
Yes	19/35 (54.3)	1.02 (0.16, NE)	16/93 (17.2)	NE (NE, NE)	0.16 (0.08, 0.33)	<0.0001	
No	27/74 (36.5)	NE (1.31, NE)	35/174 (20.1)	NE (NE, NE)	0.37 (0.22, 0.62)	<0.0001	
Race							0.7483
Caucasian	35/90 (38.9)	1.77 (1.51, NE)	37/226 (16.4)	NE (NE, NE)	0.28 (0.17, 0.45)	<0.0001	
Others	11/19 (57.9)	0.59 (0.10, NE)	14/41 (34.1)	5.41 (1.67, NE)	0.27 (0.12, 0.62)	0.0012	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6831
<50%	11/27 (40.7)	NE (0.56, NE)	12/73 (16.4)	NE (NE, NE)	0.20 (0.08, 0.48)	0.0001	
≥50%	33/77 (42.9)	1.61 (0.89, NE)	32/168 (19.0)	NE (NE, NE)	0.30 (0.18, 0.49)	<0.0001	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Constipation							
Overall	28/109 (25.7)	NE (1.90, NE)	35/267 (13.1)	NE (NE, NE)	0.39 (0.24, 0.65)	0.0002	
Age group 1							0.7823
<35 years	10/50 (20.0)	NE (1.90, NE)	11/123 (8.9)	NE (NE, NE)	0.33 (0.14, 0.80)	0.0098	
≥35 years	18/59 (30.5)	NE (1.28, NE)	24/144 (16.7)	NE (NE, NE)	0.44 (0.23, 0.81)	0.0075	
Age group 2							0.0322
<35 years	10/50 (20.0)	NE (1.90, NE)	11/124 (8.9)	NE (NE, NE)	0.33 (0.14, 0.80)	0.0096	
35 - 54 years	10/25 (40.0)	NE (0.56, NE)	10/77 (13.0)	NE (NE, NE)	0.25 (0.10, 0.61)	0.0010	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	10/33 (30.3)	NE (1.31, NE)	1.94 (0.52, 7.21)	0.3100	
≥65 years	5/12 (41.7)	1.57 (0.16, NE)	4/33 (12.1)	NE (NE, NE)	0.25 (0.06, 0.93)	0.0250	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0895
Male	12/64 (18.8)	NE (NE, NE)	22/159 (13.8)	NE (NE, NE)	0.57 (0.28, 1.17)	0.1205	
Female	16/45 (35.6)	1.90 (1.28, NE)	13/108 (12.0)	NE (NE, NE)	0.27 (0.13, 0.57)	0.0003	
Region							0.7611
USA	3/13 (23.1)	NE (0.59, NE)	5/30 (16.7)	NE (NE, NE)	0.68 (0.16, 2.83)	0.5887	
Europe	17/68 (25.0)	NE (1.57, NE)	21/177 (11.9)	NE (NE, NE)	0.41 (0.21, 0.77)	0.0046	
Rest of the world	8/28 (28.6)	1.90 (1.90, NE)	9/60 (15.0)	NE (NE, NE)	0.28 (0.10, 0.79)	0.0106	
Prior salvage therapy							0.0647
Yes	10/63 (15.9)	NE (1.90, NE)	21/161 (13.0)	NE (NE, NE)	0.62 (0.29, 1.35)	0.2263	
No	18/46 (39.1)	NE (0.98, NE)	14/106 (13.2)	NE (NE, NE)	0.27 (0.13, 0.55)	0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
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Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4159
0	20/55 (36.4)	NE (1.28, NE)	18/112 (16.1)	NE (NE, NE)	0.32 (0.16, 0.61)	0.0003	
1	4/34 (11.8)	NE (1.90, NE)	10/91 (11.0)	NE (NE, NE)	0.87 (0.27, 2.79)	0.8115	
≥2	4/20 (20.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	0.44 (0.12, 1.53)	0.1853	
Prior alloHSCT							0.5870
Yes	10/35 (28.6)	NE (1.28, NE)	12/93 (12.9)	NE (NE, NE)	0.30 (0.13, 0.72)	0.0047	
No	18/74 (24.3)	NE (1.57, NE)	23/174 (13.2)	NE (NE, NE)	0.45 (0.24, 0.84)	0.0104	
Race							0.2413
Caucasian	21/90 (23.3)	NE (1.90, NE)	30/226 (13.3)	NE (NE, NE)	0.46 (0.26, 0.81)	0.0057	
Others	7/19 (36.8)	NE (0.43, NE)	5/41 (12.2)	NE (NE, NE)	0.21 (0.06, 0.67)	0.0040	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0300
<50%	9/27 (33.3)	NE (0.98, NE)	5/73 (6.8)	NE (NE, NE)	0.13 (0.04, 0.44)	0.0001	
≥50%	19/77 (24.7)	NE (1.90, NE)	28/168 (16.7)	NE (NE, NE)	0.54 (0.30, 0.97)	0.0366	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Vomiting							
Overall	26/109 (23.9)	NE (NE, NE)	35/267 (13.1)	NE (NE, NE)	0.23 (0.13, 0.41)	<0.0001	
Age group 1							0.7327
<35 years	13/50 (26.0)	NE (1.70, NE)	19/123 (15.4)	NE (6.62, NE)	0.28 (0.13, 0.59)	0.0005	
≥35 years	13/59 (22.0)	NE (NE, NE)	16/144 (11.1)	NE (NE, NE)	0.19 (0.08, 0.44)	<0.0001	
Age group 2							0.8490
<35 years	13/50 (26.0)	NE (1.70, NE)	20/124 (16.1)	NE (6.62, NE)	0.30 (0.14, 0.64)	0.0010	
35 - 54 years	7/25 (28.0)	NE (NE, NE)	10/77 (13.0)	NE (8.30, NE)	0.13 (0.04, 0.45)	0.0002	
55 - 64 years	4/22 (18.2)	NE (1.44, NE)	3/33 (9.1)	NE (5.64, NE)	0.10 (0.01, 0.93)	0.0156	
≥65 years	2/12 (16.7)	NE (0.30, NE)	2/33 (6.1)	NE (NE, NE)	0.27 (0.04, 1.93)	0.1611	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2798
Male	13/64 (20.3)	NE (NE, NE)	20/159 (12.6)	NE (NE, NE)	0.35 (0.17, 0.72)	0.0033	
Female	13/45 (28.9)	NE (1.44, NE)	15/108 (13.9)	NE (8.30, NE)	0.12 (0.05, 0.31)	<0.0001	
Region							0.8575
USA	5/13 (38.5)	NE (0.13, NE)	4/30 (13.3)	5.64 (2.98, NE)	0.17 (0.04, 0.75)	0.0088	
Europe	13/68 (19.1)	NE (NE, NE)	21/177 (11.9)	NE (NE, NE)	0.28 (0.13, 0.61)	0.0006	
Rest of the world	8/28 (28.6)	1.77 (1.70, NE)	10/60 (16.7)	NE (5.67, NE)	0.21 (0.07, 0.61)	0.0018	
Prior salvage therapy							0.2334
Yes	10/63 (15.9)	NE (NE, NE)	17/161 (10.6)	NE (NE, NE)	0.35 (0.15, 0.80)	0.0097	
No	16/46 (34.8)	NE (1.44, NE)	18/106 (17.0)	NE (6.62, NE)	0.16 (0.07, 0.36)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4185
0	18/55 (32.7)	NE (1.44, NE)	19/112 (17.0)	NE (8.30, NE)	0.17 (0.08, 0.38)	<0.0001	
1	6/34 (17.6)	NE (NE, NE)	10/91 (11.0)	NE (NE, NE)	0.32 (0.11, 0.92)	0.0278	
≥2	2/20 (10.0)	NE (1.11, NE)	6/64 (9.4)	NE (5.67, NE)	0.53 (0.10, 2.79)	0.4448	
Prior alloHSCT							0.3256
Yes	12/35 (34.3)	1.70 (1.44, NE)	17/93 (18.3)	NE (8.30, NE)	0.19 (0.08, 0.45)	<0.0001	
No	14/74 (18.9)	NE (NE, NE)	18/174 (10.3)	NE (NE, NE)	0.25 (0.11, 0.54)	0.0002	
Race							0.4363
Caucasian	19/90 (21.1)	NE (NE, NE)	29/226 (12.8)	NE (NE, NE)	0.25 (0.13, 0.49)	<0.0001	
Others	7/19 (36.8)	1.77 (0.23, NE)	6/41 (14.6)	NE (5.64, NE)	0.19 (0.06, 0.61)	0.0023	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4236
<50%	8/27 (29.6)	NE (1.77, NE)	10/73 (13.7)	NE (NE, NE)	0.13 (0.04, 0.41)	<0.0001	
≥50%	17/77 (22.1)	NE (1.70, NE)	23/168 (13.7)	NE (8.30, NE)	0.30 (0.15, 0.59)	0.0003	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Abdominal pain							
Overall	19/109 (17.4)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.23 (0.12, 0.46)	<0.0001	
Age group 1							0.3539
<35 years	8/50 (16.0)	NE (NE, NE)	10/123 (8.1)	NE (13.41, NE)	0.31 (0.12, 0.81)	0.0120	
≥35 years	11/59 (18.6)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)	0.18 (0.07, 0.49)	0.0002	
Age group 2							0.9195
<35 years	8/50 (16.0)	NE (NE, NE)	10/124 (8.1)	NE (13.41, NE)	0.31 (0.12, 0.81)	0.0120	
35 - 54 years	5/25 (20.0)	NE (1.34, NE)	7/77 (9.1)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0197	
55 - 64 years	3/22 (13.6)	NE (NE, NE)	1/33 (3.0)	NE (5.64, NE)	0.00 (0.00, NE)	0.0328	
≥65 years	3/12 (25.0)	NE (0.36, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0050	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0733
Male	8/64 (12.5)	NE (NE, NE)	12/159 (7.5)	NE (NE, NE)	0.40 (0.16, 1.01)	0.0448	
Female	11/45 (24.4)	NE (1.70, NE)	6/108 (5.6)	NE (NE, NE)	0.11 (0.04, 0.35)	<0.0001	
Region							0.0398
USA	2/13 (15.4)	NE (0.66, NE)	5/30 (16.7)	5.64 (2.98, NE)	0.71 (0.13, 3.89)	0.6929	
Europe	12/68 (17.6)	NE (NE, NE)	5/177 (2.8)	NE (NE, NE)	0.09 (0.03, 0.29)	<0.0001	
Rest of the world	5/28 (17.9)	NE (1.70, NE)	8/60 (13.3)	NE (NE, NE)	0.43 (0.13, 1.43)	0.1566	
Prior salvage therapy							0.1021
Yes	9/63 (14.3)	NE (NE, NE)	13/161 (8.1)	NE (13.41, NE)	0.35 (0.15, 0.86)	0.0169	
No	10/46 (21.7)	NE (NE, NE)	5/106 (4.7)	NE (NE, NE)	0.13 (0.04, 0.43)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1032
0	11/55 (20.0)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)	0.10 (0.03, 0.38)	<0.0001	
1	6/34 (17.6)	NE (NE, NE)	7/91 (7.7)	NE (13.41, NE)	0.25 (0.08, 0.82)	0.0137	
≥2	2/20 (10.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	0.67 (0.13, 3.29)	0.6153	
Prior alloHSCT							0.6711
Yes	5/35 (14.3)	NE (1.70, NE)	7/93 (7.5)	NE (NE, NE)	0.30 (0.09, 1.03)	0.0428	
No	14/74 (18.9)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	0.20 (0.09, 0.47)	<0.0001	
Race							0.3015
Caucasian	13/90 (14.4)	NE (NE, NE)	10/226 (4.4)	NE (NE, NE)	0.20 (0.09, 0.48)	<0.0001	
Others	6/19 (31.6)	NE (0.46, NE)	8/41 (19.5)	NE (2.98, NE)	0.29 (0.09, 0.90)	0.0233	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4597
<50%	5/27 (18.5)	NE (NE, NE)	4/73 (5.5)	NE (13.41, NE)	0.08 (0.01, 0.47)	0.0005	
≥50%	14/77 (18.2)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	0.26 (0.12, 0.59)	0.0005	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Stomatitis							
Overall	14/109 (12.8)	NE (2.79, NE)	18/267 (6.7)	NE (NE, NE)	0.31 (0.15, 0.66)	0.0015	
Age group 1							0.2621
<35 years	8/50 (16.0)	NE (2.07, NE)	7/123 (5.7)	NE (11.80, NE)	0.14 (0.05, 0.46)	0.0002	
≥35 years	6/59 (10.2)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)	0.59 (0.21, 1.64)	0.3043	
Age group 2							0.7049
<35 years	8/50 (16.0)	NE (2.07, NE)	7/124 (5.6)	NE (11.80, NE)	0.14 (0.05, 0.46)	0.0002	
35 - 54 years	4/25 (16.0)	NE (NE, NE)	8/77 (10.4)	NE (NE, NE)	0.50 (0.14, 1.73)	0.2635	
55 - 64 years	1/22 (4.5)	NE (1.28, NE)	2/33 (6.1)	NE (NE, NE)	1.21 (0.11, 13.51)	0.8789	
≥65 years	1/12 (8.3)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.32 (0.02, 5.27)	0.4049	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1825
Male	5/64 (7.8)	NE (2.79, NE)	10/159 (6.3)	NE (NE, NE)	0.47 (0.15, 1.49)	0.1910	
Female	9/45 (20.0)	NE (NE, NE)	8/108 (7.4)	NE (NE, NE)	0.22 (0.08, 0.61)	0.0016	
Region							0.3523
USA	2/13 (15.4)	NE (1.28, NE)	3/30 (10.0)	NE (NE, NE)	0.61 (0.10, 3.63)	0.5796	
Europe	7/68 (10.3)	NE (2.79, NE)	5/177 (2.8)	NE (NE, NE)	0.14 (0.04, 0.50)	0.0006	
Rest of the world	5/28 (17.9)	2.07 (2.07, NE)	10/60 (16.7)	NE (NE, NE)	0.50 (0.15, 1.62)	0.2421	
Prior salvage therapy							0.3962
Yes	6/63 (9.5)	NE (2.07, NE)	10/161 (6.2)	NE (11.80, NE)	0.43 (0.15, 1.25)	0.1124	
No	8/46 (17.4)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	0.23 (0.08, 0.69)	0.0047	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6415
0	12/55 (21.8)	NE (2.79, NE)	9/112 (8.0)	NE (NE, NE)	0.19 (0.07, 0.50)	0.0002	
1	2/34 (5.9)	NE (NE, NE)	4/91 (4.4)	NE (NE, NE)	0.60 (0.11, 3.35)	0.5541	
≥2	0/20 (0.0)	NE (NE, NE)	5/64 (7.8)	11.80 (11.80, NE)	NE (NE, NE)	0.3246	
Prior alloHSCT							0.1392
Yes	6/35 (17.1)	NE (NE, NE)	5/93 (5.4)	NE (NE, NE)	0.13 (0.03, 0.56)	0.0014	
No	8/74 (10.8)	NE (2.79, NE)	13/174 (7.5)	NE (NE, NE)	0.46 (0.18, 1.15)	0.0909	
Race							0.0204
Caucasian	11/90 (12.2)	NE (2.79, NE)	8/226 (3.5)	NE (NE, NE)	0.15 (0.05, 0.42)	<0.0001	
Others	3/19 (15.8)	NE (2.07, NE)	10/41 (24.4)	NE (2.95, NE)	1.03 (0.28, 3.89)	0.9594	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6334
<50%	4/27 (14.8)	NE (2.07, NE)	7/73 (9.6)	NE (NE, NE)	0.31 (0.08, 1.24)	0.0828	
≥50%	10/77 (13.0)	NE (2.79, NE)	8/168 (4.8)	NE (NE, NE)	0.25 (0.09, 0.68)	0.0033	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Abdominal pain upper							
Overall	5/109 (4.6)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.38 (0.12, 1.26)	0.1012	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Dyspepsia							
Overall	7/109 (6.4)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.43 (0.16, 1.16)	0.0854	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: General disorders and administration site conditions							
Overall	83/109 (76.1)	0.33 (0.23, 0.39)	210/267 (78.7)	0.20 (0.13, 0.33)	1.09 (0.85, 1.41)	0.6260	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pyrexia							
Overall	49/109 (45.0)	1.70 (1.08, 2.62)	159/267 (59.6)	0.69 (0.36, 1.34)	1.54 (1.11, 2.12)	0.0125	
Age group 1							0.7741
<35 years	24/50 (48.0)	1.70 (1.05, 2.62)	76/123 (61.8)	0.59 (0.20, 1.54)	1.45 (0.91, 2.29)	0.1399	
≥35 years	25/59 (42.4)	1.51 (0.75, NE)	83/144 (57.6)	0.75 (0.33, 1.84)	1.63 (1.04, 2.55)	0.0399	
Age group 2							0.2164
<35 years	24/50 (48.0)	1.70 (1.05, 2.62)	76/124 (61.3)	0.59 (0.20, 1.54)	1.44 (0.90, 2.28)	0.1468	
35 - 54 years	9/25 (36.0)	NE (0.56, NE)	53/77 (68.8)	0.36 (0.13, 1.25)	2.31 (1.13, 4.70)	0.0191	
55 - 64 years	11/22 (50.0)	1.51 (0.33, NE)	13/33 (39.4)	NE (0.46, NE)	0.79 (0.35, 1.77)	0.5512	
≥65 years	5/12 (41.7)	NE (0.26, NE)	17/33 (51.5)	0.85 (0.07, NE)	1.68 (0.62, 4.58)	0.3664	

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[a] p-values were calculated using the unstratified log-rank test.
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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4475
Male	32/64 (50.0)	1.41 (0.52, 2.62)	97/159 (61.0)	0.56 (0.30, 1.54)	1.37 (0.92, 2.05)	0.1488	
Female	17/45 (37.8)	2.10 (1.51, NE)	62/108 (57.4)	0.75 (0.20, 5.41)	1.83 (1.06, 3.14)	0.0321	
Region							0.6103
USA	3/13 (23.1)	NE (2.10, NE)	10/30 (33.3)	NE (1.25, NE)	1.62 (0.44, 5.89)	0.4909	
Europe	31/68 (45.6)	1.51 (0.98, NE)	111/177 (62.7)	0.39 (0.20, 1.25)	1.71 (1.14, 2.55)	0.0116	
Rest of the world	15/28 (53.6)	1.05 (0.39, NE)	38/60 (63.3)	0.66 (0.13, 1.54)	1.18 (0.65, 2.16)	0.6193	
Prior salvage therapy							0.4301
Yes	27/63 (42.9)	2.30 (0.66, NE)	88/161 (54.7)	0.85 (0.36, 6.23)	1.43 (0.93, 2.20)	0.1176	
No	22/46 (47.8)	1.70 (1.08, NE)	71/106 (67.0)	0.46 (0.07, 1.44)	1.71 (1.05, 2.77)	0.0420	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4669
0	28/55 (50.9)	1.51 (0.75, 2.62)	78/112 (69.6)	0.33 (0.07, 0.89)	1.66 (1.07, 2.56)	0.0330	
1	16/34 (47.1)	1.51 (0.33, NE)	47/91 (51.6)	0.85 (0.26, NE)	1.29 (0.73, 2.27)	0.4265	
≥2	5/20 (25.0)	NE (0.52, NE)	34/64 (53.1)	1.25 (0.36, NE)	2.39 (0.93, 6.13)	0.0613	
Prior alloHSCT							0.8206
Yes	16/35 (45.7)	1.70 (0.52, NE)	61/93 (65.6)	0.66 (0.20, 1.44)	1.51 (0.87, 2.64)	0.1601	
No	33/74 (44.6)	1.51 (1.08, NE)	98/174 (56.3)	0.69 (0.30, 1.67)	1.53 (1.03, 2.27)	0.0507	
Race							0.5998
Caucasian	40/90 (44.4)	1.70 (1.08, NE)	129/226 (57.1)	0.85 (0.43, 1.57)	1.49 (1.04, 2.13)	0.0381	
Others	9/19 (47.4)	1.41 (0.07, NE)	30/41 (73.2)	0.13 (0.07, 0.56)	1.82 (0.86, 3.86)	0.1133	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3072
<50%	11/27 (40.7)	NE (0.39, NE)	50/73 (68.5)	0.36 (0.07, 1.25)	2.10 (1.09, 4.05)	0.0284	
≥50%	36/77 (46.8)	1.70 (0.75, NE)	100/168 (59.5)	0.56 (0.30, 1.34)	1.49 (1.02, 2.19)	0.0510	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Oedema peripheral							
Overall	16/109 (14.7)	NE (NE, NE)	40/267 (15.0)	NE (NE, NE)	0.84 (0.47, 1.51)	0.5607	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Fatigue							
Overall	14/109 (12.8)	NE (NE, NE)	36/267 (13.5)	NE (NE, NE)	0.74 (0.39, 1.41)	0.3586	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Asthenia							
Overall	11/109 (10.1)	NE (NE, NE)	22/267 (8.2)	NE (NE, NE)	0.60 (0.29, 1.26)	0.1734	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Chills							
Overall	12/109 (11.0)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	0.45 (0.21, 0.96)	0.0338	
Age group 1							0.3476
<35 years	4/50 (8.0)	NE (NE, NE)	10/123 (8.1)	NE (14.30, NE)	0.56 (0.16, 1.96)	0.3564	
≥35 years	8/59 (13.6)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)	0.40 (0.15, 1.07)	0.0573	
Age group 2							0.1616
<35 years	4/50 (8.0)	NE (NE, NE)	11/124 (8.9)	NE (14.30, NE)	0.65 (0.19, 2.21)	0.4896	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	7/77 (9.1)	NE (10.03, NE)	0.76 (0.15, 3.87)	0.7405	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2278	
≥65 years	5/12 (41.7)	NE (0.20, NE)	2/33 (6.1)	NE (NE, NE)	0.14 (0.03, 0.72)	0.0058	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2524
Male	9/64 (14.1)	NE (NE, NE)	11/159 (6.9)	NE (14.30, NE)	0.31 (0.12, 0.82)	0.0122	
Female	3/45 (6.7)	NE (NE, NE)	9/108 (8.3)	NE (NE, NE)	0.87 (0.22, 3.44)	0.8363	
Region							0.4804
USA	3/13 (23.1)	NE (0.39, NE)	7/30 (23.3)	NE (NE, NE)	0.97 (0.25, 3.78)	0.9737	
Europe	5/68 (7.4)	NE (NE, NE)	9/177 (5.1)	NE (NE, NE)	0.34 (0.10, 1.18)	0.0739	
Rest of the world	4/28 (14.3)	NE (2.00, NE)	4/60 (6.7)	NE (10.03, NE)	0.26 (0.06, 1.21)	0.0666	
Prior salvage therapy							0.6313
Yes	4/63 (6.3)	NE (NE, NE)	8/161 (5.0)	NE (10.03, NE)	0.40 (0.11, 1.52)	0.1647	
No	8/46 (17.4)	NE (NE, NE)	12/106 (11.3)	NE (NE, NE)	0.47 (0.18, 1.22)	0.1141	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4610
0	9/55 (16.4)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	0.38 (0.14, 0.99)	0.0391	
1	2/34 (5.9)	NE (NE, NE)	7/91 (7.7)	14.30 (10.03, NE)	0.91 (0.18, 4.71)	0.9122	
≥2	1/20 (5.0)	NE (NE, NE)	3/64 (4.7)	NE (5.90, NE)	0.49 (0.04, 5.69)	0.5646	
Prior alloHSCT							0.2617
Yes	2/35 (5.7)	NE (NE, NE)	9/93 (9.7)	NE (14.30, NE)	0.65 (0.12, 3.58)	0.6151	
No	10/74 (13.5)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	0.41 (0.17, 0.98)	0.0374	
Race							0.7820
Caucasian	9/90 (10.0)	NE (NE, NE)	15/226 (6.6)	NE (NE, NE)	0.39 (0.16, 0.97)	0.0351	
Others	3/19 (15.8)	NE (2.00, NE)	5/41 (12.2)	NE (NE, NE)	0.67 (0.16, 2.81)	0.5754	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0343
<50%	8/27 (29.6)	NE (0.95, NE)	7/73 (9.6)	NE (14.30, NE)	0.20 (0.06, 0.62)	0.0019	
≥50%	3/77 (3.9)	NE (NE, NE)	10/168 (6.0)	NE (NE, NE)	1.03 (0.27, 3.95)	0.9640	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pain							
Overall	6/109 (5.5)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.77 (0.29, 2.01)	0.5898	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Mucosal inflammation							
Overall	14/109 (12.8)	NE (NE, NE)	9/267 (3.4)	NE (NE, NE)	0.20 (0.08, 0.47)	<0.0001	
Age group 1							0.5817
<35 years	6/50 (12.0)	NE (NE, NE)	3/123 (2.4)	NE (NE, NE)	0.11 (0.03, 0.50)	0.0008	
≥35 years	8/59 (13.6)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.28 (0.10, 0.82)	0.0137	
Age group 2							0.8907
<35 years	6/50 (12.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	4/25 (16.0)	-	5/77 (6.5)	-	-	-	
55 - 64 years	3/22 (13.6)	-	0/33 (0.0)	-	-	-	
≥65 years	1/12 (8.3)	-	1/33 (3.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9321
Male	5/64 (7.8)	NE (NE, NE)	3/159 (1.9)	NE (NE, NE)	0.16 (0.04, 0.71)	0.0067	
Female	9/45 (20.0)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	0.23 (0.08, 0.68)	0.0038	
Region							0.8789
USA	1/13 (7.7)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	0.41 (0.03, 6.61)	0.5180	
Europe	13/68 (19.1)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.17 (0.07, 0.44)	<0.0001	
Rest of the world	0/28 (0.0)	NE (NE, NE)	0/60 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
Prior salvage therapy							0.6866
Yes	10/63 (15.9)	NE (NE, NE)	6/161 (3.7)	NE (NE, NE)	0.16 (0.06, 0.48)	0.0002	
No	4/46 (8.7)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.29 (0.07, 1.32)	0.0899	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9722
0	8/55 (14.5)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)	0.22 (0.07, 0.73)	0.0068	
1	4/34 (11.8)	NE (NE, NE)	3/91 (3.3)	NE (NE, NE)	0.12 (0.02, 0.75)	0.0080	
≥2	2/20 (10.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.28 (0.04, 2.00)	0.1756	
Prior alloHSCT							0.3571
Yes	5/35 (14.3)	NE (NE, NE)	2/93 (2.2)	NE (NE, NE)	0.14 (0.03, 0.72)	0.0059	
No	9/74 (12.2)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.23 (0.08, 0.66)	0.0031	
Race							0.9922
Caucasian	13/90 (14.4)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.21 (0.09, 0.51)	0.0001	
Others	1/19 (5.3)	NE (NE, NE)	0/41 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1360	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0130
<50%	8/27 (29.6)	NE (1.70, NE)	1/73 (1.4)	NE (NE, NE)	0.04 (0.00, 0.30)	<0.0001	
≥50%	5/77 (6.5)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.57 (0.18, 1.81)	0.3372	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Hepatobiliary disorders							
Overall	14/109 (12.8)	NE (NE, NE)	30/267 (11.2)	NE (NE, NE)	0.72 (0.38, 1.38)	0.3231	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Immune system disorders							
Overall	4/109 (3.7)	NE (NE, NE)	66/267 (24.7)	14.79 (7.74, NE)	5.50 (1.99, 15.20)	0.0002	
Age group 1							0.9834
<35 years	0/50 (0.0)	NE (NE, NE)	31/123 (25.2)	NE (7.02, NE)	NE (NE, NE)	0.0006	
≥35 years	4/59 (6.8)	NE (NE, NE)	35/144 (24.3)	14.79 (7.74, NE)	2.56 (0.89, 7.36)	0.0725	
Age group 2							0.6720
<35 years	0/50 (0.0)	NE (NE, NE)	31/124 (25.0)	NE (7.02, NE)	NE (NE, NE)	0.0007	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	21/77 (27.3)	8.30 (4.59, NE)	4.03 (0.53, 30.80)	0.1468	
55 - 64 years	3/22 (13.6)	NE (NE, NE)	6/33 (18.2)	NE (5.80, NE)	1.15 (0.27, 4.80)	0.8646	
≥65 years	0/12 (0.0)	NE (NE, NE)	8/33 (24.2)	7.74 (7.74, NE)	NE (NE, NE)	0.1201	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7930
Male	2/64 (3.1)	NE (NE, NE)	37/159 (23.3)	NE (7.02, NE)	6.38 (1.53, 26.62)	0.0035	
Female	2/45 (4.4)	NE (NE, NE)	29/108 (26.9)	14.79 (5.80, NE)	4.47 (1.05, 19.05)	0.0269	
Region							0.9998
USA	0/13 (0.0)	NE (NE, NE)	8/30 (26.7)	NE (3.02, NE)	NE (NE, NE)	0.0533	
Europe	4/68 (5.9)	NE (NE, NE)	38/177 (21.5)	14.79 (7.74, NE)	2.56 (0.90, 7.30)	0.0683	
Rest of the world	0/28 (0.0)	NE (NE, NE)	20/60 (33.3)	NE (2.52, NE)	NE (NE, NE)	0.0024	
Prior salvage therapy							0.2080
Yes	1/63 (1.6)	NE (NE, NE)	39/161 (24.2)	NE (7.02, NE)	14.00 (1.92, 102.23)	0.0006	
No	3/46 (6.5)	NE (NE, NE)	27/106 (25.5)	14.79 (7.74, NE)	2.67 (0.79, 9.00)	0.1014	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9344
0	3/55 (5.5)	NE (NE, NE)	29/112 (25.9)	14.79 (7.02, NE)	3.28 (0.98, 11.00)	0.0420	
1	0/34 (0.0)	NE (NE, NE)	28/91 (30.8)	5.80 (4.59, NE)	NE (NE, NE)	0.0017	
≥2	1/20 (5.0)	NE (1.15, NE)	9/64 (14.1)	NE (NE, NE)	2.40 (0.30, 19.12)	0.3945	
Prior alloHSCT							0.6482
Yes	2/35 (5.7)	NE (NE, NE)	29/93 (31.2)	8.30 (4.59, NE)	3.56 (0.83, 15.21)	0.0683	
No	2/74 (2.7)	NE (NE, NE)	37/174 (21.3)	NE (7.74, NE)	7.32 (1.76, 30.51)	0.0013	
Race							0.9857
Caucasian	4/90 (4.4)	NE (NE, NE)	58/226 (25.7)	14.79 (7.02, NE)	4.83 (1.74, 13.40)	0.0008	
Others	0/19 (0.0)	NE (NE, NE)	8/41 (19.5)	NE (3.02, NE)	NE (NE, NE)	0.1156	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3982
<50%	2/27 (7.4)	NE (NE, NE)	22/73 (30.1)	7.02 (5.80, NE)	2.73 (0.62, 11.91)	0.1676	
≥50%	2/77 (2.6)	NE (NE, NE)	38/168 (22.6)	NE (8.30, NE)	7.90 (1.90, 32.92)	0.0008	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Cytokine release syndrome							
Overall	0/109 (0.0)	NE (NE, NE)	38/267 (14.2)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Age group 1							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/123 (14.6)	NE (NE, NE)	NE (NE, NE)	0.0057	
≥35 years	0/59 (0.0)	NE (NE, NE)	20/144 (13.9)	NE (NE, NE)	NE (NE, NE)	0.0033	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	18/124 (14.5)	NE (NE, NE)	NE (NE, NE)	0.0059	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	10/77 (13.0)	NE (NE, NE)	NE (NE, NE)	0.0726	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	5/33 (15.2)	NE (NE, NE)	NE (NE, NE)	0.0595	
≥65 years	0/12 (0.0)	NE (NE, NE)	5/33 (15.2)	NE (NE, NE)	NE (NE, NE)	0.1600	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9999
Male	0/64 (0.0)	NE (NE, NE)	20/159 (12.6)	NE (NE, NE)	NE (NE, NE)	0.0034	
Female	0/45 (0.0)	NE (NE, NE)	18/108 (16.7)	NE (NE, NE)	NE (NE, NE)	0.0056	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (NE, NE)	NE (NE, NE)	0.0629	
Europe	0/68 (0.0)	NE (NE, NE)	15/177 (8.5)	NE (NE, NE)	NE (NE, NE)	0.0155	
Rest of the world	0/28 (0.0)	NE (NE, NE)	16/60 (26.7)	NE (NE, NE)	NE (NE, NE)	0.0040	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	NE (NE, NE)	27/161 (16.8)	NE (NE, NE)	NE (NE, NE)	0.0008	
No	0/46 (0.0)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	NE (NE, NE)	0.0273	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)	NE (NE, NE)	0.0141	
1	0/34 (0.0)	NE (NE, NE)	19/91 (20.9)	NE (NE, NE)	NE (NE, NE)	0.0046	
≥2	0/20 (0.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	NE (NE, NE)	0.1500	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	NE (NE, NE)	12/93 (12.9)	NE (NE, NE)	NE (NE, NE)	0.0319	
No	0/74 (0.0)	NE (NE, NE)	26/174 (14.9)	NE (NE, NE)	NE (NE, NE)	0.0006	
Race							0.9998
Caucasian	0/90 (0.0)	NE (NE, NE)	35/226 (15.5)	NE (NE, NE)	NE (NE, NE)	0.0001	
Others	0/19 (0.0)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	NE (NE, NE)	0.2831	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	NE (NE, NE)	11/73 (15.1)	NE (NE, NE)	NE (NE, NE)	0.0353	
≥50%	0/77 (0.0)	NE (NE, NE)	25/168 (14.9)	NE (NE, NE)	NE (NE, NE)	0.0005	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypogammaglobulinaemia							
Overall	1/109 (0.9)	NE (NE, NE)	19/267 (7.1)	NE (14.79, NE)	2.39 (0.30, 18.91)	0.3931	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Infections and infestations							
Overall	79/109 (72.5)	0.49 (0.39, 0.62)	172/267 (64.4)	1.31 (1.05, 1.90)	0.50 (0.38, 0.66)	<0.0001	
Age group 1							0.1429
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/123 (61.0)	1.28 (1.02, 2.72)	0.62 (0.40, 0.95)	0.0282	
≥35 years	48/59 (81.4)	0.43 (0.33, 0.56)	97/144 (67.4)	1.31 (0.75, 1.90)	0.42 (0.29, 0.61)	<0.0001	
Age group 2							0.2637
<35 years	31/50 (62.0)	0.56 (0.43, 1.61)	75/124 (60.5)	1.28 (1.02, 2.72)	0.62 (0.40, 0.95)	0.0277	
35 - 54 years	20/25 (80.0)	0.43 (0.30, 0.62)	54/77 (70.1)	1.08 (0.69, 2.49)	0.37 (0.21, 0.65)	0.0003	
55 - 64 years	17/22 (77.3)	0.41 (0.30, 0.79)	25/33 (75.8)	1.15 (0.46, 1.84)	0.55 (0.28, 1.07)	0.0714	
≥65 years	11/12 (91.7)	0.41 (0.10, 1.54)	18/33 (54.5)	3.08 (0.56, 5.54)	0.33 (0.15, 0.74)	0.0047	

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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7424
Male	46/64 (71.9)	0.49 (0.39, 0.72)	101/159 (63.5)	1.28 (0.79, 1.97)	0.51 (0.36, 0.74)	0.0002	
Female	33/45 (73.3)	0.49 (0.33, 0.69)	71/108 (65.7)	1.48 (0.95, 2.52)	0.48 (0.31, 0.74)	0.0008	
Region							0.8320
USA	8/13 (61.5)	1.21 (0.16, NE)	17/30 (56.7)	1.31 (0.72, NE)	0.64 (0.27, 1.52)	0.3130	
Europe	49/68 (72.1)	0.49 (0.36, 0.72)	112/177 (63.3)	1.80 (1.11, 2.69)	0.47 (0.33, 0.67)	<0.0001	
Rest of the world	22/28 (78.6)	0.46 (0.36, 0.49)	43/60 (71.7)	0.79 (0.56, 1.48)	0.48 (0.27, 0.84)	0.0090	
Prior salvage therapy							0.0372
Yes	42/63 (66.7)	0.49 (0.39, 1.11)	109/161 (67.7)	0.95 (0.69, 1.41)	0.66 (0.46, 0.95)	0.0261	
No	37/46 (80.4)	0.49 (0.33, 0.62)	63/106 (59.4)	2.75 (1.31, 3.31)	0.32 (0.21, 0.50)	<0.0001	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.0662
0	40/55 (72.7)	0.49 (0.36, 0.72)	70/112 (62.5)	2.75 (1.28, 3.64)	0.38 (0.25, 0.58)	<0.0001	
1	27/34 (79.4)	0.46 (0.30, 0.66)	57/91 (62.6)	1.21 (0.69, 1.97)	0.42 (0.26, 0.69)	0.0003	
≥2	12/20 (60.0)	0.49 (0.33, NE)	45/64 (70.3)	0.72 (0.46, 1.28)	0.95 (0.50, 1.82)	0.8630	
Prior alloHSCT							0.5862
Yes	24/35 (68.6)	0.49 (0.36, 1.11)	66/93 (71.0)	1.31 (0.92, 2.00)	0.48 (0.29, 0.81)	0.0049	
No	55/74 (74.3)	0.49 (0.39, 0.62)	106/174 (60.9)	1.28 (0.75, 2.69)	0.49 (0.35, 0.68)	<0.0001	
Race							0.2421
Caucasian	66/90 (73.3)	0.49 (0.39, 0.62)	141/226 (62.4)	1.61 (1.15, 2.52)	0.46 (0.34, 0.63)	<0.0001	
Others	13/19 (68.4)	0.43 (0.20, 1.11)	31/41 (75.6)	0.72 (0.36, 1.02)	0.70 (0.36, 1.38)	0.2942	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0860
<50%	22/27 (81.5)	0.49 (0.33, 1.51)	45/73 (61.6)	3.21 (2.52, 4.10)	0.23 (0.13, 0.43)	<0.0001	
≥50%	54/77 (70.1)	0.49 (0.39, 0.59)	109/168 (64.9)	1.02 (0.69, 1.31)	0.60 (0.42, 0.84)	0.0026	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Upper respiratory tract infection							
Overall	1/109 (0.9)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	3.24 (0.42, 25.18)	0.2358	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Device related infection							
Overall	6/109 (5.5)	NE (NE, NE)	18/267 (6.7)	NE (16.66, NE)	0.60 (0.22, 1.64)	0.3121	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pneumonia							
Overall	16/109 (14.7)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.22 (0.10, 0.48)	<0.0001	
Age group 1							0.0517
<35 years	9/50 (18.0)	NE (NE, NE)	4/123 (3.3)	NE (NE, NE)	0.11 (0.03, 0.42)	<0.0001	
≥35 years	7/59 (11.9)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)	0.37 (0.13, 1.03)	0.0486	
Age group 2							0.4246
<35 years	9/50 (18.0)	NE (NE, NE)	4/124 (3.2)	NE (NE, NE)	0.11 (0.03, 0.42)	<0.0001	
35 - 54 years	4/25 (16.0)	NE (1.48, NE)	7/77 (9.1)	NE (NE, NE)	0.28 (0.07, 1.09)	0.0519	
55 - 64 years	3/22 (13.6)	NE (1.57, NE)	3/33 (9.1)	NE (NE, NE)	0.47 (0.09, 2.50)	0.3654	
≥65 years	0/12 (0.0)	NE (NE, NE)	2/33 (6.1)	NE (5.54, NE)	NE (NE, NE)	0.7893	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8824
Male	9/64 (14.1)	NE (NE, NE)	9/159 (5.7)	NE (NE, NE)	0.21 (0.07, 0.61)	0.0016	
Female	7/45 (15.6)	NE (NE, NE)	7/108 (6.5)	NE (NE, NE)	0.23 (0.07, 0.74)	0.0078	
Region							0.9991
USA	0/13 (0.0)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	NE (NE, NE)	0.5032	
Europe	12/68 (17.6)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	0.16 (0.06, 0.42)	<0.0001	
Rest of the world	4/28 (14.3)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	0.32 (0.07, 1.43)	0.1163	
Prior salvage therapy							0.4039
Yes	12/63 (19.0)	NE (NE, NE)	10/161 (6.2)	NE (NE, NE)	0.24 (0.10, 0.58)	0.0006	
No	4/46 (8.7)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	0.15 (0.03, 0.76)	0.0106	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4461
0	7/55 (12.7)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	0.27 (0.08, 0.84)	0.0166	
1	7/34 (20.6)	NE (1.57, NE)	4/91 (4.4)	NE (NE, NE)	0.11 (0.03, 0.45)	0.0002	
≥2	2/20 (10.0)	NE (NE, NE)	4/64 (6.3)	NE (NE, NE)	0.44 (0.07, 2.64)	0.3585	
Prior alloHSCT							0.3712
Yes	5/35 (14.3)	NE (NE, NE)	9/93 (9.7)	NE (NE, NE)	0.33 (0.10, 1.11)	0.0605	
No	11/74 (14.9)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.17 (0.06, 0.47)	0.0001	
Race							0.3532
Caucasian	14/90 (15.6)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	0.17 (0.07, 0.42)	<0.0001	
Others	2/19 (10.5)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.68 (0.12, 3.90)	0.6572	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2546
<50%	5/27 (18.5)	NE (1.48, NE)	3/73 (4.1)	NE (NE, NE)	0.11 (0.02, 0.57)	0.0017	
≥50%	11/77 (14.3)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.27 (0.11, 0.68)	0.0030	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Oral herpes							
Overall	9/109 (8.3)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.47 (0.20, 1.11)	0.0772	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Urinary tract infection							
Overall	2/109 (1.8)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	1.56 (0.34, 7.24)	0.5694	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Viral upper respiratory tract infection							
Overall	0/109 (0.0)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	NE (NE, NE)	0.1373	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sepsis							
Overall	8/109 (7.3)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.44 (0.18, 1.08)	0.0647	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
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Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Injury, poisoning and procedural complications							
Overall	11/109 (10.1)	NE (NE, NE)	40/267 (15.0)	NE (NE, NE)	0.99 (0.50, 1.98)	0.9876	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Investigations							
Overall	40/109 (36.7)	NE (1.41, NE)	112/267 (41.9)	5.31 (2.85, NE)	1.02 (0.71, 1.46)	0.9348	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Alanine aminotransferase increased							
Overall	11/109 (10.1)	NE (NE, NE)	24/267 (9.0)	NE (NE, NE)	0.82 (0.40, 1.69)	0.5936	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Platelet count decreased							
Overall	13/109 (11.9)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.42 (0.20, 0.89)	0.0190	
Age group 1							0.6587
<35 years	6/50 (12.0)	NE (NE, NE)	7/123 (5.7)	NE (NE, NE)	0.29 (0.09, 0.95)	0.0294	
≥35 years	7/59 (11.9)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)	0.54 (0.20, 1.43)	0.2057	
Age group 2							0.7075
<35 years	6/50 (12.0)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)	0.29 (0.09, 0.94)	0.0289	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	6/77 (7.8)	NE (NE, NE)	0.69 (0.13, 3.66)	0.6585	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	2/33 (6.1)	NE (NE, NE)	0.32 (0.06, 1.72)	0.1598	
≥65 years	1/12 (8.3)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	1.13 (0.12, 10.89)	0.9142	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2729
Male	7/64 (10.9)	NE (NE, NE)	6/159 (3.8)	NE (NE, NE)	0.16 (0.04, 0.59)	0.0019	
Female	6/45 (13.3)	NE (NE, NE)	12/108 (11.1)	NE (NE, NE)	0.77 (0.28, 2.07)	0.5991	
Region							0.7854
USA	4/13 (30.8)	NE (0.30, NE)	3/30 (10.0)	NE (NE, NE)	0.31 (0.07, 1.38)	0.0998	
Europe	4/68 (5.9)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.54 (0.15, 1.94)	0.3389	
Rest of the world	5/28 (17.9)	NE (NE, NE)	7/60 (11.7)	NE (NE, NE)	0.43 (0.13, 1.44)	0.1588	
Prior salvage therapy							0.1034
Yes	5/63 (7.9)	NE (NE, NE)	12/161 (7.5)	NE (10.82, NE)	0.63 (0.21, 1.90)	0.4105	
No	8/46 (17.4)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	0.29 (0.10, 0.85)	0.0164	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9667
0	7/55 (12.7)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)	0.40 (0.13, 1.17)	0.0812	
1	4/34 (11.8)	NE (NE, NE)	6/91 (6.6)	NE (10.82, NE)	0.39 (0.10, 1.48)	0.1518	
≥2	2/20 (10.0)	NE (1.25, NE)	4/64 (6.3)	NE (NE, NE)	0.56 (0.10, 3.08)	0.4990	
Prior alloHSCT							0.2383
Yes	5/35 (14.3)	NE (1.25, NE)	5/93 (5.4)	NE (NE, NE)	0.21 (0.05, 0.83)	0.0153	
No	8/74 (10.8)	NE (NE, NE)	13/174 (7.5)	NE (NE, NE)	0.57 (0.23, 1.40)	0.2139	
Race							0.2934
Caucasian	11/90 (12.2)	NE (NE, NE)	13/226 (5.8)	NE (NE, NE)	0.37 (0.16, 0.85)	0.0148	
Others	2/19 (10.5)	NE (NE, NE)	5/41 (12.2)	NE (4.59, NE)	0.73 (0.13, 4.09)	0.7196	

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[a] p-values were calculated using the unstratified log-rank test.
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The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.6201
<50%	3/27 (11.1)	NE (NE, NE)	3/73 (4.1)	NE (10.82, NE)	0.16 (0.02, 1.12)	0.0387	
≥50%	10/77 (13.0)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.38 (0.15, 0.93)	0.0272	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Aspartate aminotransferase increased							
Overall	10/109 (9.2)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.57 (0.25, 1.27)	0.1631	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: White blood cell count decreased							
Overall	6/109 (5.5)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.79 (0.30, 2.09)	0.6282	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Gamma-glutamyltransferase increased							
Overall	4/109 (3.7)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	1.17 (0.38, 3.64)	0.7822	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Blood bilirubin increased							
Overall	9/109 (8.3)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.42 (0.17, 1.03)	0.0515	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutrophil count decreased							
Overall	11/109 (10.1)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.27 (0.11, 0.67)	0.0025	
Age group 1							0.8223
<35 years	6/50 (12.0)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	0.27 (0.08, 0.89)	0.0209	
≥35 years	5/59 (8.5)	NE (NE, NE)	5/144 (3.5)	NE (NE, NE)	0.28 (0.07, 1.07)	0.0469	
Age group 2							0.9989
<35 years	6/50 (12.0)	NE (NE, NE)	5/124 (4.0)	NE (NE, NE)	0.27 (0.08, 0.88)	0.0205	
35 - 54 years	3/25 (12.0)	NE (NE, NE)	4/77 (5.2)	NE (NE, NE)	0.24 (0.05, 1.28)	0.0721	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0797	
≥65 years	0/12 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.5403	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3164
Male	7/64 (10.9)	NE (NE, NE)	4/159 (2.5)	NE (NE, NE)	0.13 (0.03, 0.52)	0.0007	
Female	4/45 (8.9)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	0.58 (0.16, 2.08)	0.3949	
Region							0.8369
USA	4/13 (30.8)	NE (0.26, NE)	2/30 (6.7)	NE (NE, NE)	0.21 (0.04, 1.16)	0.0484	
Europe	2/68 (2.9)	NE (NE, NE)	2/177 (1.1)	NE (NE, NE)	0.29 (0.04, 2.10)	0.1935	
Rest of the world	5/28 (17.9)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.29 (0.08, 1.12)	0.0585	
Prior salvage therapy							0.0497
Yes	5/63 (7.9)	NE (NE, NE)	9/161 (5.6)	NE (NE, NE)	0.57 (0.19, 1.75)	0.3204	
No	6/46 (13.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	0.05 (0.01, 0.43)	0.0002	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4261
0	7/55 (12.7)	NE (NE, NE)	3/112 (2.7)	NE (NE, NE)	0.11 (0.02, 0.52)	0.0008	
1	3/34 (8.8)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)	0.54 (0.13, 2.31)	0.4013	
≥2	1/20 (5.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.63 (0.06, 6.94)	0.6980	
Prior alloHSCT							0.5273
Yes	4/35 (11.4)	NE (NE, NE)	3/93 (3.2)	NE (NE, NE)	0.21 (0.05, 1.02)	0.0340	
No	7/74 (9.5)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.31 (0.10, 0.94)	0.0294	
Race							0.2739
Caucasian	8/90 (8.9)	NE (NE, NE)	5/226 (2.2)	NE (NE, NE)	0.20 (0.06, 0.62)	0.0022	
Others	3/19 (15.8)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	0.50 (0.11, 2.29)	0.3609	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9918
<50%	3/27 (11.1)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0040	
≥50%	8/77 (10.4)	NE (NE, NE)	9/168 (5.4)	NE (NE, NE)	0.40 (0.15, 1.07)	0.0593	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Transaminases increased							
Overall	0/109 (0.0)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	NE (NE, NE)	0.0539	
Age group 1							>0.9999
<35 years	0/50 (0.0)	-	5/123 (4.1)	-	-	-	
≥35 years	0/59 (0.0)	-	5/144 (3.5)	-	-	-	
Age group 2							>0.9999
<35 years	0/50 (0.0)	-	5/124 (4.0)	-	-	-	
35 - 54 years	0/25 (0.0)	-	5/77 (6.5)	-	-	-	
55 - 64 years	0/22 (0.0)	-	0/33 (0.0)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9998
Male	0/64 (0.0)	-	8/159 (5.0)	-	-	-	
Female	0/45 (0.0)	-	2/108 (1.9)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	0/68 (0.0)	-	5/177 (2.8)	-	-	-	
Rest of the world	0/28 (0.0)	-	4/60 (6.7)	-	-	-	
Prior salvage therapy							0.9999
Yes	0/63 (0.0)	-	4/161 (2.5)	-	-	-	
No	0/46 (0.0)	-	6/106 (5.7)	-	-	-	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	-	7/112 (6.3)	-	-	-	
1	0/34 (0.0)	-	0/91 (0.0)	-	-	-	
≥2	0/20 (0.0)	-	3/64 (4.7)	-	-	-	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	-	5/93 (5.4)	-	-	-	
No	0/74 (0.0)	-	5/174 (2.9)	-	-	-	
Race							>0.9999
Caucasian	0/90 (0.0)	-	9/226 (4.0)	-	-	-	
Others	0/19 (0.0)	-	1/41 (2.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							>0.9999
<50%	0/27 (0.0)	-	3/73 (4.1)	-	-	-	
≥50%	0/77 (0.0)	-	6/168 (3.6)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Metabolism and nutrition disorders							
Overall	57/109 (52.3)	0.82 (0.49, 2.82)	116/267 (43.4)	8.00 (1.90, NE)	0.67 (0.48, 0.92)	0.0134	
Age group 1							0.9124
<35 years	25/50 (50.0)	1.25 (0.43, NE)	53/123 (43.1)	6.49 (1.84, NE)	0.62 (0.38, 1.00)	0.0513	
≥35 years	32/59 (54.2)	0.79 (0.36, NE)	63/144 (43.8)	8.00 (1.41, NE)	0.72 (0.47, 1.10)	0.1195	
Age group 2							0.8817
<35 years	25/50 (50.0)	1.25 (0.43, NE)	53/124 (42.7)	6.49 (1.84, NE)	0.61 (0.38, 1.00)	0.0492	
35 - 54 years	14/25 (56.0)	0.82 (0.39, NE)	34/77 (44.2)	8.00 (1.41, NE)	0.66 (0.35, 1.25)	0.1860	
55 - 64 years	11/22 (50.0)	0.56 (0.07, NE)	17/33 (51.5)	1.41 (0.20, NE)	0.96 (0.45, 2.05)	0.9436	
≥65 years	7/12 (58.3)	0.48 (0.07, NE)	12/33 (36.4)	NE (0.43, NE)	0.60 (0.24, 1.53)	0.2676	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.4799
Male	33/64 (51.6)	0.66 (0.46, NE)	73/159 (45.9)	3.87 (1.41, 10.16)	0.70 (0.46, 1.06)	0.0897	
Female	24/45 (53.3)	0.82 (0.36, NE)	43/108 (39.8)	12.00 (1.84, NE)	0.62 (0.38, 1.04)	0.0651	
Region							0.6724
USA	8/13 (61.5)	0.33 (0.07, NE)	19/30 (63.3)	0.43 (0.10, NE)	0.98 (0.43, 2.25)	0.9773	
Europe	32/68 (47.1)	1.74 (0.49, NE)	64/177 (36.2)	NE (6.49, NE)	0.63 (0.41, 0.97)	0.0347	
Rest of the world	17/28 (60.7)	0.56 (0.26, NE)	33/60 (55.0)	1.84 (0.66, 12.00)	0.64 (0.35, 1.18)	0.1479	
Prior salvage therapy							0.2695
Yes	31/63 (49.2)	1.25 (0.46, NE)	74/161 (46.0)	3.87 (1.41, NE)	0.75 (0.49, 1.14)	0.1750	
No	26/46 (56.5)	0.66 (0.30, NE)	42/106 (39.6)	NE (1.84, NE)	0.57 (0.35, 0.94)	0.0245	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3057
0	32/55 (58.2)	0.59 (0.36, 2.33)	44/112 (39.3)	8.00 (2.56, NE)	0.52 (0.33, 0.83)	0.0055	
1	16/34 (47.1)	2.82 (0.26, NE)	42/91 (46.2)	10.16 (0.95, NE)	0.82 (0.46, 1.47)	0.5001	
≥2	9/20 (45.0)	1.25 (0.26, NE)	30/64 (46.9)	2.92 (0.82, NE)	0.84 (0.39, 1.80)	0.6421	
Prior alloHSCT							0.8292
Yes	17/35 (48.6)	1.25 (0.49, NE)	40/93 (43.0)	3.87 (1.41, NE)	0.63 (0.35, 1.13)	0.1167	
No	40/74 (54.1)	0.62 (0.36, NE)	76/174 (43.7)	8.00 (1.64, NE)	0.68 (0.46, 1.00)	0.0475	
Race							0.4976
Caucasian	48/90 (53.3)	0.66 (0.46, NE)	97/226 (42.9)	8.00 (1.90, NE)	0.64 (0.45, 0.92)	0.0136	
Others	9/19 (47.4)	2.33 (0.33, NE)	19/41 (46.3)	1.87 (0.66, NE)	0.81 (0.36, 1.82)	0.6023	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1232
<50%	15/27 (55.6)	1.74 (0.26, NE)	24/73 (32.9)	10.16 (8.00, NE)	0.43 (0.22, 0.84)	0.0098	
≥50%	39/77 (50.6)	0.82 (0.46, NE)	80/168 (47.6)	2.56 (1.21, NE)	0.80 (0.54, 1.18)	0.2698	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypokalaemia							
Overall	30/109 (27.5)	NE (NE, NE)	46/267 (17.2)	NE (NE, NE)	0.48 (0.30, 0.77)	0.0019	
Age group 1							0.8277
<35 years	15/50 (30.0)	NE (1.48, NE)	23/123 (18.7)	NE (12.26, NE)	0.49 (0.25, 0.95)	0.0321	
≥35 years	15/59 (25.4)	NE (1.74, NE)	23/144 (16.0)	NE (NE, NE)	0.46 (0.23, 0.91)	0.0218	
Age group 2							0.9596
<35 years	15/50 (30.0)	NE (1.48, NE)	23/124 (18.5)	NE (12.26, NE)	0.49 (0.25, 0.95)	0.0315	
35 - 54 years	7/25 (28.0)	1.74 (0.79, NE)	13/77 (16.9)	NE (7.28, NE)	0.35 (0.13, 0.94)	0.0297	
55 - 64 years	5/22 (22.7)	NE (1.11, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.13, 1.79)	0.2640	
≥65 years	3/12 (25.0)	NE (0.46, NE)	6/33 (18.2)	NE (4.79, NE)	0.64 (0.15, 2.69)	0.5392	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1400
Male	13/64 (20.3)	NE (NE, NE)	27/159 (17.0)	NE (12.26, NE)	0.67 (0.34, 1.32)	0.2444	
Female	17/45 (37.8)	NE (0.79, NE)	19/108 (17.6)	NE (NE, NE)	0.34 (0.17, 0.68)	0.0014	
Region							0.3367
USA	6/13 (46.2)	1.48 (0.26, NE)	8/30 (26.7)	NE (1.48, NE)	0.48 (0.17, 1.42)	0.1726	
Europe	13/68 (19.1)	NE (NE, NE)	27/177 (15.3)	NE (12.26, NE)	0.65 (0.33, 1.28)	0.2075	
Rest of the world	11/28 (39.3)	NE (0.52, NE)	11/60 (18.3)	NE (NE, NE)	0.28 (0.11, 0.67)	0.0023	
Prior salvage therapy							0.6450
Yes	16/63 (25.4)	NE (NE, NE)	28/161 (17.4)	NE (12.26, NE)	0.53 (0.28, 1.00)	0.0479	
No	14/46 (30.4)	NE (1.74, NE)	18/106 (17.0)	NE (NE, NE)	0.41 (0.20, 0.85)	0.0137	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6193
0	15/55 (27.3)	NE (1.74, NE)	16/112 (14.3)	NE (NE, NE)	0.41 (0.20, 0.84)	0.0124	
1	9/34 (26.5)	NE (NE, NE)	20/91 (22.0)	12.26 (5.51, NE)	0.62 (0.27, 1.40)	0.2401	
≥2	6/20 (30.0)	1.48 (0.59, NE)	10/64 (15.6)	NE (NE, NE)	0.39 (0.14, 1.08)	0.0618	
Prior alloHSCT							0.3005
Yes	12/35 (34.3)	NE (1.11, NE)	17/93 (18.3)	NE (12.26, NE)	0.26 (0.12, 0.58)	0.0005	
No	18/74 (24.3)	NE (NE, NE)	29/174 (16.7)	NE (NE, NE)	0.63 (0.35, 1.15)	0.1277	
Race							0.8925
Caucasian	26/90 (28.9)	NE (1.74, NE)	40/226 (17.7)	NE (NE, NE)	0.48 (0.29, 0.79)	0.0034	
Others	4/19 (21.1)	NE (0.46, NE)	6/41 (14.6)	NE (NE, NE)	0.48 (0.13, 1.81)	0.2680	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0130
<50%	10/27 (37.0)	NE (0.52, NE)	7/73 (9.6)	NE (12.26, NE)	0.13 (0.04, 0.41)	<0.0001	
≥50%	19/77 (24.7)	NE (NE, NE)	35/168 (20.8)	NE (NE, NE)	0.72 (0.41, 1.27)	0.2481	

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[a] p-values were calculated using the unstratified log-rank test.
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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypomagnesaemia							
Overall	18/109 (16.5)	NE (NE, NE)	29/267 (10.9)	NE (NE, NE)	0.55 (0.30, 0.99)	0.0440	
Age group 1							0.9790
<35 years	9/50 (18.0)	NE (1.97, NE)	15/123 (12.2)	NE (NE, NE)	0.54 (0.23, 1.25)	0.1443	
≥35 years	9/59 (15.3)	NE (NE, NE)	14/144 (9.7)	NE (NE, NE)	0.55 (0.23, 1.30)	0.1669	
Age group 2							0.7897
<35 years	9/50 (18.0)	NE (1.97, NE)	15/124 (12.1)	NE (NE, NE)	0.54 (0.23, 1.25)	0.1422	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	8/77 (10.4)	NE (NE, NE)	1.00 (0.21, 4.88)	0.9940	
55 - 64 years	5/22 (22.7)	NE (1.15, NE)	4/33 (12.1)	NE (NE, NE)	0.47 (0.13, 1.78)	0.2582	
≥65 years	2/12 (16.7)	NE (0.59, NE)	2/33 (6.1)	NE (NE, NE)	0.39 (0.06, 2.79)	0.3264	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1309
Male	8/64 (12.5)	NE (NE, NE)	19/159 (11.9)	NE (NE, NE)	0.83 (0.36, 1.91)	0.6508	
Female	10/45 (22.2)	NE (1.97, NE)	10/108 (9.3)	NE (NE, NE)	0.32 (0.13, 0.79)	0.0094	
Region							0.0693
USA	7/13 (53.8)	1.25 (0.59, NE)	4/30 (13.3)	NE (3.84, NE)	0.12 (0.03, 0.48)	0.0005	
Europe	7/68 (10.3)	NE (NE, NE)	10/177 (5.6)	NE (NE, NE)	0.54 (0.21, 1.42)	0.2068	
Rest of the world	4/28 (14.3)	NE (NE, NE)	15/60 (25.0)	NE (NE, NE)	1.38 (0.45, 4.25)	0.5792	
Prior salvage therapy							0.3559
Yes	11/63 (17.5)	NE (NE, NE)	22/161 (13.7)	NE (NE, NE)	0.64 (0.31, 1.35)	0.2379	
No	7/46 (15.2)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	0.36 (0.13, 1.05)	0.0506	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9042
0	7/55 (12.7)	NE (NE, NE)	7/112 (6.3)	NE (NE, NE)	0.43 (0.15, 1.25)	0.1097	
1	5/34 (14.7)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)	0.56 (0.18, 1.68)	0.2924	
≥2	6/20 (30.0)	NE (0.52, NE)	13/64 (20.3)	NE (5.51, NE)	0.51 (0.19, 1.37)	0.1701	
Prior alloHSCT							0.3133
Yes	9/35 (25.7)	NE (1.25, NE)	12/93 (12.9)	NE (NE, NE)	0.36 (0.14, 0.89)	0.0211	
No	9/74 (12.2)	NE (NE, NE)	17/174 (9.8)	NE (NE, NE)	0.73 (0.32, 1.64)	0.4376	
Race							0.7953
Caucasian	14/90 (15.6)	NE (NE, NE)	24/226 (10.6)	NE (NE, NE)	0.59 (0.30, 1.14)	0.1123	
Others	4/19 (21.1)	NE (1.97, NE)	5/41 (12.2)	NE (NE, NE)	0.40 (0.10, 1.65)	0.1926	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2077
<50%	3/27 (11.1)	NE (NE, NE)	2/73 (2.7)	NE (NE, NE)	0.22 (0.04, 1.33)	0.0689	
≥50%	14/77 (18.2)	NE (NE, NE)	24/168 (14.3)	NE (NE, NE)	0.65 (0.33, 1.27)	0.1993	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Adverse events coded using MedDRA version 20.0.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hyperglycaemia							
Overall	9/109 (8.3)	NE (NE, NE)	22/267 (8.2)	NE (NE, NE)	0.86 (0.39, 1.88)	0.6961	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Decreased appetite							
Overall	15/109 (13.8)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	0.26 (0.13, 0.55)	0.0001	
Age group 1							0.2905
<35 years	5/50 (10.0)	NE (NE, NE)	10/123 (8.1)	NE (15.80, NE)	0.31 (0.10, 0.99)	0.0382	
≥35 years	10/59 (16.9)	NE (2.82, NE)	10/144 (6.9)	NE (NE, NE)	0.26 (0.10, 0.66)	0.0026	
Age group 2							0.6205
<35 years	5/50 (10.0)	NE (NE, NE)	10/124 (8.1)	NE (15.80, NE)	0.31 (0.10, 0.99)	0.0379	
35 - 54 years	5/25 (20.0)	2.82 (2.82, NE)	9/77 (11.7)	NE (NE, NE)	0.35 (0.11, 1.12)	0.0666	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.12 (0.01, 1.09)	0.0266	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1336	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1130
Male	9/64 (14.1)	NE (2.82, NE)	16/159 (10.1)	NE (15.80, NE)	0.36 (0.15, 0.86)	0.0166	
Female	6/45 (13.3)	NE (NE, NE)	4/108 (3.7)	NE (NE, NE)	0.14 (0.03, 0.61)	0.0027	
Region							0.8533
USA	3/13 (23.1)	NE (0.59, NE)	3/30 (10.0)	NE (NE, NE)	0.27 (0.05, 1.38)	0.0940	
Europe	9/68 (13.2)	NE (2.82, NE)	11/177 (6.2)	NE (NE, NE)	0.20 (0.07, 0.55)	0.0006	
Rest of the world	3/28 (10.7)	2.33 (2.33, NE)	6/60 (10.0)	NE (NE, NE)	0.48 (0.11, 2.16)	0.3300	
Prior salvage therapy							0.0817
Yes	6/63 (9.5)	NE (2.82, NE)	13/161 (8.1)	NE (15.80, NE)	0.41 (0.14, 1.14)	0.0789	
No	9/46 (19.6)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	0.17 (0.05, 0.50)	0.0004	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3328
0	9/55 (16.4)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)	0.25 (0.09, 0.71)	0.0054	
1	5/34 (14.7)	NE (2.82, NE)	5/91 (5.5)	15.80 (15.80, NE)	0.19 (0.05, 0.73)	0.0080	
≥2	1/20 (5.0)	NE (NE, NE)	6/64 (9.4)	NE (NE, NE)	0.69 (0.08, 6.19)	0.7402	
Prior alloHSCT							0.2220
Yes	3/35 (8.6)	NE (2.82, NE)	10/93 (10.8)	NE (15.80, NE)	0.33 (0.08, 1.40)	0.1164	
No	12/74 (16.2)	NE (NE, NE)	10/174 (5.7)	NE (NE, NE)	0.23 (0.10, 0.56)	0.0005	
Race							0.3261
Caucasian	12/90 (13.3)	NE (NE, NE)	14/226 (6.2)	NE (NE, NE)	0.20 (0.08, 0.48)	<0.0001	
Others	3/19 (15.8)	2.33 (2.33, NE)	6/41 (14.6)	NE (NE, NE)	0.54 (0.13, 2.30)	0.3982	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1042
<50%	6/27 (22.2)	NE (2.33, NE)	6/73 (8.2)	NE (15.80, NE)	0.13 (0.03, 0.51)	0.0008	
≥50%	8/77 (10.4)	NE (2.82, NE)	14/168 (8.3)	NE (NE, NE)	0.44 (0.18, 1.11)	0.0743	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypoalbuminaemia							
Overall	11/109 (10.1)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.43 (0.19, 0.97)	0.0355	
Age group 1							0.4302
<35 years	6/50 (12.0)	NE (NE, NE)	10/123 (8.1)	NE (13.61, NE)	0.55 (0.19, 1.54)	0.2452	
≥35 years	5/59 (8.5)	NE (NE, NE)	4/144 (2.8)	NE (NE, NE)	0.28 (0.07, 1.05)	0.0446	
Age group 2							0.9529
<35 years	6/50 (12.0)	NE (NE, NE)	10/124 (8.1)	NE (13.61, NE)	0.54 (0.19, 1.54)	0.2429	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	1/77 (1.3)	NE (NE, NE)	0.32 (0.02, 5.19)	0.4017	
55 - 64 years	3/22 (13.6)	NE (1.84, NE)	3/33 (9.1)	NE (NE, NE)	0.55 (0.11, 2.78)	0.4638	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1489	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9694
Male	7/64 (10.9)	NE (NE, NE)	9/159 (5.7)	NE (NE, NE)	0.39 (0.14, 1.07)	0.0576	
Female	4/45 (8.9)	NE (NE, NE)	5/108 (4.6)	NE (NE, NE)	0.54 (0.14, 2.00)	0.3487	
Region							0.7320
USA	2/13 (15.4)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	0.46 (0.06, 3.24)	0.4199	
Europe	7/68 (10.3)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	0.48 (0.18, 1.28)	0.1368	
Rest of the world	2/28 (7.1)	NE (NE, NE)	1/60 (1.7)	NE (NE, NE)	0.19 (0.02, 2.07)	0.1281	
Prior salvage therapy							0.4250
Yes	7/63 (11.1)	NE (NE, NE)	11/161 (6.8)	NE (13.61, NE)	0.46 (0.17, 1.23)	0.1159	
No	4/46 (8.7)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.32 (0.07, 1.45)	0.1220	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3552
0	5/55 (9.1)	NE (NE, NE)	2/112 (1.8)	NE (NE, NE)	0.19 (0.04, 0.99)	0.0276	
1	4/34 (11.8)	NE (1.84, NE)	7/91 (7.7)	NE (13.61, NE)	0.47 (0.13, 1.69)	0.2334	
≥2	2/20 (10.0)	NE (NE, NE)	5/64 (7.8)	NE (NE, NE)	0.67 (0.13, 3.51)	0.6379	
Prior alloHSCT							0.6320
Yes	3/35 (8.6)	NE (NE, NE)	6/93 (6.5)	NE (NE, NE)	0.56 (0.13, 2.36)	0.4251	
No	8/74 (10.8)	NE (NE, NE)	8/174 (4.6)	NE (NE, NE)	0.38 (0.14, 1.03)	0.0477	
Race							0.1844
Caucasian	10/90 (11.1)	NE (NE, NE)	10/226 (4.4)	NE (NE, NE)	0.31 (0.13, 0.78)	0.0083	
Others	1/19 (5.3)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	1.78 (0.20, 15.91)	0.6030	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0966
<50%	5/27 (18.5)	NE (1.84, NE)	3/73 (4.1)	NE (13.61, NE)	0.12 (0.02, 0.65)	0.0035	
≥50%	6/77 (7.8)	NE (NE, NE)	11/168 (6.5)	NE (NE, NE)	0.78 (0.29, 2.11)	0.6221	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypophosphataemia							
Overall	6/109 (5.5)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.74 (0.28, 1.99)	0.5478	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypocalcaemia							
Overall	10/109 (9.2)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	0.37 (0.16, 0.90)	0.0225	
Age group 1							0.1470
<35 years	7/50 (14.0)	NE (NE, NE)	5/123 (4.1)	NE (16.13, NE)	0.14 (0.04, 0.53)	0.0008	
≥35 years	3/59 (5.1)	NE (NE, NE)	7/144 (4.9)	NE (NE, NE)	0.99 (0.26, 3.82)	0.9851	
Age group 2							0.2823
<35 years	7/50 (14.0)	NE (NE, NE)	5/124 (4.0)	NE (16.13, NE)	0.14 (0.03, 0.53)	0.0008	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	2/77 (2.6)	NE (NE, NE)	0.66 (0.06, 7.25)	0.7305	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	4/33 (12.1)	NE (NE, NE)	2.83 (0.32, 25.29)	0.3316	
≥65 years	1/12 (8.3)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.39 (0.02, 6.21)	0.4874	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8383
Male	7/64 (10.9)	NE (NE, NE)	9/159 (5.7)	NE (16.13, NE)	0.36 (0.13, 1.02)	0.0455	
Female	3/45 (6.7)	NE (NE, NE)	3/108 (2.8)	NE (NE, NE)	0.40 (0.08, 1.99)	0.2455	
Region							0.3311
USA	1/13 (7.7)	NE (1.25, NE)	3/30 (10.0)	NE (NE, NE)	1.32 (0.14, 12.68)	0.8101	
Europe	8/68 (11.8)	NE (NE, NE)	7/177 (4.0)	NE (NE, NE)	0.22 (0.07, 0.68)	0.0038	
Rest of the world	1/28 (3.6)	NE (NE, NE)	2/60 (3.3)	NE (NE, NE)	0.89 (0.08, 9.83)	0.9250	
Prior salvage therapy							0.9017
Yes	7/63 (11.1)	NE (NE, NE)	8/161 (5.0)	NE (16.13, NE)	0.29 (0.10, 0.86)	0.0181	
No	3/46 (6.5)	NE (NE, NE)	4/106 (3.8)	NE (NE, NE)	0.57 (0.13, 2.55)	0.4569	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3739
0	5/55 (9.1)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)	0.38 (0.10, 1.40)	0.1285	
1	1/34 (2.9)	NE (NE, NE)	4/91 (4.4)	16.13 (16.13, NE)	1.01 (0.10, 9.80)	0.9917	
≥2	4/20 (20.0)	NE (1.25, NE)	3/64 (4.7)	NE (NE, NE)	0.19 (0.04, 0.89)	0.0187	
Prior alloHSCT							0.1112
Yes	4/35 (11.4)	NE (NE, NE)	2/93 (2.2)	NE (NE, NE)	0.08 (0.01, 0.69)	0.0035	
No	6/74 (8.1)	NE (NE, NE)	10/174 (5.7)	NE (NE, NE)	0.60 (0.21, 1.69)	0.3307	
Race							0.9911
Caucasian	10/90 (11.1)	NE (NE, NE)	11/226 (4.9)	NE (NE, NE)	0.33 (0.13, 0.81)	0.0109	
Others	0/19 (0.0)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	NE (NE, NE)	0.5023	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1247
<50%	5/27 (18.5)	NE (NE, NE)	3/73 (4.1)	NE (16.13, NE)	0.13 (0.03, 0.68)	0.0043	
≥50%	5/77 (6.5)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.59 (0.19, 1.85)	0.3570	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Tumour lysis syndrome							
Overall	1/109 (0.9)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	3.42 (0.43, 27.02)	0.2148	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Musculoskeletal and connective tissue disorders							
Overall	37/109 (33.9)	NE (1.70, NE)	110/267 (41.2)	3.84 (2.92, 8.23)	0.92 (0.63, 1.34)	0.6507	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Back pain							
Overall	10/109 (9.2)	NE (NE, NE)	36/267 (13.5)	NE (NE, NE)	0.91 (0.44, 1.87)	0.7889	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Bone pain							
Overall	8/109 (7.3)	NE (NE, NE)	31/267 (11.6)	NE (NE, NE)	1.09 (0.49, 2.43)	0.8332	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pain in extremity							
Overall	8/109 (7.3)	NE (NE, NE)	25/267 (9.4)	NE (NE, NE)	0.82 (0.36, 1.87)	0.6303	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Myalgia							
Overall	6/109 (5.5)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	0.95 (0.37, 2.45)	0.9219	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Arthralgia							
Overall	5/109 (4.6)	NE (NE, NE)	17/267 (6.4)	NE (NE, NE)	0.74 (0.25, 2.15)	0.5734	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Muscle spasms							
Overall	4/109 (3.7)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.70 (0.21, 2.35)	0.5597	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Musculoskeletal pain							
Overall	3/109 (2.8)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.92 (0.24, 3.51)	0.9036	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Nervous system disorders							
Overall	46/109 (42.2)	NE (0.82, NE)	141/267 (52.8)	1.54 (1.08, 2.85)	1.15 (0.82, 1.61)	0.4135	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Headache							
Overall	32/109 (29.4)	NE (NE, NE)	79/267 (29.6)	NE (6.23, NE)	0.80 (0.53, 1.22)	0.3000	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Tremor							
Overall	0/109 (0.0)	NE (NE, NE)	26/267 (9.7)	NE (NE, NE)	NE (NE, NE)	0.0013	
Age group 1							0.9998
<35 years	0/50 (0.0)	NE (NE, NE)	9/123 (7.3)	NE (NE, NE)	NE (NE, NE)	0.0747	
≥35 years	0/59 (0.0)	NE (NE, NE)	17/144 (11.8)	NE (NE, NE)	NE (NE, NE)	0.0068	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)	NE (NE, NE)	0.0748	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	11/77 (14.3)	NE (NE, NE)	NE (NE, NE)	0.0615	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	NE (NE, NE)	0.1486	
≥65 years	0/12 (0.0)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	NE (NE, NE)	0.2654	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	NE (NE, NE)	15/159 (9.4)	NE (NE, NE)	NE (NE, NE)	0.0190	
Female	0/45 (0.0)	NE (NE, NE)	11/108 (10.2)	NE (NE, NE)	NE (NE, NE)	0.0256	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	5/30 (16.7)	NE (NE, NE)	NE (NE, NE)	0.1247	
Europe	0/68 (0.0)	NE (NE, NE)	16/177 (9.0)	NE (NE, NE)	NE (NE, NE)	0.0154	
Rest of the world	0/28 (0.0)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)	NE (NE, NE)	0.1302	
Prior salvage therapy							>0.9999
Yes	0/63 (0.0)	NE (NE, NE)	17/161 (10.6)	NE (NE, NE)	NE (NE, NE)	0.0127	
No	0/46 (0.0)	NE (NE, NE)	9/106 (8.5)	NE (NE, NE)	NE (NE, NE)	0.0430	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	NE (NE, NE)	0.0269	
1	0/34 (0.0)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)	NE (NE, NE)	0.0632	
≥2	0/20 (0.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)	NE (NE, NE)	0.1644	
Prior alloHSCT							0.9999
Yes	0/35 (0.0)	NE (NE, NE)	11/93 (11.8)	NE (NE, NE)	NE (NE, NE)	0.0488	
No	0/74 (0.0)	NE (NE, NE)	15/174 (8.6)	NE (NE, NE)	NE (NE, NE)	0.0112	
Race							0.9996
Caucasian	0/90 (0.0)	NE (NE, NE)	25/226 (11.1)	NE (NE, NE)	NE (NE, NE)	0.0016	
Others	0/19 (0.0)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	NE (NE, NE)	0.5023	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
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Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9998
<50%	0/27 (0.0)	NE (NE, NE)	11/73 (15.1)	NE (NE, NE)	NE (NE, NE)	0.0360	
≥50%	0/77 (0.0)	NE (NE, NE)	14/168 (8.3)	NE (NE, NE)	NE (NE, NE)	0.0146	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Dizziness							
Overall	8/109 (7.3)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.72 (0.31, 1.70)	0.4512	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Somnolence							
Overall	1/109 (0.9)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	5.17 (0.68, 39.43)	0.0773	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Paraesthesia							
Overall	1/109 (0.9)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	4.29 (0.55, 33.15)	0.1282	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Psychiatric disorders							
Overall	21/109 (19.3)	NE (NE, NE)	70/267 (26.2)	NE (10.59, NE)	1.11 (0.68, 1.83)	0.6690	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Insomnia							
Overall	10/109 (9.2)	NE (NE, NE)	31/267 (11.6)	NE (NE, NE)	0.87 (0.42, 1.83)	0.7128	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Anxiety							
Overall	6/109 (5.5)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.65 (0.24, 1.76)	0.3945	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Renal and urinary disorders							
Overall	24/109 (22.0)	NE (2.59, NE)	36/267 (13.5)	NE (NE, NE)	0.38 (0.22, 0.65)	0.0003	
Age group 1							0.6699
<35 years	11/50 (22.0)	NE (NE, NE)	18/123 (14.6)	NE (NE, NE)	0.44 (0.21, 0.96)	0.0344	
≥35 years	13/59 (22.0)	2.85 (2.59, NE)	18/144 (12.5)	NE (NE, NE)	0.32 (0.15, 0.68)	0.0019	
Age group 2							0.9469
<35 years	11/50 (22.0)	NE (NE, NE)	18/124 (14.5)	NE (NE, NE)	0.44 (0.21, 0.96)	0.0342	
35 - 54 years	6/25 (24.0)	2.85 (1.28, NE)	10/77 (13.0)	NE (NE, NE)	0.20 (0.07, 0.59)	0.0016	
55 - 64 years	5/22 (22.7)	2.59 (1.28, NE)	5/33 (15.2)	NE (NE, NE)	0.44 (0.12, 1.61)	0.1987	
≥65 years	2/12 (16.7)	NE (0.52, NE)	3/33 (9.1)	NE (NE, NE)	0.59 (0.10, 3.54)	0.5620	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5788
Male	15/64 (23.4)	NE (2.59, NE)	24/159 (15.1)	NE (NE, NE)	0.44 (0.23, 0.85)	0.0118	
Female	9/45 (20.0)	NE (1.28, NE)	12/108 (11.1)	NE (NE, NE)	0.28 (0.11, 0.72)	0.0053	
Region							0.5726
USA	2/13 (15.4)	NE (1.21, NE)	4/30 (13.3)	NE (2.82, NE)	0.61 (0.11, 3.42)	0.5728	
Europe	16/68 (23.5)	NE (2.59, NE)	20/177 (11.3)	NE (NE, NE)	0.33 (0.17, 0.65)	0.0009	
Rest of the world	6/28 (21.4)	NE (NE, NE)	12/60 (20.0)	NE (10.00, NE)	0.43 (0.15, 1.23)	0.1066	
Prior salvage therapy							0.7620
Yes	15/63 (23.8)	2.85 (2.59, NE)	25/161 (15.5)	NE (10.00, NE)	0.38 (0.19, 0.74)	0.0031	
No	9/46 (19.6)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	0.37 (0.15, 0.92)	0.0266	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.8111
0	11/55 (20.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	0.37 (0.16, 0.87)	0.0175	
1	7/34 (20.6)	2.59 (2.59, NE)	14/91 (15.4)	NE (NE, NE)	0.42 (0.16, 1.09)	0.0653	
≥2	6/20 (30.0)	NE (0.49, NE)	9/64 (14.1)	NE (10.00, NE)	0.26 (0.09, 0.76)	0.0082	
Prior alloHSCT							0.5688
Yes	7/35 (20.0)	2.85 (1.28, NE)	15/93 (16.1)	NE (NE, NE)	0.41 (0.16, 1.08)	0.0621	
No	17/74 (23.0)	NE (2.59, NE)	21/174 (12.1)	NE (NE, NE)	0.37 (0.19, 0.71)	0.0019	
Race							0.6603
Caucasian	22/90 (24.4)	NE (2.59, NE)	32/226 (14.2)	NE (NE, NE)	0.36 (0.21, 0.64)	0.0003	
Others	2/19 (10.5)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.52 (0.09, 3.07)	0.4660	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1669
<50%	7/27 (25.9)	2.59 (1.28, NE)	8/73 (11.0)	NE (NE, NE)	0.11 (0.03, 0.40)	<0.0001	
≥50%	15/77 (19.5)	NE (2.85, NE)	24/168 (14.3)	NE (NE, NE)	0.52 (0.27, 1.02)	0.0518	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Acute kidney injury							
Overall	8/109 (7.3)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.38 (0.15, 0.97)	0.0360	
Age group 1							0.7548
<35 years	5/50 (10.0)	NE (NE, NE)	6/123 (4.9)	NE (NE, NE)	0.35 (0.11, 1.19)	0.0792	
≥35 years	3/59 (5.1)	NE (2.85, NE)	5/144 (3.5)	NE (NE, NE)	0.41 (0.09, 1.82)	0.2275	
Age group 2							0.9396
<35 years	5/50 (10.0)	NE (NE, NE)	6/124 (4.8)	NE (NE, NE)	0.35 (0.11, 1.19)	0.0792	
35 - 54 years	3/25 (12.0)	2.85 (2.85, NE)	3/77 (3.9)	NE (NE, NE)	0.16 (0.03, 0.88)	0.0183	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.6464	
≥65 years	0/12 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.5127	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8587
Male	5/64 (7.8)	NE (2.85, NE)	7/159 (4.4)	NE (NE, NE)	0.38 (0.12, 1.22)	0.0911	
Female	3/45 (6.7)	NE (NE, NE)	4/108 (3.7)	NE (NE, NE)	0.40 (0.08, 1.87)	0.2286	
Region							0.8465
USA	1/13 (7.7)	-	2/30 (6.7)	-	-	-	
Europe	4/68 (5.9)	-	5/177 (2.8)	-	-	-	
Rest of the world	3/28 (10.7)	-	4/60 (6.7)	-	-	-	
Prior salvage therapy							0.7602
Yes	5/63 (7.9)	NE (2.85, NE)	8/161 (5.0)	NE (NE, NE)	0.40 (0.13, 1.25)	0.1018	
No	3/46 (6.5)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.34 (0.07, 1.73)	0.1748	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7888
0	4/55 (7.3)	-	5/112 (4.5)	-	-	-	
1	2/34 (5.9)	-	4/91 (4.4)	-	-	-	
≥2	2/20 (10.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.1626
Yes	5/35 (14.3)	NE (2.85, NE)	4/93 (4.3)	NE (NE, NE)	0.16 (0.04, 0.67)	0.0048	
No	3/74 (4.1)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.76 (0.19, 2.98)	0.6930	
Race							0.7288
Caucasian	7/90 (7.8)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.35 (0.13, 0.97)	0.0357	
Others	1/19 (5.3)	NE (NE, NE)	2/41 (4.9)	NE (NE, NE)	0.56 (0.05, 6.68)	0.6387	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.7473
<50%	2/27 (7.4)	NE (NE, NE)	3/73 (4.1)	NE (NE, NE)	0.32 (0.04, 2.30)	0.2320	
≥50%	5/77 (6.5)	NE (2.85, NE)	7/168 (4.2)	NE (NE, NE)	0.44 (0.14, 1.41)	0.1553	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Reproductive system and breast disorders							
Overall	3/109 (2.8)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	1.18 (0.32, 4.27)	0.8046	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Respiratory, thoracic and mediastinal disorders							
Overall	37/109 (33.9)	NE (2.03, NE)	102/267 (38.2)	4.46 (3.61, 7.84)	0.74 (0.50, 1.10)	0.1347	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Cough							
Overall	6/109 (5.5)	NE (NE, NE)	42/267 (15.7)	NE (16.36, NE)	1.74 (0.72, 4.18)	0.2110	

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[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Epistaxis							
Overall	9/109 (8.3)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.62 (0.27, 1.41)	0.2501	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Dyspnoea							
Overall	8/109 (7.3)	NE (NE, NE)	17/267 (6.4)	NE (NE, NE)	0.63 (0.27, 1.49)	0.2876	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-soc-pt-saf.sas
Output: t14-06-002-011-tte-sub-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:27) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_aette_socpref

Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Oropharyngeal pain							
Overall	7/109 (6.4)	NE (NE, NE)	15/267 (5.6)	18.72 (NE, NE)	0.31 (0.11, 0.84)	0.0160	
Age group 1							0.8803
<35 years	4/50 (8.0)	NE (NE, NE)	9/123 (7.3)	18.72 (NE, NE)	0.31 (0.08, 1.17)	0.0695	
≥35 years	3/59 (5.1)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.25 (0.05, 1.33)	0.0848	
Age group 2							0.9730
<35 years	4/50 (8.0)	NE (NE, NE)	9/124 (7.3)	18.72 (NE, NE)	0.31 (0.08, 1.17)	0.0689	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	5/77 (6.5)	NE (NE, NE)	0.53 (0.05, 5.37)	0.5815	
55 - 64 years	1/22 (4.5)	NE (NE, NE)	1/33 (3.0)	NE (3.61, NE)	0.00 (0.00, NE)	0.2131	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1266	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3572
Male	3/64 (4.7)	NE (NE, NE)	4/159 (2.5)	18.72 (NE, NE)	0.23 (0.04, 1.38)	0.0784	
Female	4/45 (8.9)	NE (NE, NE)	11/108 (10.2)	NE (NE, NE)	0.34 (0.09, 1.20)	0.0806	
Region							0.9624
USA	0/13 (0.0)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
Europe	5/68 (7.4)	NE (NE, NE)	11/177 (6.2)	18.72 (NE, NE)	0.30 (0.09, 0.97)	0.0342	
Rest of the world	2/28 (7.1)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	0.22 (0.02, 2.47)	0.1808	
Prior salvage therapy							0.5408
Yes	3/63 (4.8)	NE (NE, NE)	4/161 (2.5)	NE (NE, NE)	0.19 (0.04, 1.06)	0.0384	
No	4/46 (8.7)	NE (NE, NE)	11/106 (10.4)	18.72 (NE, NE)	0.38 (0.10, 1.42)	0.1386	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9157
0	6/55 (10.9)	NE (NE, NE)	10/112 (8.9)	18.72 (NE, NE)	0.27 (0.08, 0.90)	0.0242	
1	0/34 (0.0)	NE (NE, NE)	4/91 (4.4)	NE (NE, NE)	NE (NE, NE)	0.5505	
≥2	1/20 (5.0)	NE (NE, NE)	1/64 (1.6)	NE (5.70, NE)	0.00 (0.00, NE)	0.0833	
Prior alloHSCT							0.7649
Yes	3/35 (8.6)	NE (NE, NE)	8/93 (8.6)	18.72 (NE, NE)	0.24 (0.05, 1.18)	0.0599	
No	4/74 (5.4)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.35 (0.09, 1.29)	0.1006	
Race							0.0587
Caucasian	4/90 (4.4)	NE (NE, NE)	14/226 (6.2)	18.72 (NE, NE)	0.48 (0.14, 1.62)	0.2268	
Others	3/19 (15.8)	NE (NE, NE)	1/41 (2.4)	NE (NE, NE)	0.00 (0.00, NE)	0.0064	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.8644
<50%	2/27 (7.4)	NE (NE, NE)	6/73 (8.2)	NE (NE, NE)	0.23 (0.03, 1.62)	0.1132	
≥50%	5/77 (6.5)	NE (NE, NE)	8/168 (4.8)	18.72 (NE, NE)	0.31 (0.09, 1.10)	0.0586	

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[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Productive cough							
Overall	1/109 (0.9)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	1.54 (0.18, 12.92)	0.6891	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Skin and subcutaneous tissue disorders							
Overall	41/109 (37.6)	2.72 (1.25, NE)	93/267 (34.8)	7.84 (3.84, NE)	0.65 (0.44, 0.94)	0.0231	
Age group 1							0.5152
<35 years	16/50 (32.0)	NE (1.54, NE)	42/123 (34.1)	5.87 (3.02, NE)	0.73 (0.41, 1.32)	0.3062	
≥35 years	25/59 (42.4)	2.72 (1.05, NE)	51/144 (35.4)	8.30 (3.74, NE)	0.59 (0.36, 0.97)	0.0351	
Age group 2							0.7402
<35 years	16/50 (32.0)	NE (1.54, NE)	42/124 (33.9)	5.87 (3.02, NE)	0.73 (0.41, 1.32)	0.3031	
35 - 54 years	9/25 (36.0)	1.25 (0.52, NE)	31/77 (40.3)	6.03 (2.33, 8.66)	0.67 (0.31, 1.44)	0.2999	
55 - 64 years	11/22 (50.0)	1.08 (0.49, NE)	13/33 (39.4)	NE (1.02, NE)	0.65 (0.29, 1.47)	0.2897	
≥65 years	5/12 (41.7)	NE (0.23, NE)	7/33 (21.2)	NE (2.30, NE)	0.45 (0.14, 1.42)	0.1666	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2062
Male	22/64 (34.4)	2.72 (1.25, NE)	58/159 (36.5)	6.03 (2.66, 8.66)	0.75 (0.45, 1.25)	0.2709	
Female	19/45 (42.2)	1.70 (0.52, NE)	35/108 (32.4)	NE (3.25, NE)	0.53 (0.30, 0.95)	0.0294	
Region							0.3853
USA	5/13 (38.5)	1.70 (0.30, NE)	15/30 (50.0)	2.62 (0.62, NE)	1.22 (0.44, 3.36)	0.7011	
Europe	21/68 (30.9)	2.72 (1.25, NE)	47/177 (26.6)	NE (7.84, NE)	0.60 (0.35, 1.02)	0.0593	
Rest of the world	15/28 (53.6)	1.05 (0.43, 1.70)	31/60 (51.7)	2.66 (1.08, 6.03)	0.53 (0.28, 1.03)	0.0567	
Prior salvage therapy							0.2035
Yes	21/63 (33.3)	1.70 (1.25, NE)	58/161 (36.0)	6.03 (3.02, NE)	0.76 (0.46, 1.27)	0.3012	
No	20/46 (43.5)	NE (0.59, NE)	35/106 (33.0)	NE (3.74, NE)	0.52 (0.29, 0.92)	0.0225	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6861
0	23/55 (41.8)	NE (0.59, NE)	42/112 (37.5)	8.30 (3.28, NE)	0.59 (0.35, 1.00)	0.0504	
1	13/34 (38.2)	1.54 (1.05, NE)	32/91 (35.2)	7.84 (2.62, NE)	0.58 (0.30, 1.15)	0.1165	
≥2	5/20 (25.0)	NE (1.25, NE)	19/64 (29.7)	NE (2.56, NE)	0.98 (0.36, 2.63)	0.9646	
Prior alloHSCT							0.7259
Yes	13/35 (37.1)	1.54 (0.69, NE)	34/93 (36.6)	7.84 (3.08, NE)	0.52 (0.26, 1.04)	0.0610	
No	28/74 (37.8)	2.72 (1.25, NE)	59/174 (33.9)	8.30 (3.25, NE)	0.69 (0.44, 1.09)	0.1117	
Race							0.6700
Caucasian	32/90 (35.6)	2.72 (1.25, NE)	77/226 (34.1)	8.30 (3.74, NE)	0.68 (0.45, 1.04)	0.0767	
Others	9/19 (47.4)	1.70 (0.43, NE)	16/41 (39.0)	6.03 (3.02, NE)	0.53 (0.23, 1.24)	0.1438	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1746
<50%	13/27 (48.1)	1.70 (0.49, NE)	26/73 (35.6)	7.84 (3.28, NE)	0.38 (0.19, 0.78)	0.0064	
≥50%	27/77 (35.1)	NE (1.25, NE)	58/168 (34.5)	6.03 (3.02, NE)	0.78 (0.49, 1.24)	0.2861	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Rash							
Overall	13/109 (11.9)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	0.46 (0.22, 0.95)	0.0311	
Age group 1							0.1812
<35 years	8/50 (16.0)	NE (NE, NE)	8/123 (6.5)	NE (NE, NE)	0.32 (0.12, 0.86)	0.0169	
≥35 years	5/59 (8.5)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)	0.69 (0.23, 2.06)	0.5057	
Age group 2							0.3906
<35 years	8/50 (16.0)	NE (NE, NE)	8/124 (6.5)	NE (NE, NE)	0.31 (0.12, 0.85)	0.0166	
35 - 54 years	1/25 (4.0)	NE (NE, NE)	9/77 (11.7)	NE (NE, NE)	1.65 (0.20, 13.73)	0.6377	
55 - 64 years	3/22 (13.6)	NE (NE, NE)	2/33 (6.1)	NE (NE, NE)	0.42 (0.07, 2.53)	0.3377	
≥65 years	1/12 (8.3)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.39 (0.02, 6.29)	0.4942	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9783
Male	8/64 (12.5)	NE (NE, NE)	12/159 (7.5)	NE (NE, NE)	0.46 (0.18, 1.15)	0.0902	
Female	5/45 (11.1)	NE (NE, NE)	8/108 (7.4)	NE (NE, NE)	0.46 (0.14, 1.50)	0.1891	
Region							0.3567
USA	2/13 (15.4)	NE (NE, NE)	4/30 (13.3)	NE (3.28, NE)	0.81 (0.15, 4.43)	0.8029	
Europe	3/68 (4.4)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.99 (0.26, 3.74)	0.9877	
Rest of the world	8/28 (28.6)	NE (1.08, NE)	8/60 (13.3)	NE (6.62, NE)	0.19 (0.06, 0.59)	0.0016	
Prior salvage therapy							0.8859
Yes	6/63 (9.5)	NE (NE, NE)	10/161 (6.2)	NE (NE, NE)	0.48 (0.17, 1.35)	0.1552	
No	7/46 (15.2)	NE (NE, NE)	10/106 (9.4)	NE (NE, NE)	0.46 (0.17, 1.25)	0.1150	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.2003
0	9/55 (16.4)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)	0.40 (0.15, 1.02)	0.0452	
1	2/34 (5.9)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)	1.28 (0.27, 6.09)	0.7546	
≥2	2/20 (10.0)	NE (NE, NE)	1/64 (1.6)	NE (NE, NE)	0.10 (0.01, 1.20)	0.0292	
Prior alloHSCT							0.0311
Yes	7/35 (20.0)	NE (NE, NE)	5/93 (5.4)	NE (NE, NE)	0.13 (0.04, 0.50)	0.0006	
No	6/74 (8.1)	NE (NE, NE)	15/174 (8.6)	NE (NE, NE)	0.87 (0.33, 2.28)	0.7765	
Race							0.3542
Caucasian	10/90 (11.1)	NE (NE, NE)	18/226 (8.0)	NE (NE, NE)	0.57 (0.26, 1.26)	0.1583	
Others	3/19 (15.8)	NE (1.70, NE)	2/41 (4.9)	NE (NE, NE)	0.10 (0.01, 0.99)	0.0165	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4558
<50%	2/27 (7.4)	NE (NE, NE)	6/73 (8.2)	NE (NE, NE)	0.42 (0.07, 2.56)	0.3318	
≥50%	11/77 (14.3)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	0.44 (0.19, 1.00)	0.0434	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hyperhidrosis							
Overall	2/109 (1.8)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	1.76 (0.38, 8.16)	0.4617	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Vascular disorders							
Overall	28/109 (25.7)	NE (NE, NE)	64/267 (24.0)	14.20 (10.10, NE)	0.65 (0.41, 1.03)	0.0648	

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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypotension							
Overall	13/109 (11.9)	NE (NE, NE)	33/267 (12.4)	NE (NE, NE)	0.80 (0.41, 1.55)	0.5117	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.11. Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypertension							
Overall	9/109 (8.3)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.54 (0.24, 1.26)	0.1508	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Blood and lymphatic system disorders							
Overall	17/109 (15.6)	NE (2.82, NE)	38/267 (14.2)	NE (NE, NE)	0.55 (0.30, 1.01)	0.0504	
Age group 1							0.6189
<35 years	8/50 (16.0)	NE (2.82, NE)	20/123 (16.3)	NE (11.05, NE)	0.63 (0.27, 1.49)	0.2944	
≥35 years	9/59 (15.3)	NE (1.87, NE)	18/144 (12.5)	NE (NE, NE)	0.48 (0.21, 1.11)	0.0803	
Age group 2							0.6142
<35 years	8/50 (16.0)	NE (2.82, NE)	20/124 (16.1)	NE (11.05, NE)	0.63 (0.27, 1.49)	0.2932	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	6/77 (7.8)	NE (NE, NE)	0.82 (0.16, 4.06)	0.8099	
55 - 64 years	3/22 (13.6)	NE (1.28, NE)	7/33 (21.2)	NE (2.59, NE)	0.97 (0.24, 3.84)	0.9605	
≥65 years	4/12 (33.3)	NE (0.20, NE)	5/33 (15.2)	NE (4.59, NE)	0.07 (0.01, 0.67)	0.0026	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1841
Male	9/64 (14.1)	NE (2.82, NE)	26/159 (16.4)	NE (NE, NE)	0.77 (0.35, 1.67)	0.5022	
Female	8/45 (17.8)	NE (1.77, NE)	12/108 (11.1)	NE (11.05, NE)	0.33 (0.12, 0.88)	0.0200	
Region							0.5625
USA	3/13 (23.1)	NE (1.28, NE)	9/30 (30.0)	NE (1.31, NE)	1.08 (0.29, 4.05)	0.9074	
Europe	8/68 (11.8)	NE (2.82, NE)	18/177 (10.2)	NE (NE, NE)	0.52 (0.22, 1.25)	0.1389	
Rest of the world	6/28 (21.4)	1.97 (1.77, NE)	11/60 (18.3)	NE (6.26, NE)	0.42 (0.14, 1.27)	0.1159	
Prior salvage therapy							0.0062
Yes	7/63 (11.1)	NE (1.84, NE)	30/161 (18.6)	NE (11.05, NE)	1.04 (0.45, 2.42)	0.9309	
No	10/46 (21.7)	2.82 (1.97, NE)	8/106 (7.5)	NE (NE, NE)	0.21 (0.08, 0.55)	0.0006	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1131
0	10/55 (18.2)	NE (2.82, NE)	9/112 (8.0)	NE (NE, NE)	0.25 (0.09, 0.65)	0.0024	
1	3/34 (8.8)	NE (1.77, NE)	15/91 (16.5)	NE (11.05, NE)	1.11 (0.31, 3.99)	0.8756	
≥2	4/20 (20.0)	NE (1.84, NE)	14/64 (21.9)	NE (6.26, NE)	0.65 (0.20, 2.06)	0.4564	
Prior alloHSCT							0.0156
Yes	9/35 (25.7)	1.97 (1.28, NE)	11/93 (11.8)	NE (NE, NE)	0.20 (0.07, 0.52)	0.0003	
No	8/74 (10.8)	NE (NE, NE)	27/174 (15.5)	NE (11.05, NE)	0.98 (0.43, 2.20)	0.9562	
Race							0.3483
Caucasian	16/90 (17.8)	NE (2.82, NE)	33/226 (14.6)	NE (NE, NE)	0.51 (0.27, 0.95)	0.0305	
Others	1/19 (5.3)	NE (1.84, NE)	5/41 (12.2)	11.05 (NE, NE)	1.41 (0.16, 12.68)	0.7605	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.4683
<50%	4/27 (14.8)	NE (NE, NE)	8/73 (11.0)	NE (NE, NE)	0.46 (0.13, 1.60)	0.2109	
≥50%	13/77 (16.9)	NE (1.97, NE)	29/168 (17.3)	NE (11.05, NE)	0.62 (0.31, 1.23)	0.1701	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Febrile neutropenia							
Overall	12/109 (11.0)	NE (2.82, NE)	24/267 (9.0)	NE (NE, NE)	0.49 (0.24, 1.02)	0.0530	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Gastrointestinal disorders							
Overall	2/109 (1.8)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.78 (0.15, 4.07)	0.7691	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: General disorders and administration site conditions							
Overall	2/109 (1.8)	NE (NE, NE)	27/267 (10.1)	NE (NE, NE)	3.53 (0.83, 15.07)	0.0694	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pyrexia							
Overall	1/109 (0.9)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	4.01 (0.52, 30.89)	0.1490	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Immune system disorders							
Overall	0/109 (0.0)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	NE (NE, NE)	0.0566	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Infections and infestations							
Overall	33/109 (30.3)	NE (2.03, NE)	79/267 (29.6)	8.07 (5.87, 16.13)	0.51 (0.33, 0.80)	0.0023	
Age group 1							0.6650
<35 years	13/50 (26.0)	NE (2.03, NE)	35/123 (28.5)	7.57 (5.74, NE)	0.57 (0.29, 1.12)	0.0955	
≥35 years	20/59 (33.9)	NE (1.57, NE)	44/144 (30.6)	8.07 (5.54, 16.33)	0.49 (0.28, 0.86)	0.0122	
Age group 2							0.5965
<35 years	13/50 (26.0)	NE (2.03, NE)	35/124 (28.2)	7.57 (5.74, NE)	0.57 (0.29, 1.11)	0.0946	
35 - 54 years	9/25 (36.0)	1.87 (0.66, NE)	21/77 (27.3)	10.10 (5.05, NE)	0.31 (0.13, 0.72)	0.0046	
55 - 64 years	7/22 (31.8)	NE (0.62, NE)	11/33 (33.3)	8.07 (1.84, NE)	0.61 (0.22, 1.67)	0.3297	
≥65 years	4/12 (33.3)	NE (0.75, NE)	12/33 (36.4)	6.10 (4.79, NE)	0.80 (0.24, 2.68)	0.7208	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1848
Male	19/64 (29.7)	NE (2.03, NE)	52/159 (32.7)	6.10 (5.54, 10.10)	0.61 (0.35, 1.07)	0.0830	
Female	14/45 (31.1)	NE (1.87, NE)	27/108 (25.0)	14.75 (5.80, NE)	0.39 (0.19, 0.80)	0.0076	
Region							0.2188
USA	2/13 (15.4)	NE (1.21, NE)	7/30 (23.3)	5.74 (2.46, NE)	1.10 (0.22, 5.52)	0.9097	
Europe	18/68 (26.5)	NE (2.03, NE)	48/177 (27.1)	9.97 (7.25, 16.33)	0.54 (0.30, 0.96)	0.0340	
Rest of the world	13/28 (46.4)	1.11 (0.39, NE)	24/60 (40.0)	4.79 (2.56, NE)	0.36 (0.17, 0.77)	0.0059	
Prior salvage therapy							0.2640
Yes	17/63 (27.0)	NE (1.57, NE)	47/161 (29.2)	7.57 (4.79, NE)	0.68 (0.38, 1.20)	0.1795	
No	16/46 (34.8)	NE (1.87, NE)	32/106 (30.2)	9.97 (5.74, 16.33)	0.34 (0.17, 0.68)	0.0013	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3650
0	16/55 (29.1)	NE (2.03, NE)	33/112 (29.5)	9.97 (7.25, 16.33)	0.45 (0.23, 0.89)	0.0185	
1	13/34 (38.2)	1.57 (0.98, NE)	26/91 (28.6)	5.80 (4.59, NE)	0.37 (0.18, 0.75)	0.0044	
≥2	4/20 (20.0)	NE (1.21, NE)	20/64 (31.3)	6.07 (4.03, NE)	1.02 (0.34, 3.08)	0.9693	
Prior alloHSCT							0.1129
Yes	14/35 (40.0)	NE (0.56, NE)	33/93 (35.5)	7.57 (5.54, NE)	0.36 (0.18, 0.71)	0.0022	
No	19/74 (25.7)	NE (2.03, NE)	46/174 (26.4)	8.07 (5.74, NE)	0.63 (0.36, 1.10)	0.0998	
Race							0.3993
Caucasian	28/90 (31.1)	NE (1.87, NE)	66/226 (29.2)	9.97 (6.10, 16.33)	0.49 (0.31, 0.79)	0.0030	
Others	5/19 (26.3)	NE (0.89, NE)	13/41 (31.7)	4.79 (2.56, NE)	0.66 (0.22, 1.96)	0.4469	

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Table 14-6.2.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.3979
<50%	10/27 (37.0)	2.10 (1.57, NE)	22/73 (30.1)	8.07 (5.74, 16.13)	0.21 (0.08, 0.54)	0.0004	
≥50%	22/77 (28.6)	NE (2.03, NE)	46/168 (27.4)	7.57 (5.54, NE)	0.57 (0.33, 0.97)	0.0362	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sepsis							
Overall	7/109 (6.4)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.44 (0.17, 1.15)	0.0865	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pneumonia							
Overall	2/109 (1.8)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	1.22 (0.25, 5.96)	0.8010	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Injury, poisoning and procedural complications							
Overall	1/109 (0.9)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	5.70 (0.75, 43.24)	0.0573	

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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Metabolism and nutrition disorders							
Overall	2/109 (1.8)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	1.82 (0.40, 8.36)	0.4337	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Nervous system disorders							
Overall	4/109 (3.7)	NE (NE, NE)	21/267 (7.9)	NE (NE, NE)	1.40 (0.47, 4.17)	0.5482	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Respiratory, thoracic and mediastinal disorders							
Overall	5/109 (4.6)	NE (NE, NE)	16/267 (6.0)	NE (NE, NE)	0.92 (0.33, 2.57)	0.8730	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-ser-teae-soc-pt-saf.sas
Output: t14-06-002-012-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:33) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_ser_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Blood and lymphatic system disorders							
Overall	75/109 (68.8)	0.30 (0.26, 0.39)	154/267 (57.7)	1.44 (0.75, 2.36)	0.58 (0.44, 0.77)	0.0001	
Age group 1							0.2505
<35 years	28/50 (56.0)	0.39 (0.26, NE)	68/123 (55.3)	2.03 (0.92, 3.57)	0.67 (0.43, 1.06)	0.0849	
≥35 years	47/59 (79.7)	0.26 (0.20, 0.33)	86/144 (59.7)	0.75 (0.46, 2.36)	0.52 (0.36, 0.75)	0.0004	
Age group 2							0.6287
<35 years	28/50 (56.0)	0.39 (0.26, NE)	68/124 (54.8)	2.03 (0.92, 3.57)	0.67 (0.43, 1.05)	0.0820	
35 - 54 years	21/25 (84.0)	0.26 (0.16, 0.33)	46/77 (59.7)	0.72 (0.39, 2.36)	0.48 (0.28, 0.81)	0.0054	
55 - 64 years	19/22 (86.4)	0.26 (0.10, 0.43)	23/33 (69.7)	0.46 (0.10, 1.44)	0.62 (0.33, 1.15)	0.1185	
≥65 years	7/12 (58.3)	0.30 (0.03, NE)	17/33 (51.5)	4.62 (0.33, 4.95)	0.50 (0.19, 1.29)	0.1400	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2443
Male	39/64 (60.9)	0.33 (0.26, 0.59)	92/159 (57.9)	1.44 (0.72, 2.52)	0.65 (0.45, 0.96)	0.0284	
Female	36/45 (80.0)	0.26 (0.23, 0.33)	62/108 (57.4)	0.98 (0.49, 3.11)	0.51 (0.33, 0.78)	0.0014	
Region							0.3032
USA	8/13 (61.5)	0.39 (0.16, NE)	21/30 (70.0)	0.52 (0.33, 1.15)	0.94 (0.41, 2.14)	0.8776	
Europe	46/68 (67.6)	0.26 (0.23, 0.43)	98/177 (55.4)	1.64 (0.72, 3.57)	0.60 (0.42, 0.86)	0.0049	
Rest of the world	21/28 (75.0)	0.26 (0.16, 0.43)	35/60 (58.3)	2.10 (0.59, 3.87)	0.38 (0.22, 0.69)	0.0009	
Prior salvage therapy							0.0388
Yes	39/63 (61.9)	0.36 (0.26, 1.05)	97/161 (60.2)	1.18 (0.59, 2.10)	0.70 (0.48, 1.03)	0.0636	
No	36/46 (78.3)	0.26 (0.20, 0.26)	57/106 (53.8)	2.03 (0.49, 6.85)	0.46 (0.30, 0.70)	0.0003	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4575
0	39/55 (70.9)	0.26 (0.23, 0.33)	61/112 (54.5)	2.03 (0.59, 4.95)	0.52 (0.34, 0.79)	0.0018	
1	23/34 (67.6)	0.34 (0.20, 0.59)	53/91 (58.2)	1.64 (0.72, 3.11)	0.54 (0.32, 0.90)	0.0153	
≥2	13/20 (65.0)	0.39 (0.20, 1.93)	40/64 (62.5)	0.59 (0.33, 2.07)	0.76 (0.40, 1.43)	0.3662	
Prior alloHSCT							0.6610
Yes	26/35 (74.3)	0.30 (0.23, 0.49)	54/93 (58.1)	1.74 (0.46, 2.59)	0.56 (0.34, 0.91)	0.0147	
No	49/74 (66.2)	0.30 (0.23, 0.43)	100/174 (57.5)	1.15 (0.62, 3.02)	0.60 (0.42, 0.85)	0.0035	
Race							0.7867
Caucasian	63/90 (70.0)	0.26 (0.23, 0.36)	131/226 (58.0)	1.44 (0.72, 2.52)	0.58 (0.43, 0.79)	0.0004	
Others	12/19 (63.2)	0.43 (0.26, NE)	23/41 (56.1)	1.08 (0.46, NE)	0.58 (0.28, 1.18)	0.1350	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2193
<50%	19/27 (70.4)	0.26 (0.13, 1.93)	39/73 (53.4)	2.59 (1.15, 6.85)	0.41 (0.23, 0.74)	0.0023	
≥50%	53/77 (68.8)	0.30 (0.26, 0.43)	98/168 (58.3)	0.79 (0.46, 2.03)	0.64 (0.46, 0.90)	0.0092	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Febrile neutropenia							
Overall	38/109 (34.9)	NE (1.77, NE)	58/267 (21.7)	NE (NE, NE)	0.48 (0.32, 0.73)	0.0004	
Age group 1							0.9096
<35 years	17/50 (34.0)	2.82 (1.77, NE)	27/123 (22.0)	NE (NE, NE)	0.45 (0.24, 0.83)	0.0095	
≥35 years	21/59 (35.6)	NE (0.59, NE)	31/144 (21.5)	NE (NE, NE)	0.52 (0.30, 0.91)	0.0206	
Age group 2							0.8658
<35 years	17/50 (34.0)	2.82 (1.77, NE)	27/124 (21.8)	NE (NE, NE)	0.45 (0.24, 0.83)	0.0094	
35 - 54 years	10/25 (40.0)	NE (0.33, NE)	16/77 (20.8)	NE (NE, NE)	0.46 (0.21, 1.02)	0.0520	
55 - 64 years	8/22 (36.4)	NE (0.43, NE)	9/33 (27.3)	NE (NE, NE)	0.66 (0.25, 1.72)	0.3903	
≥65 years	3/12 (25.0)	NE (0.33, NE)	6/33 (18.2)	NE (4.59, NE)	0.49 (0.11, 2.18)	0.3395	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7555
Male	24/64 (37.5)	2.82 (0.59, NE)	39/159 (24.5)	NE (NE, NE)	0.48 (0.29, 0.81)	0.0046	
Female	14/45 (31.1)	NE (1.77, NE)	19/108 (17.6)	NE (NE, NE)	0.48 (0.24, 0.97)	0.0386	
Region							0.7894
USA	6/13 (46.2)	NE (0.33, NE)	12/30 (40.0)	NE (0.72, NE)	0.61 (0.23, 1.64)	0.3320	
Europe	18/68 (26.5)	NE (2.82, NE)	28/177 (15.8)	NE (NE, NE)	0.48 (0.26, 0.89)	0.0161	
Rest of the world	14/28 (50.0)	0.59 (0.36, NE)	18/60 (30.0)	NE (3.87, NE)	0.41 (0.20, 0.86)	0.0150	
Prior salvage therapy							0.0242
Yes	20/63 (31.7)	NE (1.77, NE)	43/161 (26.7)	NE (6.69, NE)	0.67 (0.39, 1.14)	0.1352	
No	18/46 (39.1)	2.82 (0.46, NE)	15/106 (14.2)	NE (NE, NE)	0.27 (0.14, 0.55)	0.0001	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4150
0	18/55 (32.7)	NE (2.82, NE)	17/112 (15.2)	NE (NE, NE)	0.35 (0.18, 0.70)	0.0018	
1	12/34 (35.3)	1.77 (0.59, NE)	26/91 (28.6)	NE (NE, NE)	0.63 (0.32, 1.27)	0.1935	
≥2	8/20 (40.0)	NE (0.39, NE)	15/64 (23.4)	NE (6.26, NE)	0.43 (0.18, 1.04)	0.0519	
Prior alloHSCT							0.1563
Yes	14/35 (40.0)	1.77 (0.56, NE)	16/93 (17.2)	NE (NE, NE)	0.27 (0.13, 0.58)	0.0004	
No	24/74 (32.4)	NE (NE, NE)	42/174 (24.1)	NE (NE, NE)	0.61 (0.37, 1.01)	0.0535	
Race							0.2282
Caucasian	28/90 (31.1)	NE (2.82, NE)	48/226 (21.2)	NE (NE, NE)	0.54 (0.33, 0.86)	0.0092	
Others	10/19 (52.6)	0.56 (0.30, NE)	10/41 (24.4)	NE (NE, NE)	0.30 (0.12, 0.73)	0.0051	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1499
<50%	9/27 (33.3)	NE (0.46, NE)	10/73 (13.7)	NE (NE, NE)	0.30 (0.12, 0.77)	0.0080	
≥50%	29/77 (37.7)	2.82 (1.77, NE)	45/168 (26.8)	NE (6.69, NE)	0.57 (0.35, 0.91)	0.0173	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Anaemia							
Overall	38/109 (34.9)	NE (1.93, NE)	53/267 (19.9)	NE (15.93, NE)	0.48 (0.32, 0.73)	0.0005	
Age group 1							0.3179
<35 years	18/50 (36.0)	NE (0.66, NE)	21/123 (17.1)	NE (11.90, NE)	0.35 (0.18, 0.67)	0.0010	
≥35 years	20/59 (33.9)	NE (1.15, NE)	32/144 (22.2)	NE (NE, NE)	0.61 (0.35, 1.07)	0.0796	
Age group 2							0.8304
<35 years	18/50 (36.0)	NE (0.66, NE)	21/124 (16.9)	NE (11.90, NE)	0.35 (0.18, 0.67)	0.0009	
35 - 54 years	9/25 (36.0)	NE (0.95, NE)	19/77 (24.7)	NE (NE, NE)	0.62 (0.28, 1.37)	0.2336	
55 - 64 years	7/22 (31.8)	NE (0.49, NE)	6/33 (18.2)	NE (NE, NE)	0.58 (0.20, 1.73)	0.3161	
≥65 years	4/12 (33.3)	NE (0.10, NE)	7/33 (21.2)	NE (NE, NE)	0.56 (0.16, 1.93)	0.3525	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6388
Male	20/64 (31.3)	NE (1.15, NE)	27/159 (17.0)	NE (15.93, NE)	0.42 (0.23, 0.76)	0.0033	
Female	18/45 (40.0)	1.93 (0.59, NE)	26/108 (24.1)	NE (NE, NE)	0.56 (0.31, 1.04)	0.0598	
Region							0.0582
USA	6/13 (46.2)	NE (0.26, NE)	6/30 (20.0)	NE (NE, NE)	0.41 (0.13, 1.29)	0.1147	
Europe	19/68 (27.9)	NE (NE, NE)	39/177 (22.0)	NE (15.93, NE)	0.70 (0.40, 1.22)	0.2029	
Rest of the world	13/28 (46.4)	1.08 (0.36, NE)	8/60 (13.3)	NE (NE, NE)	0.21 (0.09, 0.51)	0.0002	
Prior salvage therapy							0.7058
Yes	19/63 (30.2)	NE (1.15, NE)	29/161 (18.0)	15.93 (11.90, NE)	0.49 (0.27, 0.88)	0.0148	
No	19/46 (41.3)	NE (0.43, NE)	24/106 (22.6)	NE (NE, NE)	0.48 (0.26, 0.89)	0.0160	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.9828
0	21/55 (38.2)	NE (0.52, NE)	26/112 (23.2)	NE (NE, NE)	0.53 (0.30, 0.94)	0.0281	
1	11/34 (32.4)	NE (1.08, NE)	17/91 (18.7)	15.93 (15.93, NE)	0.51 (0.23, 1.09)	0.0765	
≥2	6/20 (30.0)	1.93 (0.59, NE)	10/64 (15.6)	11.90 (11.90, NE)	0.39 (0.14, 1.10)	0.0652	
Prior alloHSCT							0.4454
Yes	16/35 (45.7)	1.15 (0.46, NE)	21/93 (22.6)	NE (15.93, NE)	0.37 (0.19, 0.73)	0.0025	
No	22/74 (29.7)	NE (1.93, NE)	32/174 (18.4)	NE (NE, NE)	0.55 (0.32, 0.96)	0.0319	
Race							0.7403
Caucasian	33/90 (36.7)	NE (1.93, NE)	48/226 (21.2)	NE (15.93, NE)	0.49 (0.31, 0.77)	0.0015	
Others	5/19 (26.3)	NE (1.15, NE)	5/41 (12.2)	NE (NE, NE)	0.40 (0.11, 1.40)	0.1414	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5639
<50%	12/27 (44.4)	1.93 (0.39, NE)	15/73 (20.5)	NE (15.93, NE)	0.37 (0.17, 0.80)	0.0089	
≥50%	24/77 (31.2)	NE (NE, NE)	30/168 (17.9)	NE (NE, NE)	0.51 (0.30, 0.88)	0.0132	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutropenia							
Overall	29/109 (26.6)	NE (NE, NE)	47/267 (17.6)	NE (NE, NE)	0.41 (0.25, 0.66)	0.0002	
Age group 1							0.7250
<35 years	12/50 (24.0)	NE (2.30, NE)	21/123 (17.1)	NE (NE, NE)	0.45 (0.22, 0.95)	0.0320	
≥35 years	17/59 (28.8)	NE (NE, NE)	26/144 (18.1)	NE (8.26, NE)	0.38 (0.19, 0.72)	0.0025	
Age group 2							0.7589
<35 years	12/50 (24.0)	NE (2.30, NE)	21/124 (16.9)	NE (NE, NE)	0.45 (0.22, 0.95)	0.0315	
35 - 54 years	7/25 (28.0)	NE (NE, NE)	16/77 (20.8)	NE (6.69, NE)	0.46 (0.18, 1.15)	0.0902	
55 - 64 years	8/22 (36.4)	NE (0.26, NE)	5/33 (15.2)	NE (NE, NE)	0.32 (0.10, 1.00)	0.0395	
≥65 years	2/12 (16.7)	NE (0.36, NE)	5/33 (15.2)	8.26 (4.75, NE)	0.19 (0.02, 2.08)	0.1267	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.0662
Male	12/64 (18.8)	NE (NE, NE)	27/159 (17.0)	NE (8.26, NE)	0.57 (0.28, 1.16)	0.1193	
Female	17/45 (37.8)	NE (0.36, NE)	20/108 (18.5)	NE (NE, NE)	0.30 (0.15, 0.60)	0.0003	
Region							0.2486
USA	1/13 (7.7)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)	1.80 (0.20, 16.11)	0.5889	
Europe	18/68 (26.5)	NE (2.30, NE)	33/177 (18.6)	NE (8.26, NE)	0.45 (0.25, 0.83)	0.0086	
Rest of the world	10/28 (35.7)	NE (0.30, NE)	10/60 (16.7)	NE (4.95, NE)	0.18 (0.07, 0.51)	0.0003	
Prior salvage therapy							0.9919
Yes	13/63 (20.6)	NE (NE, NE)	21/161 (13.0)	NE (NE, NE)	0.36 (0.17, 0.74)	0.0039	
No	16/46 (34.8)	NE (2.30, NE)	26/106 (24.5)	NE (6.69, NE)	0.47 (0.24, 0.90)	0.0209	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.7778
0	17/55 (30.9)	NE (2.30, NE)	25/112 (22.3)	NE (8.26, NE)	0.45 (0.23, 0.86)	0.0145	
1	8/34 (23.5)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)	0.30 (0.11, 0.80)	0.0113	
≥2	4/20 (20.0)	NE (NE, NE)	10/64 (15.6)	NE (3.61, NE)	0.52 (0.16, 1.70)	0.2668	
Prior alloHSCT							0.0726
Yes	15/35 (42.9)	NE (0.26, NE)	19/93 (20.4)	NE (6.69, NE)	0.23 (0.11, 0.49)	<0.0001	
No	14/74 (18.9)	NE (NE, NE)	28/174 (16.1)	NE (8.26, NE)	0.59 (0.30, 1.14)	0.1126	
Race							0.4369
Caucasian	27/90 (30.0)	NE (2.30, NE)	42/226 (18.6)	NE (8.26, NE)	0.36 (0.22, 0.61)	<0.0001	
Others	2/19 (10.5)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	1.07 (0.21, 5.52)	0.9349	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5428
<50%	6/27 (22.2)	NE (NE, NE)	16/73 (21.9)	NE (6.69, NE)	0.49 (0.18, 1.34)	0.1582	
≥50%	21/77 (27.3)	NE (2.30, NE)	28/168 (16.7)	NE (8.26, NE)	0.43 (0.24, 0.77)	0.0036	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Thrombocytopenia							
Overall	30/109 (27.5)	NE (NE, NE)	40/267 (15.0)	NE (NE, NE)	0.46 (0.29, 0.75)	0.0014	
Age group 1							0.5559
<35 years	14/50 (28.0)	NE (2.03, NE)	17/123 (13.8)	NE (16.26, NE)	0.36 (0.17, 0.75)	0.0042	
≥35 years	16/59 (27.1)	NE (NE, NE)	23/144 (16.0)	NE (NE, NE)	0.58 (0.31, 1.10)	0.0890	
Age group 2							0.8348
<35 years	14/50 (28.0)	NE (2.03, NE)	17/124 (13.7)	NE (16.26, NE)	0.36 (0.17, 0.74)	0.0041	
35 - 54 years	6/25 (24.0)	NE (NE, NE)	14/77 (18.2)	NE (NE, NE)	0.75 (0.29, 1.94)	0.5465	
55 - 64 years	7/22 (31.8)	NE (0.36, NE)	5/33 (15.2)	NE (NE, NE)	0.45 (0.14, 1.42)	0.1631	
≥65 years	3/12 (25.0)	NE (0.16, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.11, 2.16)	0.3270	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9416
Male	16/64 (25.0)	NE (NE, NE)	22/159 (13.8)	NE (16.26, NE)	0.45 (0.23, 0.86)	0.0141	
Female	14/45 (31.1)	NE (2.03, NE)	18/108 (16.7)	NE (NE, NE)	0.49 (0.24, 1.00)	0.0450	
Region							0.3001
USA	1/13 (7.7)	NE (2.03, NE)	4/30 (13.3)	NE (NE, NE)	1.61 (0.18, 14.53)	0.6709	
Europe	24/68 (35.3)	NE (NE, NE)	33/177 (18.6)	NE (NE, NE)	0.44 (0.26, 0.75)	0.0020	
Rest of the world	5/28 (17.9)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.26 (0.06, 1.09)	0.0481	
Prior salvage therapy							0.8125
Yes	14/63 (22.2)	NE (NE, NE)	20/161 (12.4)	NE (16.26, NE)	0.48 (0.24, 0.97)	0.0352	
No	16/46 (34.8)	NE (2.03, NE)	20/106 (18.9)	NE (NE, NE)	0.46 (0.24, 0.90)	0.0204	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6279
0	19/55 (34.5)	NE (2.03, NE)	20/112 (17.9)	NE (NE, NE)	0.43 (0.23, 0.81)	0.0072	
1	8/34 (23.5)	NE (NE, NE)	11/91 (12.1)	16.26 (16.26, NE)	0.41 (0.16, 1.07)	0.0575	
≥2	3/20 (15.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)	0.89 (0.24, 3.28)	0.8519	
Prior alloHSCT							0.7037
Yes	10/35 (28.6)	NE (NE, NE)	17/93 (18.3)	NE (16.26, NE)	0.52 (0.23, 1.16)	0.1006	
No	20/74 (27.0)	NE (NE, NE)	23/174 (13.2)	NE (NE, NE)	0.44 (0.24, 0.80)	0.0058	
Race							0.5934
Caucasian	29/90 (32.2)	NE (2.03, NE)	38/226 (16.8)	NE (NE, NE)	0.44 (0.27, 0.72)	0.0007	
Others	1/19 (5.3)	NE (NE, NE)	2/41 (4.9)	NE (NE, NE)	0.91 (0.08, 10.00)	0.9365	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0379
<50%	14/27 (51.9)	0.39 (0.26, NE)	11/73 (15.1)	NE (16.26, NE)	0.19 (0.08, 0.44)	<0.0001	
≥50%	15/77 (19.5)	NE (NE, NE)	24/168 (14.3)	NE (NE, NE)	0.70 (0.37, 1.34)	0.2815	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Cardiac disorders							
Overall	4/109 (3.7)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.89 (0.28, 2.86)	0.8490	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Gastrointestinal disorders							
Overall	15/109 (13.8)	NE (NE, NE)	21/267 (7.9)	NE (NE, NE)	0.28 (0.13, 0.59)	0.0004	
Age group 1							0.4746
<35 years	10/50 (20.0)	NE (1.87, NE)	12/123 (9.8)	NE (11.80, NE)	0.20 (0.08, 0.52)	0.0003	
≥35 years	5/59 (8.5)	NE (NE, NE)	9/144 (6.3)	NE (NE, NE)	0.47 (0.15, 1.52)	0.1983	
Age group 2							0.6423
<35 years	10/50 (20.0)	NE (1.87, NE)	12/124 (9.7)	NE (11.80, NE)	0.20 (0.08, 0.52)	0.0003	
35 - 54 years	5/25 (20.0)	NE (NE, NE)	3/77 (3.9)	NE (NE, NE)	0.17 (0.04, 0.71)	0.0059	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	4/33 (12.1)	NE (5.64, NE)	NE (NE, NE)	0.2100	
≥65 years	0/12 (0.0)	NE (NE, NE)	2/33 (6.1)	NE (7.48, NE)	NE (NE, NE)	0.6080	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.8732
Male	8/64 (12.5)	NE (NE, NE)	11/159 (6.9)	NE (15.97, NE)	0.33 (0.13, 0.89)	0.0211	
Female	7/45 (15.6)	NE (NE, NE)	10/108 (9.3)	NE (9.64, NE)	0.21 (0.06, 0.68)	0.0048	
Region							0.6941
USA	2/13 (15.4)	NE (1.21, NE)	2/30 (6.7)	5.64 (5.64, NE)	0.21 (0.02, 2.30)	0.1574	
Europe	11/68 (16.2)	NE (NE, NE)	14/177 (7.9)	NE (15.97, NE)	0.27 (0.11, 0.64)	0.0016	
Rest of the world	2/28 (7.1)	NE (1.87, NE)	5/60 (8.3)	NE (9.64, NE)	0.32 (0.05, 2.08)	0.2103	
Prior salvage therapy							0.3844
Yes	7/63 (11.1)	NE (NE, NE)	12/161 (7.5)	15.97 (11.80, NE)	0.39 (0.14, 1.07)	0.0587	
No	8/46 (17.4)	NE (NE, NE)	9/106 (8.5)	NE (NE, NE)	0.18 (0.06, 0.58)	0.0013	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3565
0	9/55 (16.4)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)	0.19 (0.06, 0.59)	0.0015	
1	5/34 (14.7)	NE (NE, NE)	6/91 (6.6)	15.97 (9.64, NE)	0.24 (0.06, 0.92)	0.0241	
≥2	1/20 (5.0)	NE (1.21, NE)	6/64 (9.4)	11.80 (11.80, NE)	1.00 (0.11, 8.80)	0.9980	
Prior alloHSCT							0.0346
Yes	7/35 (20.0)	NE (1.87, NE)	6/93 (6.5)	NE (NE, NE)	0.14 (0.04, 0.50)	0.0005	
No	8/74 (10.8)	NE (NE, NE)	15/174 (8.6)	NE (8.16, NE)	0.41 (0.16, 1.05)	0.0566	
Race							0.5969
Caucasian	14/90 (15.6)	NE (NE, NE)	19/226 (8.4)	NE (NE, NE)	0.29 (0.14, 0.62)	0.0008	
Others	1/19 (5.3)	NE (NE, NE)	2/41 (4.9)	9.64 (5.64, NE)	0.00 (0.00, NE)	0.1360	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2355
<50%	1/27 (3.7)	NE (NE, NE)	5/73 (6.8)	NE (15.97, NE)	0.36 (0.03, 4.99)	0.4262	
≥50%	14/77 (18.2)	NE (NE, NE)	12/168 (7.1)	NE (NE, NE)	0.25 (0.11, 0.58)	0.0004	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: General disorders and administration site conditions							
Overall	16/109 (14.7)	NE (NE, NE)	47/267 (17.6)	NE (NE, NE)	0.92 (0.52, 1.65)	0.7762	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pyrexia							
Overall	5/109 (4.6)	NE (NE, NE)	20/267 (7.5)	NE (NE, NE)	1.25 (0.46, 3.39)	0.6701	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Hepatobiliary disorders							
Overall	6/109 (5.5)	NE (NE, NE)	14/267 (5.2)	NE (NE, NE)	0.73 (0.28, 1.94)	0.5289	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Immune system disorders							
Overall	0/109 (0.0)	NE (NE, NE)	19/267 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0231	
Age group 1							0.9998
<35 years	0/50 (0.0)	NE (NE, NE)	11/123 (8.9)	NE (NE, NE)	NE (NE, NE)	0.0766	
≥35 years	0/59 (0.0)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)	NE (NE, NE)	0.1559	
Age group 2							>0.9999
<35 years	0/50 (0.0)	NE (NE, NE)	11/124 (8.9)	NE (NE, NE)	NE (NE, NE)	0.0772	
35 - 54 years	0/25 (0.0)	NE (NE, NE)	5/77 (6.5)	NE (NE, NE)	NE (NE, NE)	0.3702	
55 - 64 years	0/22 (0.0)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
≥65 years	0/12 (0.0)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	NE (NE, NE)	0.3644	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							>0.9999
Male	0/64 (0.0)	NE (NE, NE)	10/159 (6.3)	NE (NE, NE)	NE (NE, NE)	0.1097	
Female	0/45 (0.0)	NE (NE, NE)	9/108 (8.3)	NE (NE, NE)	NE (NE, NE)	0.1106	
Region							>0.9999
USA	0/13 (0.0)	NE (NE, NE)	3/30 (10.0)	NE (3.02, NE)	NE (NE, NE)	0.2850	
Europe	0/68 (0.0)	NE (NE, NE)	13/177 (7.3)	NE (NE, NE)	NE (NE, NE)	0.0662	
Rest of the world	0/28 (0.0)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	NE (NE, NE)	0.4072	
Prior salvage therapy							0.9998
Yes	0/63 (0.0)	NE (NE, NE)	13/161 (8.1)	NE (NE, NE)	NE (NE, NE)	0.0750	
No	0/46 (0.0)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	NE (NE, NE)	0.1533	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	0/55 (0.0)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)	NE (NE, NE)	0.1585	
1	0/34 (0.0)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)	NE (NE, NE)	0.0915	
≥2	0/20 (0.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	NE (NE, NE)	0.6304	
Prior alloHSCT							>0.9999
Yes	0/35 (0.0)	NE (NE, NE)	8/93 (8.6)	NE (NE, NE)	NE (NE, NE)	0.2635	
No	0/74 (0.0)	NE (NE, NE)	11/174 (6.3)	NE (NE, NE)	NE (NE, NE)	0.0486	
Race							>0.9999
Caucasian	0/90 (0.0)	NE (NE, NE)	16/226 (7.1)	NE (NE, NE)	NE (NE, NE)	0.0342	
Others	0/19 (0.0)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	NE (NE, NE)	0.4216	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9999
<50%	0/27 (0.0)	NE (NE, NE)	4/73 (5.5)	NE (NE, NE)	NE (NE, NE)	0.6480	
≥50%	0/77 (0.0)	NE (NE, NE)	13/168 (7.7)	NE (NE, NE)	NE (NE, NE)	0.0241	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Infections and infestations							
Overall	57/109 (52.3)	1.11 (0.62, 2.03)	93/267 (34.8)	7.25 (5.54, 16.13)	0.33 (0.23, 0.48)	<0.0001	
Age group 1							0.1820
<35 years	21/50 (42.0)	2.00 (0.62, NE)	42/123 (34.1)	6.07 (4.36, NE)	0.40 (0.23, 0.71)	0.0010	
≥35 years	36/59 (61.0)	0.66 (0.43, 1.51)	51/144 (35.4)	7.25 (5.05, NE)	0.30 (0.19, 0.47)	<0.0001	
Age group 2							0.6514
<35 years	21/50 (42.0)	2.00 (0.62, NE)	42/124 (33.9)	6.07 (4.36, NE)	0.40 (0.23, 0.71)	0.0010	
35 - 54 years	14/25 (56.0)	0.66 (0.36, NE)	26/77 (33.8)	7.25 (2.75, NE)	0.25 (0.13, 0.52)	<0.0001	
55 - 64 years	14/22 (63.6)	0.67 (0.30, NE)	13/33 (39.4)	5.80 (1.84, NE)	0.30 (0.13, 0.70)	0.0033	
≥65 years	8/12 (66.7)	0.62 (0.26, NE)	12/33 (36.4)	NE (1.48, NE)	0.40 (0.16, 1.02)	0.0465	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.7934
Male	35/64 (54.7)	1.11 (0.52, 2.03)	59/159 (37.1)	6.10 (4.59, 10.10)	0.33 (0.21, 0.52)	<0.0001	
Female	22/45 (48.9)	1.34 (0.49, NE)	34/108 (31.5)	7.25 (4.79, NE)	0.35 (0.20, 0.62)	0.0002	
Region							0.2520
USA	5/13 (38.5)	NE (0.33, NE)	11/30 (36.7)	5.74 (1.48, NE)	0.62 (0.21, 1.86)	0.3896	
Europe	33/68 (48.5)	1.51 (0.62, NE)	56/177 (31.6)	7.57 (5.87, NE)	0.34 (0.22, 0.55)	<0.0001	
Rest of the world	19/28 (67.9)	0.49 (0.39, 0.69)	26/60 (43.3)	4.36 (2.10, NE)	0.21 (0.11, 0.42)	<0.0001	
Prior salvage therapy							0.1232
Yes	32/63 (50.8)	1.11 (0.49, NE)	63/161 (39.1)	5.80 (2.75, 16.13)	0.42 (0.27, 0.65)	<0.0001	
No	25/46 (54.3)	1.34 (0.49, 2.10)	30/106 (28.3)	10.10 (5.87, NE)	0.22 (0.12, 0.41)	<0.0001	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.1291
0	28/55 (50.9)	1.34 (0.52, NE)	34/112 (30.4)	10.10 (6.10, NE)	0.26 (0.15, 0.46)	<0.0001	
1	22/34 (64.7)	0.59 (0.33, 1.11)	34/91 (37.4)	4.79 (2.69, 16.13)	0.27 (0.15, 0.47)	<0.0001	
≥2	7/20 (35.0)	NE (0.49, NE)	25/64 (39.1)	5.05 (1.61, NE)	0.70 (0.30, 1.68)	0.4250	
Prior alloHSCT							0.5074
Yes	19/35 (54.3)	0.72 (0.46, NE)	35/93 (37.6)	7.25 (5.05, NE)	0.28 (0.15, 0.52)	<0.0001	
No	38/74 (51.4)	1.34 (0.62, 2.10)	58/174 (33.3)	7.44 (4.36, NE)	0.36 (0.23, 0.55)	<0.0001	
Race							0.5493
Caucasian	47/90 (52.2)	1.34 (0.59, 2.10)	75/226 (33.2)	7.57 (5.80, NE)	0.33 (0.22, 0.49)	<0.0001	
Others	10/19 (52.6)	0.89 (0.33, NE)	18/41 (43.9)	3.38 (1.31, NE)	0.35 (0.15, 0.83)	0.0128	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.5541
<50%	14/27 (51.9)	1.51 (0.43, NE)	25/73 (34.2)	7.25 (5.54, 16.13)	0.14 (0.06, 0.33)	<0.0001	
≥50%	41/77 (53.2)	0.89 (0.52, 2.03)	59/168 (35.1)	6.10 (4.30, NE)	0.38 (0.25, 0.58)	<0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Sepsis							
Overall	7/109 (6.4)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.41 (0.16, 1.07)	0.0616	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Device related infection							
Overall	5/109 (4.6)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	0.49 (0.15, 1.55)	0.2157	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Pneumonia							
Overall	11/109 (10.1)	NE (NE, NE)	11/267 (4.1)	NE (NE, NE)	0.29 (0.12, 0.72)	0.0042	
Age group 1							0.1555
<35 years	6/50 (12.0)	NE (NE, NE)	3/123 (2.4)	NE (NE, NE)	0.19 (0.05, 0.75)	0.0077	
≥35 years	5/59 (8.5)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)	0.42 (0.13, 1.41)	0.1483	
Age group 2							0.5106
<35 years	6/50 (12.0)	-	3/124 (2.4)	-	-	-	
35 - 54 years	2/25 (8.0)	-	5/77 (6.5)	-	-	-	
55 - 64 years	3/22 (13.6)	-	3/33 (9.1)	-	-	-	
≥65 years	0/12 (0.0)	-	0/33 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.6955
Male	7/64 (10.9)	NE (NE, NE)	6/159 (3.8)	NE (NE, NE)	0.25 (0.08, 0.79)	0.0107	
Female	4/45 (8.9)	NE (NE, NE)	5/108 (4.6)	NE (NE, NE)	0.40 (0.10, 1.59)	0.1767	
Region							0.9559
USA	0/13 (0.0)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)	NE (NE, NE)	0.5032	
Europe	7/68 (10.3)	NE (NE, NE)	7/177 (4.0)	NE (NE, NE)	0.24 (0.08, 0.76)	0.0088	
Rest of the world	4/28 (14.3)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)	0.32 (0.07, 1.43)	0.1163	
Prior salvage therapy							0.5832
Yes	9/63 (14.3)	NE (NE, NE)	8/161 (5.0)	NE (NE, NE)	0.29 (0.11, 0.77)	0.0082	
No	2/46 (4.3)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.22 (0.02, 2.41)	0.1719	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.3064
0	4/55 (7.3)	-	4/112 (3.6)	-	-	-	
1	6/34 (17.6)	-	3/91 (3.3)	-	-	-	
≥2	1/20 (5.0)	-	4/64 (6.3)	-	-	-	
Prior alloHSCT							0.3708
Yes	4/35 (11.4)	NE (NE, NE)	7/93 (7.5)	NE (NE, NE)	0.38 (0.10, 1.45)	0.1419	
No	7/74 (9.5)	NE (NE, NE)	4/174 (2.3)	NE (NE, NE)	0.22 (0.06, 0.76)	0.0087	
Race							0.5790
Caucasian	9/90 (10.0)	NE (NE, NE)	8/226 (3.5)	NE (NE, NE)	0.24 (0.08, 0.67)	0.0032	
Others	2/19 (10.5)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.63 (0.11, 3.78)	0.6046	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.8170
<50%	3/27 (11.1)	NE (1.57, NE)	3/73 (4.1)	NE (NE, NE)	0.20 (0.03, 1.24)	0.0571	
≥50%	8/77 (10.4)	NE (NE, NE)	7/168 (4.2)	NE (NE, NE)	0.32 (0.11, 0.92)	0.0259	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Bacteraemia							
Overall	6/109 (5.5)	NE (NE, NE)	2/267 (0.7)	NE (NE, NE)	0.11 (0.02, 0.54)	0.0011	
Age group 1							0.9888
<35 years	3/50 (6.0)	-	1/123 (0.8)	-	-	-	
≥35 years	3/59 (5.1)	-	1/144 (0.7)	-	-	-	
Age group 2							0.9817
<35 years	3/50 (6.0)	-	1/124 (0.8)	-	-	-	
35 - 54 years	1/25 (4.0)	-	1/77 (1.3)	-	-	-	
55 - 64 years	1/22 (4.5)	-	0/33 (0.0)	-	-	-	
≥65 years	1/12 (8.3)	-	0/33 (0.0)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.9953
Male	5/64 (7.8)	-	2/159 (1.3)	-	-	-	
Female	1/45 (2.2)	-	0/108 (0.0)	-	-	-	
Region							>0.9999
USA	0/13 (0.0)	-	1/30 (3.3)	-	-	-	
Europe	3/68 (4.4)	-	1/177 (0.6)	-	-	-	
Rest of the world	3/28 (10.7)	-	0/60 (0.0)	-	-	-	
Prior salvage therapy							0.5736
Yes	4/63 (6.3)	-	1/161 (0.6)	-	-	-	
No	2/46 (4.3)	-	1/106 (0.9)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							>0.9999
0	2/55 (3.6)	-	0/112 (0.0)	-	-	-	
1	3/34 (8.8)	-	0/91 (0.0)	-	-	-	
≥2	1/20 (5.0)	-	2/64 (3.1)	-	-	-	
Prior alloHSCT							0.9950
Yes	1/35 (2.9)	-	0/93 (0.0)	-	-	-	
No	5/74 (6.8)	-	2/174 (1.1)	-	-	-	
Race							0.3464
Caucasian	5/90 (5.6)	-	1/226 (0.4)	-	-	-	
Others	1/19 (5.3)	-	1/41 (2.4)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9929
<50%	3/27 (11.1)	-	0/73 (0.0)	-	-	-	
≥50%	2/77 (2.6)	-	2/168 (1.2)	-	-	-	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Investigations							
Overall	28/109 (25.7)	NE (NE, NE)	61/267 (22.8)	NE (13.61, NE)	0.74 (0.47, 1.16)	0.1829	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Alanine aminotransferase increased							
Overall	9/109 (8.3)	NE (NE, NE)	15/267 (5.6)	NE (NE, NE)	0.60 (0.26, 1.38)	0.2217	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: White blood cell count decreased							
Overall	6/109 (5.5)	NE (NE, NE)	13/267 (4.9)	NE (NE, NE)	0.72 (0.27, 1.92)	0.4993	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Platelet count decreased							
Overall	13/109 (11.9)	NE (NE, NE)	12/267 (4.5)	NE (NE, NE)	0.29 (0.13, 0.65)	0.0015	
Age group 1							0.8325
<35 years	6/50 (12.0)	NE (NE, NE)	6/123 (4.9)	NE (16.00, NE)	0.29 (0.09, 0.95)	0.0288	
≥35 years	7/59 (11.9)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.28 (0.09, 0.90)	0.0221	
Age group 2							0.6515
<35 years	6/50 (12.0)	NE (NE, NE)	6/124 (4.8)	NE (16.00, NE)	0.29 (0.09, 0.94)	0.0283	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	2/77 (2.6)	NE (NE, NE)	0.15 (0.01, 1.63)	0.0702	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	0.16 (0.02, 1.41)	0.0573	
≥65 years	1/12 (8.3)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	1.13 (0.12, 10.89)	0.9142	

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[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5827
Male	7/64 (10.9)	NE (NE, NE)	5/159 (3.1)	NE (16.00, NE)	0.16 (0.04, 0.60)	0.0019	
Female	6/45 (13.3)	NE (NE, NE)	7/108 (6.5)	NE (NE, NE)	0.47 (0.16, 1.39)	0.1622	
Region							0.9975
USA	4/13 (30.8)	NE (0.30, NE)	3/30 (10.0)	NE (NE, NE)	0.31 (0.07, 1.38)	0.0998	
Europe	4/68 (5.9)	NE (NE, NE)	4/177 (2.3)	NE (NE, NE)	0.26 (0.06, 1.18)	0.0616	
Rest of the world	5/28 (17.9)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)	0.32 (0.09, 1.20)	0.0743	
Prior salvage therapy							0.1246
Yes	5/63 (7.9)	NE (NE, NE)	8/161 (5.0)	NE (16.00, NE)	0.44 (0.14, 1.45)	0.1655	
No	8/46 (17.4)	NE (NE, NE)	4/106 (3.8)	NE (NE, NE)	0.19 (0.06, 0.63)	0.0025	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.8954
0	7/55 (12.7)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0187	
1	4/34 (11.8)	NE (NE, NE)	4/91 (4.4)	16.00 (16.00, NE)	0.27 (0.06, 1.20)	0.0647	
≥2	2/20 (10.0)	NE (1.31, NE)	3/64 (4.7)	NE (NE, NE)	0.41 (0.07, 2.49)	0.3138	
Prior alloHSCT							0.2468
Yes	5/35 (14.3)	NE (1.31, NE)	3/93 (3.2)	NE (NE, NE)	0.12 (0.02, 0.63)	0.0031	
No	8/74 (10.8)	NE (NE, NE)	9/174 (5.2)	NE (NE, NE)	0.41 (0.15, 1.07)	0.0601	
Race							0.4298
Caucasian	11/90 (12.2)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.26 (0.10, 0.65)	0.0020	
Others	2/19 (10.5)	NE (NE, NE)	3/41 (7.3)	NE (NE, NE)	0.41 (0.06, 2.96)	0.3645	

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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.2983
<50%	3/27 (11.1)	NE (NE, NE)	1/73 (1.4)	NE (16.00, NE)	0.00 (0.00, NE)	0.0039	
≥50%	10/77 (13.0)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.29 (0.11, 0.76)	0.0073	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Neutrophil count decreased							
Overall	11/109 (10.1)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.27 (0.11, 0.66)	0.0023	
Age group 1							0.8108
<35 years	6/50 (12.0)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0188	
≥35 years	5/59 (8.5)	NE (NE, NE)	5/144 (3.5)	NE (NE, NE)	0.27 (0.07, 1.06)	0.0455	
Age group 2							0.9989
<35 years	6/50 (12.0)	NE (NE, NE)	5/124 (4.0)	NE (NE, NE)	0.26 (0.08, 0.87)	0.0185	
35 - 54 years	3/25 (12.0)	NE (NE, NE)	4/77 (5.2)	NE (NE, NE)	0.24 (0.04, 1.24)	0.0643	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0797	
≥65 years	0/12 (0.0)	NE (NE, NE)	1/33 (3.0)	NE (NE, NE)	NE (NE, NE)	0.5403	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.3108
Male	7/64 (10.9)	NE (NE, NE)	4/159 (2.5)	NE (NE, NE)	0.13 (0.03, 0.51)	0.0006	
Female	4/45 (8.9)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	0.57 (0.16, 2.06)	0.3880	
Region							0.8290
USA	4/13 (30.8)	NE (0.26, NE)	2/30 (6.7)	NE (NE, NE)	0.19 (0.03, 1.05)	0.0332	
Europe	2/68 (2.9)	NE (NE, NE)	2/177 (1.1)	NE (NE, NE)	0.29 (0.04, 2.10)	0.1935	
Rest of the world	5/28 (17.9)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.28 (0.07, 1.08)	0.0493	
Prior salvage therapy							0.0501
Yes	5/63 (7.9)	NE (NE, NE)	9/161 (5.6)	NE (NE, NE)	0.56 (0.18, 1.73)	0.3070	
No	6/46 (13.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	0.05 (0.01, 0.43)	0.0002	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4221
0	7/55 (12.7)	NE (NE, NE)	3/112 (2.7)	NE (NE, NE)	0.10 (0.02, 0.51)	0.0007	
1	3/34 (8.8)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)	0.53 (0.13, 2.27)	0.3867	
≥2	1/20 (5.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.63 (0.06, 6.94)	0.6980	
Prior alloHSCT							0.5234
Yes	4/35 (11.4)	NE (NE, NE)	3/93 (3.2)	NE (NE, NE)	0.21 (0.05, 1.01)	0.0338	
No	7/74 (9.5)	NE (NE, NE)	7/174 (4.0)	NE (NE, NE)	0.31 (0.10, 0.93)	0.0273	
Race							0.2913
Caucasian	8/90 (8.9)	NE (NE, NE)	5/226 (2.2)	NE (NE, NE)	0.20 (0.06, 0.62)	0.0021	
Others	3/19 (15.8)	NE (NE, NE)	5/41 (12.2)	NE (NE, NE)	0.48 (0.10, 2.20)	0.3299	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.9918
<50%	3/27 (11.1)	NE (NE, NE)	0/73 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0040	
≥50%	8/77 (10.4)	NE (NE, NE)	9/168 (5.4)	NE (NE, NE)	0.40 (0.15, 1.07)	0.0574	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Metabolism and nutrition disorders							
Overall	26/109 (23.9)	NE (NE, NE)	40/267 (15.0)	NE (NE, NE)	0.48 (0.29, 0.80)	0.0038	
Age group 1							0.2412
<35 years	9/50 (18.0)	NE (2.33, NE)	19/123 (15.4)	NE (12.00, NE)	0.61 (0.27, 1.39)	0.2392	
≥35 years	17/59 (28.8)	NE (1.74, NE)	21/144 (14.6)	NE (NE, NE)	0.41 (0.21, 0.78)	0.0052	
Age group 2							0.3321
<35 years	9/50 (18.0)	NE (2.33, NE)	19/124 (15.3)	NE (12.00, NE)	0.61 (0.27, 1.39)	0.2367	
35 - 54 years	8/25 (32.0)	1.74 (0.79, NE)	9/77 (11.7)	NE (NE, NE)	0.24 (0.09, 0.66)	0.0028	
55 - 64 years	6/22 (27.3)	NE (0.66, NE)	8/33 (24.2)	NE (NE, NE)	0.74 (0.25, 2.17)	0.5759	
≥65 years	3/12 (25.0)	NE (0.46, NE)	4/33 (12.1)	NE (NE, NE)	0.48 (0.11, 2.15)	0.3281	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.1033
Male	13/64 (20.3)	NE (NE, NE)	27/159 (17.0)	NE (10.16, NE)	0.68 (0.35, 1.33)	0.2585	
Female	13/45 (28.9)	NE (1.74, NE)	13/108 (12.0)	NE (NE, NE)	0.28 (0.12, 0.62)	0.0009	
Region							0.1487
USA	4/13 (30.8)	NE (0.46, NE)	11/30 (36.7)	NE (0.79, NE)	1.15 (0.37, 3.63)	0.8268	
Europe	10/68 (14.7)	NE (NE, NE)	18/177 (10.2)	NE (NE, NE)	0.51 (0.23, 1.14)	0.0945	
Rest of the world	12/28 (42.9)	2.33 (0.56, NE)	11/60 (18.3)	NE (12.00, NE)	0.28 (0.12, 0.67)	0.0021	
Prior salvage therapy							0.0323
Yes	14/63 (22.2)	NE (2.33, NE)	32/161 (19.9)	12.00 (10.16, NE)	0.65 (0.34, 1.24)	0.1891	
No	12/46 (26.1)	NE (NE, NE)	8/106 (7.5)	NE (NE, NE)	0.26 (0.11, 0.64)	0.0015	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.2912
0	12/55 (21.8)	NE (2.33, NE)	10/112 (8.9)	NE (NE, NE)	0.32 (0.13, 0.77)	0.0072	
1	11/34 (32.4)	NE (0.66, NE)	18/91 (19.8)	NE (10.16, NE)	0.38 (0.18, 0.84)	0.0125	
≥2	3/20 (15.0)	NE (NE, NE)	12/64 (18.8)	NE (NE, NE)	1.09 (0.30, 3.90)	0.8968	
Prior alloHSCT							0.8405
Yes	6/35 (17.1)	NE (NE, NE)	12/93 (12.9)	NE (NE, NE)	0.56 (0.20, 1.54)	0.2566	
No	20/74 (27.0)	NE (2.33, NE)	28/174 (16.1)	NE (12.00, NE)	0.46 (0.26, 0.83)	0.0083	
Race							0.4297
Caucasian	22/90 (24.4)	NE (NE, NE)	37/226 (16.4)	NE (NE, NE)	0.53 (0.31, 0.91)	0.0190	
Others	4/19 (21.1)	2.33 (2.33, NE)	3/41 (7.3)	12.00 (NE, NE)	0.17 (0.03, 0.99)	0.0264	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.0503
<50%	8/27 (29.6)	NE (1.74, NE)	6/73 (8.2)	NE (NE, NE)	0.18 (0.06, 0.56)	0.0009	
≥50%	16/77 (20.8)	NE (NE, NE)	29/168 (17.3)	NE (12.00, NE)	0.66 (0.35, 1.23)	0.1826	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hypokalaemia							
Overall	11/109 (10.1)	NE (NE, NE)	10/267 (3.7)	NE (NE, NE)	0.28 (0.11, 0.68)	0.0026	
Age group 1							0.5047
<35 years	3/50 (6.0)	NE (NE, NE)	4/123 (3.3)	NE (12.26, NE)	0.34 (0.07, 1.70)	0.1693	
≥35 years	8/59 (13.6)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)	0.25 (0.09, 0.74)	0.0069	
Age group 2							0.8107
<35 years	3/50 (6.0)	-	4/124 (3.2)	-	-	-	
35 - 54 years	5/25 (20.0)	-	4/77 (5.2)	-	-	-	
55 - 64 years	1/22 (4.5)	-	0/33 (0.0)	-	-	-	
≥65 years	2/12 (16.7)	-	2/33 (6.1)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
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Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.5028
Male	5/64 (7.8)	NE (NE, NE)	6/159 (3.8)	NE (12.26, NE)	0.37 (0.11, 1.29)	0.1064	
Female	6/45 (13.3)	NE (NE, NE)	4/108 (3.7)	NE (NE, NE)	0.19 (0.05, 0.70)	0.0057	
Region							0.5960
USA	1/13 (7.7)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	0.93 (0.08, 10.25)	0.9521	
Europe	6/68 (8.8)	NE (NE, NE)	4/177 (2.3)	NE (NE, NE)	0.17 (0.04, 0.69)	0.0049	
Rest of the world	4/28 (14.3)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)	0.29 (0.07, 1.21)	0.0728	
Prior salvage therapy							0.2553
Yes	6/63 (9.5)	NE (NE, NE)	8/161 (5.0)	NE (12.26, NE)	0.36 (0.12, 1.08)	0.0582	
No	5/46 (10.9)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	0.16 (0.03, 0.81)	0.0114	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.6274
0	5/55 (9.1)	NE (NE, NE)	2/112 (1.8)	NE (NE, NE)	0.17 (0.03, 0.90)	0.0184	
1	4/34 (11.8)	NE (NE, NE)	6/91 (6.6)	NE (12.26, NE)	0.32 (0.08, 1.24)	0.0820	
≥2	2/20 (10.0)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)	0.28 (0.04, 1.98)	0.1729	
Prior alloHSCT							0.4186
Yes	3/35 (8.6)	NE (NE, NE)	2/93 (2.2)	NE (NE, NE)	0.12 (0.01, 1.11)	0.0242	
No	8/74 (10.8)	NE (NE, NE)	8/174 (4.6)	NE (NE, NE)	0.36 (0.13, 0.96)	0.0332	
Race							0.9913
Caucasian	9/90 (10.0)	NE (NE, NE)	10/226 (4.4)	NE (NE, NE)	0.34 (0.13, 0.86)	0.0165	
Others	2/19 (10.5)	NE (NE, NE)	0/41 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0229	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1042
<50%	4/27 (14.8)	NE (NE, NE)	1/73 (1.4)	NE (12.26, NE)	0.00 (0.00, NE)	0.0003	
≥50%	7/77 (9.1)	NE (NE, NE)	8/168 (4.8)	NE (NE, NE)	0.45 (0.16, 1.26)	0.1197	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
PT: Hyperglycaemia							
Overall	7/109 (6.4)	NE (NE, NE)	9/267 (3.4)	NE (NE, NE)	0.43 (0.15, 1.18)	0.0903	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Musculoskeletal and connective tissue disorders							
Overall	6/109 (5.5)	NE (NE, NE)	18/267 (6.7)	NE (NE, NE)	0.73 (0.28, 1.91)	0.5138	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Nervous system disorders							
Overall	10/109 (9.2)	NE (NE, NE)	25/267 (9.4)	NE (NE, NE)	0.78 (0.37, 1.64)	0.5056	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Respiratory, thoracic and mediastinal disorders							
Overall	13/109 (11.9)	NE (NE, NE)	21/267 (7.9)	NE (NE, NE)	0.50 (0.25, 1.02)	0.0506	
Age group 1							0.2291
<35 years	4/50 (8.0)	NE (NE, NE)	11/123 (8.9)	NE (16.39, NE)	0.83 (0.26, 2.65)	0.7457	
≥35 years	9/59 (15.3)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)	0.34 (0.13, 0.88)	0.0195	
Age group 2							0.4482
<35 years	4/50 (8.0)	NE (NE, NE)	11/124 (8.9)	NE (16.39, NE)	0.82 (0.26, 2.65)	0.7440	
35 - 54 years	6/25 (24.0)	NE (1.48, NE)	7/77 (9.1)	NE (NE, NE)	0.22 (0.07, 0.69)	0.0045	
55 - 64 years	2/22 (9.1)	NE (NE, NE)	3/33 (9.1)	NE (NE, NE)	1.03 (0.17, 6.15)	0.9747	
≥65 years	1/12 (8.3)	NE (NE, NE)	0/33 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1138	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Sex							0.2708
Male	5/64 (7.8)	NE (NE, NE)	12/159 (7.5)	NE (16.39, NE)	0.69 (0.24, 2.02)	0.4967	
Female	8/45 (17.8)	NE (2.03, NE)	9/108 (8.3)	NE (NE, NE)	0.37 (0.14, 0.97)	0.0369	
Region							0.5057
USA	1/13 (7.7)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)	0.88 (0.08, 9.70)	0.9162	
Europe	6/68 (8.8)	NE (NE, NE)	13/177 (7.3)	NE (NE, NE)	0.57 (0.21, 1.56)	0.2677	
Rest of the world	6/28 (21.4)	NE (NE, NE)	6/60 (10.0)	NE (NE, NE)	0.36 (0.11, 1.12)	0.0656	
Prior salvage therapy							0.2654
Yes	9/63 (14.3)	NE (NE, NE)	18/161 (11.2)	NE (16.39, NE)	0.60 (0.27, 1.36)	0.2192	
No	4/46 (8.7)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	0.21 (0.04, 1.02)	0.0354	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Number of salvage therapies							0.4890
0	4/55 (7.3)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)	0.27 (0.06, 1.20)	0.0696	
1	7/34 (20.6)	NE (NE, NE)	9/91 (9.9)	16.39 (16.39, NE)	0.36 (0.13, 0.99)	0.0396	
≥2	2/20 (10.0)	NE (2.03, NE)	8/64 (12.5)	NE (NE, NE)	1.08 (0.23, 5.11)	0.9253	
Prior alloHSCT							0.5610
Yes	3/35 (8.6)	NE (NE, NE)	8/93 (8.6)	NE (NE, NE)	0.80 (0.21, 3.12)	0.7498	
No	10/74 (13.5)	NE (NE, NE)	13/174 (7.5)	NE (NE, NE)	0.42 (0.18, 0.97)	0.0371	
Race							0.8733
Caucasian	10/90 (11.1)	NE (NE, NE)	17/226 (7.5)	NE (NE, NE)	0.49 (0.22, 1.09)	0.0759	
Others	3/19 (15.8)	NE (NE, NE)	4/41 (9.8)	NE (NE, NE)	0.56 (0.12, 2.49)	0.4391	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Central laboratory baseline bone marrow blasts							0.1371
<50%	4/27 (14.8)	NE (2.03, NE)	3/73 (4.1)	NE (16.39, NE)	0.06 (0.01, 0.54)	0.0008	
≥50%	9/77 (11.7)	NE (NE, NE)	16/168 (9.5)	NE (NE, NE)	0.71 (0.31, 1.63)	0.4241	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.13. Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
SOC: Vascular disorders							
Overall	6/109 (5.5)	NE (NE, NE)	9/267 (3.4)	NE (NE, NE)	0.37 (0.12, 1.12)	0.0682	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-sev-teae-soc-pt-saf.sas
Output: t14-06-002-013-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 08JUL2025:23:10) Source data: adam_fa.adsl, adam_fa.adbase, outdata.t_sev_aette_socpref

Table 14-6.2.14. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Age group 1							0.3786
<35 years	2/50 (4.0)	NE (NE, NE)	14/123 (11.4)	NE (16.33, NE)	2.12 (0.48, 9.48)	0.3136	
≥35 years	8/59 (13.6)	NE (NE, NE)	27/144 (18.8)	NE (13.15, NE)	0.99 (0.44, 2.22)	0.9786	
Age group 2							0.8151
<35 years	2/50 (4.0)	NE (NE, NE)	15/124 (12.1)	NE (16.33, NE)	2.31 (0.52, 10.25)	0.2556	
35 - 54 years	2/25 (8.0)	NE (NE, NE)	11/77 (14.3)	NE (NE, NE)	1.01 (0.22, 4.75)	0.9850	
55 - 64 years	4/22 (18.2)	NE (NE, NE)	7/33 (21.2)	13.15 (3.70, NE)	0.74 (0.20, 2.77)	0.6571	
≥65 years	2/12 (16.7)	NE (0.75, NE)	8/33 (24.2)	16.33 (16.33, NE)	1.32 (0.27, 6.39)	0.7266	
Sex							0.5997
Male	6/64 (9.4)	NE (NE, NE)	28/159 (17.6)	NE (16.33, NE)	1.33 (0.54, 3.27)	0.5273	
Female	4/45 (8.9)	NE (2.03, NE)	13/108 (12.0)	NE (13.15, NE)	1.01 (0.32, 3.20)	0.9834	

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Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-trt-disc-edp-saf.sas
Output: t14-06-002-014-tte-sub-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:21:26) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.14. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Region							0.9072
USA	0/13 (0.0)	NE (NE, NE)	7/30 (23.3)	NE (3.02, NE)	NE (NE, NE)	0.0986	
Europe	7/68 (10.3)	NE (NE, NE)	26/177 (14.7)	NE (16.33, NE)	0.96 (0.40, 2.26)	0.9200	
Rest of the world	3/28 (10.7)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)	1.03 (0.27, 3.89)	0.9683	
Prior salvage therapy							0.9860
Yes	10/63 (15.9)	NE (NE, NE)	30/161 (18.6)	16.33 (13.15, NE)	0.82 (0.39, 1.70)	0.5854	
No	0/46 (0.0)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	NE (NE, NE)	0.0581	
Number of salvage therapies							0.4945
0	2/55 (3.6)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)	2.23 (0.49, 10.19)	0.2861	
1	6/34 (17.6)	NE (NE, NE)	18/91 (19.8)	16.33 (13.15, NE)	0.77 (0.30, 1.98)	0.5880	
≥2	2/20 (10.0)	NE (2.03, NE)	10/64 (15.6)	NE (NE, NE)	1.20 (0.26, 5.60)	0.8162	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-trt-disc-edp-saf.sas
Output: t14-06-002-014-tte-sub-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:21:26) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Table 14-6.2.14. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)

	SOC Chemotherapy (N = 109)		Blinatumomab (N = 267)				
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)	Hazard Ratio (95% CI)	p-value[a]	Interaction p-value[b]
Prior alloHSCT							0.5706
Yes	4/35 (11.4)	NE (NE, NE)	16/93 (17.2)	NE (16.33, NE)	0.93 (0.30, 2.91)	0.9054	
No	6/74 (8.1)	NE (NE, NE)	25/174 (14.4)	NE (16.33, NE)	1.40 (0.57, 3.45)	0.4659	
Race							0.7362
Caucasian	8/90 (8.9)	NE (NE, NE)	35/226 (15.5)	NE (16.33, NE)	1.28 (0.58, 2.80)	0.5403	
Others	2/19 (10.5)	NE (NE, NE)	6/41 (14.6)	NE (NE, NE)	1.01 (0.20, 5.13)	0.9911	
Central laboratory baseline bone marrow blasts							0.0042
<50%	6/27 (22.2)	NE (2.03, NE)	8/73 (11.0)	NE (16.33, NE)	0.27 (0.08, 0.87)	0.0192	
≥50%	3/77 (3.9)	NE (NE, NE)	26/168 (15.5)	NE (NE, NE)	3.14 (0.94, 10.47)	0.0495	

Safety analysis set includes all subjects who received protocol-specified therapy analyzed according to the treatment they received.
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
[a] p-values were calculated using the unstratified log-rank test.
[b] p-value is from a test of the interaction term in an unstratified Cox model with terms for the covariate and treatment group included, subjects with a missing value of the covariate were not included in the model.
The hazard ratio estimate for all subjects was obtained from an unstratified Cox regression model.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-tte-sub-teae-trt-disc-edp-saf.sas
Output: t14-06-002-014-tte-sub-teae-trt-disc-edp-saf.rtf (Date generated: 03DEC2025:21:26) Source data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Anhang 4-G4.5: Subgruppenanalysen zum Datenschnitt 14. März 2017 (Binäre Analysen)

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1				0.5369
Age group 1: <35 years	60	123		
Number of subjects assessed[c]	32	95		
Events - n (%)	8 (25.0)	42 (44.2)	19.2	
Unstratified odds ratio[a]			2.38	
(95% CI)			(0.97, 5.83)	
p-value			0.0584	
Unstratified risk ratio[a]			1.77	
(95% CI)			(0.93, 3.36)	
p-value			0.0814	
Absolute risk reduction			0.19	
(95% CI)			(0.01, 0.37)	
p-value			0.0367	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1: ≥35 years	74	148		
Number of subjects assessed[c]	40	111		
Events - n (%)	13 (32.5)	49 (44.1)	11.6	
Unstratified odds ratio[a]			1.64	
(95% CI)			(0.77, 3.51)	
p-value			0.2015	
Unstratified risk ratio[a]			1.36	
(95% CI)			(0.83, 2.22)	
p-value			0.2236	
Absolute risk reduction			0.12	
(95% CI)			(-0.06, 0.29)	
p-value			0.1847	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2				0.5064
Age group 2: <35 years	60	124		
Number of subjects assessed[c]	32	95		
Events - n (%)	8 (25.0)	42 (44.2)	19.2	
Unstratified odds ratio[a]			2.38	
(95% CI)			(0.97, 5.83)	
p-value			0.0584	
Unstratified risk ratio[a]			1.77	
(95% CI)			(0.93, 3.36)	
p-value			0.0814	
Absolute risk reduction			0.19	
(95% CI)			(0.01, 0.37)	
p-value			0.0367	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 35 - 54 years	33	80		
Number of subjects assessed[c]	15	64		
Events - n (%)	5 (33.3)	27 (42.2)	8.9	
Unstratified odds ratio[a]			1.46	
(95% CI)			(0.45, 4.76)	
p-value			0.5310	
Unstratified risk ratio[a]			1.27	
(95% CI)			(0.59, 2.74)	
p-value			0.5493	
Absolute risk reduction			0.09	
(95% CI)			(-0.18, 0.36)	
p-value			0.5165	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 55 - 64 years	26	34		
Number of subjects assessed[c]	14	26		
Events - n (%)	2 (14.3)	11 (42.3)	28.0	
Unstratified odds ratio[a]			4.40	
(95% CI)			(0.81, 23.77)	
p-value			0.0852	
Unstratified risk ratio[a]			2.96	
(95% CI)			(0.76, 11.53)	
p-value			0.1175	
Absolute risk reduction			0.28	
(95% CI)			(0.02, 0.54)	
p-value			0.0374	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: ≥65 years	15	33		
Number of subjects assessed[c]	11	21		
Events - n (%)	6 (54.5)	11 (52.4)	-2.2	
Unstratified odds ratio[a]			0.92	
(95% CI)			(0.21, 3.96)	
p-value			0.9073	
Unstratified risk ratio[a]			0.96	
(95% CI)			(0.49, 1.89)	
p-value			0.9066	
Absolute risk reduction			-0.02	
(95% CI)			(-0.39, 0.34)	
p-value			0.9071	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex				0.4900
Sex: Male	77	162		
Number of subjects assessed[c]	43	119		
Events - n (%)	13 (30.2)	49 (41.2)	10.9	
Unstratified odds ratio[a]			1.62	
(95% CI)			(0.77, 3.41)	
p-value			0.2079	
Unstratified risk ratio[a]			1.36	
(95% CI)			(0.82, 2.25)	
p-value			0.2280	
Absolute risk reduction			0.11	
(95% CI)			(-0.05, 0.27)	
p-value			0.1890	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex: Female	57	109		
Number of subjects assessed[c]	29	87		
Events - n (%)	8 (27.6)	42 (48.3)	20.7	
Unstratified odds ratio[a]			2.45	
(95% CI)			(0.98, 6.13)	
p-value			0.0553	
Unstratified risk ratio[a]			1.75	
(95% CI)			(0.93, 3.28)	
p-value			0.0810	
Absolute risk reduction			0.21	
(95% CI)			(0.01, 0.40)	
p-value			0.0362	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region				0.7950
Region: USA	15	31		
Number of subjects assessed[c]	10	22		
Events - n (%)	4 (40.0)	10 (45.5)	5.5	
Unstratified odds ratio[a]			1.25	
(95% CI)			(0.27, 5.70)	
p-value			0.7733	
Unstratified risk ratio[a]			1.14	
(95% CI)			(0.47, 2.76)	
p-value			0.7774	
Absolute risk reduction			0.05	
(95% CI)			(-0.31, 0.42)	
p-value			0.7715	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Europe	85	180		
Number of subjects assessed[c]	47	140		
Events - n (%)	14 (29.8)	64 (45.7)	15.9	
Unstratified odds ratio[a]			1.98	
(95% CI)			(0.98, 4.03)	
p-value			0.0578	
Unstratified risk ratio[a]			1.53	
(95% CI)			(0.95, 2.47)	
p-value			0.0769	
Absolute risk reduction			0.16	
(95% CI)			(0.00, 0.31)	
p-value			0.0435	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Rest of the world	34	60		
Number of subjects assessed[c]	15	44		
Events - n (%)	3 (20.0)	17 (38.6)	18.6	
Unstratified odds ratio[a]			2.52	
(95% CI)			(0.62, 10.25)	
p-value			0.1970	
Unstratified risk ratio[a]			1.93	
(95% CI)			(0.66, 5.68)	
p-value			0.2314	
Absolute risk reduction			0.19	
(95% CI)			(-0.06, 0.43)	
p-value			0.1413	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy				0.1031
Prior salvage therapy: Yes	80	164		
Number of subjects assessed[c]	36	117		
Events - n (%)	5 (13.9)	45 (38.5)	24.6	
Unstratified odds ratio[a]			3.87	
(95% CI)			(1.40, 10.69)	
p-value			0.0089	
Unstratified risk ratio[a]			2.77	
(95% CI)			(1.19, 6.45)	
p-value			0.0182	
Absolute risk reduction			0.25	
(95% CI)			(0.10, 0.39)	
p-value			0.0008	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy: No	54	107		
Number of subjects assessed[c]	36	89		
Events - n (%)	16 (44.4)	46 (51.7)	7.2	
Unstratified odds ratio[a]			1.34	
(95% CI)			(0.61, 2.91)	
p-value			0.4640	
Unstratified risk ratio[a]			1.16	
(95% CI)			(0.77, 1.76)	
p-value			0.4779	
Absolute risk reduction			0.07	
(95% CI)			(-0.12, 0.27)	
p-value			0.4614	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies				0.2191
Number of salvage therapies: 0	65	114		
Number of subjects assessed[c]	39	94		
Events - n (%)	18 (46.2)	51 (54.3)	8.1	
Unstratified odds ratio[a]			1.38	
(95% CI)			(0.65, 2.93)	
p-value			0.3954	
Unstratified risk ratio[a]			1.18	
(95% CI)			(0.80, 1.73)	
p-value			0.4121	
Absolute risk reduction			0.08	
(95% CI)			(-0.11, 0.27)	
p-value			0.3935	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: 1	43	91		
Number of subjects assessed[c]	20	66		
Events - n (%)	3 (15.0)	25 (37.9)	22.9	
Unstratified odds ratio[a]			3.46	
(95% CI)			(0.92, 12.99)	
p-value			0.0665	
Unstratified risk ratio[a]			2.53	
(95% CI)			(0.85, 7.50)	
p-value			0.0952	
Absolute risk reduction			0.23	
(95% CI)			(0.03, 0.42)	
p-value			0.0217	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: ≥2	26	66		
Number of subjects assessed[c]	13	46		
Events - n (%)	0 (0.0)	15 (32.6)	32.6	
Unstratified odds ratio[a]			13.29	
(95% CI)			(0.74, 238.44)	
p-value			0.0791	
Unstratified risk ratio[a]			9.23	
(95% CI)			(0.59, 144.76)	
p-value			0.1134	
Absolute risk reduction			0.29	
(95% CI)			(0.13, 0.46)	
p-value			0.0005	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT				0.1697
Prior alloHSCT: Yes	46	94		
Number of subjects assessed[c]	19	71		
Events - n (%)	2 (10.5)	27 (38.0)	27.5	
Unstratified odds ratio[a]			5.22	
(95% CI)			(1.12, 24.37)	
p-value			0.0357	
Unstratified risk ratio[a]			3.61	
(95% CI)			(0.94, 13.85)	
p-value			0.0611	
Absolute risk reduction			0.28	
(95% CI)			(0.10, 0.45)	
p-value			0.0025	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT: No	88	177		
Number of subjects assessed[c]	53	135		
Events - n (%)	19 (35.8)	64 (47.4)	11.6	
Unstratified odds ratio[a]			1.61	
(95% CI)			(0.84, 3.11)	
p-value			0.1527	
Unstratified risk ratio[a]			1.32	
(95% CI)			(0.89, 1.98)	
p-value			0.1726	
Absolute risk reduction			0.12	
(95% CI)			(-0.04, 0.27)	
p-value			0.1417	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race				0.3272
Race: Caucasian	112	228		
Number of subjects assessed[c]	61	173		
Events - n (%)	17 (27.9)	79 (45.7)	17.8	
Unstratified odds ratio[a]			2.18	
(95% CI)			(1.15, 4.10)	
p-value			0.0164	
Unstratified risk ratio[a]			1.64	
(95% CI)			(1.06, 2.53)	
p-value			0.0262	
Absolute risk reduction			0.18	
(95% CI)			(0.04, 0.31)	
p-value			0.0097	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race: Others	22	43		
Number of subjects assessed[c]	11	33		
Events - n (%)	4 (36.4)	12 (36.4)	0.0	
Unstratified odds ratio[a]			1.00	
(95% CI)			(0.24, 4.13)	
p-value			>0.9999	
Unstratified risk ratio[a]			1.00	
(95% CI)			(0.41, 2.47)	
p-value			>0.9999	
Absolute risk reduction			-0.00	
(95% CI)			(-0.33, 0.33)	
p-value			>0.9999	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts				0.6359
Central laboratory baseline bone marrow blasts: <50%	36	73		
Number of subjects assessed[c]	22	68		
Events - n (%)	9 (40.9)	41 (60.3)	19.4	
Unstratified odds ratio[a]			2.19	
(95% CI)			(0.82, 5.84)	
p-value			0.1158	
Unstratified risk ratio[a]			1.47	
(95% CI)			(0.86, 2.52)	
p-value			0.1576	
Absolute risk reduction			0.19	
(95% CI)			(-0.04, 0.43)	
p-value			0.1075	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.1. Subgroup Analysis for Complete Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts: ≥50%	93	170		
Number of subjects assessed[c]	49	122		
Events - n (%)	11 (22.4)	39 (32.0)	9.5	
Unstratified odds ratio[a]			1.62	
(95% CI)			(0.75, 3.51)	
p-value			0.2186	
Unstratified risk ratio[a]			1.42	
(95% CI)			(0.80, 2.55)	
p-value			0.2333	
Absolute risk reduction			0.10	
(95% CI)			(-0.05, 0.24)	
p-value			0.1926	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cr-fas.sas
Output: t14-04-002-001-binary-sub-cr-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1				0.1315
Age group 1: <35 years	60	123		
Number of subjects assessed[c]	29	73		
Events - n (%)	11 (37.9)	35 (47.9)	10.0	
Unstratified odds ratio[a]			1.51	
(95% CI)			(0.63, 3.63)	
p-value			0.3606	
Unstratified risk ratio[a]			1.26	
(95% CI)			(0.75, 2.13)	
p-value			0.3803	
Absolute risk reduction			0.10	
(95% CI)			(-0.11, 0.31)	
p-value			0.3512	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1: ≥35 years	74	148		
Number of subjects assessed[c]	40	93		
Events - n (%)	8 (20.0)	46 (49.5)	29.5	
Unstratified odds ratio[a]			3.91	
(95% CI)			(1.63, 9.39)	
p-value			0.0022	
Unstratified risk ratio[a]			2.47	
(95% CI)			(1.29, 4.75)	
p-value			0.0066	
Absolute risk reduction			0.29	
(95% CI)			(0.13, 0.45)	
p-value			0.0003	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2				0.1605
Age group 2: <35 years	60	124		
Number of subjects assessed[c]	29	73		
Events - n (%)	11 (37.9)	35 (47.9)	10.0	
Unstratified odds ratio[a]			1.51	
(95% CI)			(0.63, 3.63)	
p-value			0.3606	
Unstratified risk ratio[a]			1.26	
(95% CI)			(0.75, 2.13)	
p-value			0.3803	
Absolute risk reduction			0.10	
(95% CI)			(-0.11, 0.31)	
p-value			0.3512	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 35 - 54 years	33	80		
Number of subjects assessed[c]	17	50		
Events - n (%)	3 (17.6)	25 (50.0)	32.4	
Unstratified odds ratio[a]			4.67	
(95% CI)			(1.19, 18.26)	
p-value			0.0269	
Unstratified risk ratio[a]			2.83	
(95% CI)			(0.98, 8.21)	
p-value			0.0550	
Absolute risk reduction			0.32	
(95% CI)			(0.10, 0.55)	
p-value			0.0054	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 55 - 64 years	26	34		
Number of subjects assessed[c]	11	23		
Events - n (%)	0 (0.0)	12 (52.2)	52.2	
Unstratified odds ratio[a]			25.00	
(95% CI)			(1.32, 474.08)	
p-value			0.0320	
Unstratified risk ratio[a]			12.50	
(95% CI)			(0.81, 193.67)	
p-value			0.0709	
Absolute risk reduction			0.48	
(95% CI)			(0.25, 0.71)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: ≥65 years	15	33		
Number of subjects assessed[c]	12	20		
Events - n (%)	5 (41.7)	9 (45.0)	3.3	
Unstratified odds ratio[a]			1.15	
(95% CI)			(0.27, 4.87)	
p-value			0.8540	
Unstratified risk ratio[a]			1.08	
(95% CI)			(0.47, 2.47)	
p-value			0.8552	
Absolute risk reduction			0.03	
(95% CI)			(-0.32, 0.39)	
p-value			0.8536	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex				0.7990
Sex: Male	77	162		
Number of subjects assessed[c]	42	95		
Events - n (%)	10 (23.8)	40 (42.1)	18.3	
Unstratified odds ratio[a]			2.33	
(95% CI)			(1.03, 5.28)	
p-value			0.0431	
Unstratified risk ratio[a]			1.77	
(95% CI)			(0.98, 3.19)	
p-value			0.0583	
Absolute risk reduction			0.18	
(95% CI)			(0.02, 0.35)	
p-value			0.0275	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex: Female	57	109		
Number of subjects assessed[c]	27	71		
Events - n (%)	9 (33.3)	41 (57.7)	24.4	
Unstratified odds ratio[a]			2.73	
(95% CI)			(1.08, 6.92)	
p-value			0.0338	
Unstratified risk ratio[a]			1.73	
(95% CI)			(0.98, 3.06)	
p-value			0.0585	
Absolute risk reduction			0.24	
(95% CI)			(0.03, 0.46)	
p-value			0.0238	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region				0.1852
Region: USA	15	31		
Number of subjects assessed[c]	8	19		
Events - n (%)	5 (62.5)	11 (57.9)	-4.6	
Unstratified odds ratio[a]			0.83	
(95% CI)			(0.15, 4.50)	
p-value			0.8241	
Unstratified risk ratio[a]			0.93	
(95% CI)			(0.48, 1.79)	
p-value			0.8201	
Absolute risk reduction			-0.05	
(95% CI)			(-0.45, 0.36)	
p-value			0.8225	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Europe	85	180		
Number of subjects assessed[c]	45	112		
Events - n (%)	12 (26.7)	52 (46.4)	19.8	
Unstratified odds ratio[a]			2.38	
(95% CI)			(1.12, 5.09)	
p-value			0.0247	
Unstratified risk ratio[a]			1.74	
(95% CI)			(1.03, 2.94)	
p-value			0.0380	
Absolute risk reduction			0.20	
(95% CI)			(0.04, 0.36)	
p-value			0.0147	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Rest of the world	34	60		
Number of subjects assessed[c]	16	35		
Events - n (%)	2 (12.5)	18 (51.4)	38.9	
Unstratified odds ratio[a]			7.41	
(95% CI)			(1.46, 37.57)	
p-value			0.0156	
Unstratified risk ratio[a]			4.11	
(95% CI)			(1.08, 15.65)	
p-value			0.0379	
Absolute risk reduction			0.39	
(95% CI)			(0.16, 0.62)	
p-value			0.0010	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy				0.0755
Prior salvage therapy: Yes	80	164		
Number of subjects assessed[c]	35	93		
Events - n (%)	6 (17.1)	46 (49.5)	32.3	
Unstratified odds ratio[a]			4.73	
(95% CI)			(1.80, 12.46)	
p-value			0.0017	
Unstratified risk ratio[a]			2.89	
(95% CI)			(1.35, 6.15)	
p-value			0.0061	
Absolute risk reduction			0.32	
(95% CI)			(0.16, 0.48)	
p-value			<0.0001	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy: No	54	107		
Number of subjects assessed[c]	34	73		
Events - n (%)	13 (38.2)	35 (47.9)	9.7	
Unstratified odds ratio[a]			1.49	
(95% CI)			(0.65, 3.41)	
p-value			0.3482	
Unstratified risk ratio[a]			1.25	
(95% CI)			(0.77, 2.05)	
p-value			0.3649	
Absolute risk reduction			0.10	
(95% CI)			(-0.10, 0.30)	
p-value			0.3402	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies				0.1310
Number of salvage therapies: 0	65	114		
Number of subjects assessed[c]	40	83		
Events - n (%)	15 (37.5)	40 (48.2)	10.7	
Unstratified odds ratio[a]			1.55	
(95% CI)			(0.72, 3.35)	
p-value			0.2652	
Unstratified risk ratio[a]			1.29	
(95% CI)			(0.81, 2.03)	
p-value			0.2831	
Absolute risk reduction			0.11	
(95% CI)			(-0.08, 0.29)	
p-value			0.2562	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: 1	43	91		
Number of subjects assessed[c]	18	50		
Events - n (%)	1 (5.6)	22 (44.0)	38.4	
Unstratified odds ratio[a]			13.35	
(95% CI)			(1.65, 108.22)	
p-value			0.0152	
Unstratified risk ratio[a]			7.92	
(95% CI)			(1.15, 54.58)	
p-value			0.0356	
Absolute risk reduction			0.38	
(95% CI)			(0.21, 0.56)	
p-value			<0.0001	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: ≥2	26	66		
Number of subjects assessed[c]	11	33		
Events - n (%)	3 (27.3)	19 (57.6)	30.3	
Unstratified odds ratio[a]			3.62	
(95% CI)			(0.81, 16.15)	
p-value			0.0919	
Unstratified risk ratio[a]			2.11	
(95% CI)			(0.77, 5.79)	
p-value			0.1464	
Absolute risk reduction			0.30	
(95% CI)			(-0.01, 0.62)	
p-value			0.0574	

Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-mrd-fas.sas
Output: t14-04-002-002-binary-sub-mrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT				0.2867
Prior alloHSCT: Yes	46	94		
Number of subjects assessed[c]	19	53		
Events - n (%)	3 (15.8)	25 (47.2)	31.4	
Unstratified odds ratio[a]			4.76	
(95% CI)			(1.24, 18.29)	
p-value			0.0231	
Unstratified risk ratio[a]			2.99	
(95% CI)			(1.02, 8.77)	
p-value			0.0464	
Absolute risk reduction			0.31	
(95% CI)			(0.10, 0.53)	
p-value			0.0037	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT: No	88	177		
Number of subjects assessed[c]	50	113		
Events - n (%)	16 (32.0)	56 (49.6)	17.6	
Unstratified odds ratio[a]			2.09	
(95% CI)			(1.04, 4.20)	
p-value			0.0391	
Unstratified risk ratio[a]			1.55	
(95% CI)			(0.99, 2.42)	
p-value			0.0539	
Absolute risk reduction			0.18	
(95% CI)			(0.02, 0.33)	
p-value			0.0302	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race				0.5766
Race: Caucasian	112	228		
Number of subjects assessed[c]	60	138		
Events - n (%)	15 (25.0)	65 (47.1)	22.1	
Unstratified odds ratio[a]			2.67	
(95% CI)			(1.36, 5.24)	
p-value			0.0042	
Unstratified risk ratio[a]			1.88	
(95% CI)			(1.17, 3.02)	
p-value			0.0086	
Absolute risk reduction			0.22	
(95% CI)			(0.08, 0.36)	
p-value			0.0016	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race: Others	22	43		
Number of subjects assessed[c]	9	28		
Events - n (%)	4 (44.4)	16 (57.1)	12.7	
Unstratified odds ratio[a]			1.67	
(95% CI)			(0.37, 7.57)	
p-value			0.5081	
Unstratified risk ratio[a]			1.29	
(95% CI)			(0.58, 2.86)	
p-value			0.5369	
Absolute risk reduction			0.13	
(95% CI)			(-0.25, 0.50)	
p-value			0.5044	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts				0.8920
Central laboratory baseline bone marrow blasts: <50%	36	73		
Number of subjects assessed[c]	22	60		
Events - n (%)	6 (27.3)	31 (51.7)	24.4	
Unstratified odds ratio[a]			2.85	
(95% CI)			(0.98, 8.28)	
p-value			0.0541	
Unstratified risk ratio[a]			1.89	
(95% CI)			(0.92, 3.91)	
p-value			0.0841	
Absolute risk reduction			0.24	
(95% CI)			(0.02, 0.47)	
p-value			0.0336	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.2. Subgroup Analysis of MRD (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts: ≥50%	93	170		
Number of subjects assessed[c]	46	94		
Events - n (%)	12 (26.1)	45 (47.9)	21.8	
Unstratified odds ratio[a]			2.60	
(95% CI)			(1.20, 5.63)	
p-value			0.0153	
Unstratified risk ratio[a]			1.84	
(95% CI)			(1.08, 3.12)	
p-value			0.0248	
Absolute risk reduction			0.22	
(95% CI)			(0.06, 0.38)	
p-value			0.0085	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD=Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1				0.4826
Age group 1: <35 years	60	123		
Number of subjects assessed[c]	29	73		
Events - n (%)	7 (24.1)	31 (42.5)	18.3	
Unstratified odds ratio[a]			2.32	
(95% CI)			(0.88, 6.11)	
p-value			0.0887	
Unstratified risk ratio[a]			1.76	
(95% CI)			(0.88, 3.54)	
p-value			0.1128	
Absolute risk reduction			0.18	
(95% CI)			(-0.01, 0.38)	
p-value			0.0622	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 1: ≥35 years	74	148		
Number of subjects assessed[c]	40	93		
Events - n (%)	5 (12.5)	33 (35.5)	23.0	
Unstratified odds ratio[a]			3.85	
(95% CI)			(1.38, 10.77)	
p-value			0.0102	
Unstratified risk ratio[a]			2.84	
(95% CI)			(1.20, 6.74)	
p-value			0.0180	
Absolute risk reduction			0.23	
(95% CI)			(0.09, 0.37)	
p-value			0.0014	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2				0.4957
Age group 2: <35 years	60	124		
Number of subjects assessed[c]	29	73		
Events - n (%)	7 (24.1)	31 (42.5)	18.3	
Unstratified odds ratio[a]			2.32	
(95% CI)			(0.88, 6.11)	
p-value			0.0887	
Unstratified risk ratio[a]			1.76	
(95% CI)			(0.88, 3.54)	
p-value			0.1128	
Absolute risk reduction			0.18	
(95% CI)			(-0.01, 0.38)	
p-value			0.0622	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 35 - 54 years	33	80		
Number of subjects assessed[c]	17	50		
Events - n (%)	2 (11.8)	19 (38.0)	26.2	
Unstratified odds ratio[a]			4.59	
(95% CI)			(0.94, 22.35)	
p-value			0.0588	
Unstratified risk ratio[a]			3.23	
(95% CI)			(0.84, 12.45)	
p-value			0.0885	
Absolute risk reduction			0.26	
(95% CI)			(0.06, 0.47)	
p-value			0.0117	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: 55 - 64 years	26	34		
Number of subjects assessed[c]	11	23		
Events - n (%)	0 (0.0)	8 (34.8)	34.8	
Unstratified odds ratio[a]			12.61	
(95% CI)			(0.66, 241.29)	
p-value			0.0924	
Unstratified risk ratio[a]			8.50	
(95% CI)			(0.53, 135.20)	
p-value			0.1295	
Absolute risk reduction			0.31	
(95% CI)			(0.09, 0.53)	
p-value			0.0059	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Age group 2: ≥65 years	15	33		
Number of subjects assessed[c]	12	20		
Events - n (%)	3 (25.0)	6 (30.0)	5.0	
Unstratified odds ratio[a]			1.29	
(95% CI)			(0.25, 6.49)	
p-value			0.7610	
Unstratified risk ratio[a]			1.20	
(95% CI)			(0.37, 3.93)	
p-value			0.7633	
Absolute risk reduction			0.05	
(95% CI)			(-0.27, 0.37)	
p-value			0.7571	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex				0.7171
Sex: Male	77	162		
Number of subjects assessed[c]	42	95		
Events - n (%)	5 (11.9)	30 (31.6)	19.7	
Unstratified odds ratio[a]			3.42	
(95% CI)			(1.22, 9.56)	
p-value			0.0193	
Unstratified risk ratio[a]			2.65	
(95% CI)			(1.11, 6.36)	
p-value			0.0288	
Absolute risk reduction			0.20	
(95% CI)			(0.06, 0.33)	
p-value			0.0044	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Sex: Female	57	109		
Number of subjects assessed[c]	27	71		
Events - n (%)	7 (25.9)	34 (47.9)	22.0	
Unstratified odds ratio[a]			2.63	
(95% CI)			(0.99, 6.99)	
p-value			0.0532	
Unstratified risk ratio[a]			1.85	
(95% CI)			(0.93, 3.65)	
p-value			0.0779	
Absolute risk reduction			0.22	
(95% CI)			(0.02, 0.42)	
p-value			0.0331	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region				0.2252
Region: USA	15	31		
Number of subjects assessed[c]	8	19		
Events - n (%)	5 (62.5)	11 (57.9)	-4.6	
Unstratified odds ratio[a]			0.83	
(95% CI)			(0.15, 4.50)	
p-value			0.8241	
Unstratified risk ratio[a]			0.93	
(95% CI)			(0.48, 1.79)	
p-value			0.8201	
Absolute risk reduction			-0.05	
(95% CI)			(-0.45, 0.36)	
p-value			0.8225	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Europe	85	180		
Number of subjects assessed[c]	45	112		
Events - n (%)	5 (11.1)	41 (36.6)	25.5	
Unstratified odds ratio[a]			4.62	
(95% CI)			(1.69, 12.63)	
p-value			0.0029	
Unstratified risk ratio[a]			3.29	
(95% CI)			(1.39, 7.80)	
p-value			0.0067	
Absolute risk reduction			0.25	
(95% CI)			(0.13, 0.38)	
p-value			<0.0001	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Region: Rest of the world	34	60		
Number of subjects assessed[c]	16	35		
Events - n (%)	2 (12.5)	12 (34.3)	21.8	
Unstratified odds ratio[a]			3.65	
(95% CI)			(0.71, 18.78)	
p-value			0.1211	
Unstratified risk ratio[a]			2.74	
(95% CI)			(0.69, 10.85)	
p-value			0.1504	
Absolute risk reduction			0.22	
(95% CI)			(-0.01, 0.44)	
p-value			0.0586	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy				0.0485
Prior salvage therapy: Yes	80	164		
Number of subjects assessed[c]	35	93		
Events - n (%)	2 (5.7)	34 (36.6)	30.8	
Unstratified odds ratio[a]			9.51	
(95% CI)			(2.15, 42.11)	
p-value			0.0030	
Unstratified risk ratio[a]			6.40	
(95% CI)			(1.62, 25.23)	
p-value			0.0080	
Absolute risk reduction			0.31	
(95% CI)			(0.18, 0.43)	
p-value			<0.0001	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior salvage therapy: No	54	107		
Number of subjects assessed[c]	34	73		
Events - n (%)	10 (29.4)	30 (41.1)	11.7	
Unstratified odds ratio[a]			1.67	
(95% CI)			(0.70, 4.01)	
p-value			0.2471	
Unstratified risk ratio[a]			1.40	
(95% CI)			(0.78, 2.52)	
p-value			0.2654	
Absolute risk reduction			0.12	
(95% CI)			(-0.07, 0.31)	
p-value			0.2287	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies				0.1772
Number of salvage therapies: 0	65	114		
Number of subjects assessed[c]	40	83		
Events - n (%)	11 (27.5)	33 (39.8)	12.3	
Unstratified odds ratio[a]			1.74	
(95% CI)			(0.77, 3.96)	
p-value			0.1865	
Unstratified risk ratio[a]			1.45	
(95% CI)			(0.82, 2.55)	
p-value			0.2038	
Absolute risk reduction			0.12	
(95% CI)			(-0.05, 0.30)	
p-value			0.1670	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: 1	43	91		
Number of subjects assessed[c]	18	50		
Events - n (%)	0 (0.0)	16 (32.0)	32.0	
Unstratified odds ratio[a]			17.70	
(95% CI)			(1.00, 311.97)	
p-value			0.0497	
Unstratified risk ratio[a]			12.29	
(95% CI)			(0.78, 194.97)	
p-value			0.0752	
Absolute risk reduction			0.30	
(95% CI)			(0.15, 0.44)	
p-value			<0.0001	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Number of salvage therapies: ≥2	26	66		
Number of subjects assessed[c]	11	33		
Events - n (%)	1 (9.1)	15 (45.5)	36.4	
Unstratified odds ratio[a]			8.33	
(95% CI)			(0.95, 72.75)	
p-value			0.0551	
Unstratified risk ratio[a]			5.00	
(95% CI)			(0.74, 33.62)	
p-value			0.0979	
Absolute risk reduction			0.36	
(95% CI)			(0.12, 0.60)	
p-value			0.0030	

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N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT				0.3594
Prior alloHSCT: Yes	46	94		
Number of subjects assessed[c]	19	53		
Events - n (%)	2 (10.5)	21 (39.6)	29.1	
Unstratified odds ratio[a]			5.58	
(95% CI)			(1.17, 26.68)	
p-value			0.0314	
Unstratified risk ratio[a]			3.76	
(95% CI)			(0.97, 14.55)	
p-value			0.0547	
Absolute risk reduction			0.29	
(95% CI)			(0.10, 0.48)	
p-value			0.0028	

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[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Prior alloHSCT: No	88	177		
Number of subjects assessed[c]	50	113		
Events - n (%)	10 (20.0)	43 (38.1)	18.1	
Unstratified odds ratio[a]			2.46	
(95% CI)			(1.11, 5.42)	
p-value			0.0258	
Unstratified risk ratio[a]			1.90	
(95% CI)			(1.04, 3.47)	
p-value			0.0363	
Absolute risk reduction			0.18	
(95% CI)			(0.04, 0.32)	
p-value			0.0130	

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[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
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Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race				0.1516
Race: Caucasian	112	228		
Number of subjects assessed[c]	60	138		
Events - n (%)	8 (13.3)	51 (37.0)	23.6	
Unstratified odds ratio[a]			3.81	
(95% CI)			(1.68, 8.66)	
p-value			0.0014	
Unstratified risk ratio[a]			2.77	
(95% CI)			(1.40, 5.48)	
p-value			0.0033	
Absolute risk reduction			0.24	
(95% CI)			(0.12, 0.35)	
p-value			<0.0001	

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[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
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Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Race: Others	22	43		
Number of subjects assessed[c]	9	28		
Events - n (%)	4 (44.4)	13 (46.4)	2.0	
Unstratified odds ratio[a]			1.08	
(95% CI)			(0.24, 4.90)	
p-value			0.9174	
Unstratified risk ratio[a]			1.04	
(95% CI)			(0.45, 2.40)	
p-value			0.9180	
Absolute risk reduction			0.02	
(95% CI)			(-0.35, 0.39)	
p-value			0.9171	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts				0.7824
Central laboratory baseline bone marrow blasts: <50%	36	73		
Number of subjects assessed[c]	22	60		
Events - n (%)	4 (18.2)	23 (38.3)	20.2	
Unstratified odds ratio[a]			2.80	
(95% CI)			(0.84, 9.31)	
p-value			0.0935	
Unstratified risk ratio[a]			2.11	
(95% CI)			(0.82, 5.41)	
p-value			0.1210	
Absolute risk reduction			0.20	
(95% CI)			(-0.00, 0.40)	
p-value			0.0514	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Table 14-4.2.3. Subgroup Analysis of Complete MRD Remission (Full Analysis Set)

Subgroup	SOC Chemotherapy (N=134)	Blinatumomab (N=271)	Treatment Difference	Interaction p-value[b]
Central laboratory baseline bone marrow blasts: ≥50%	93	170		
Number of subjects assessed[c]	46	94		
Events - n (%)	7 (15.2)	36 (38.3)	23.1	
Unstratified odds ratio[a]			3.46	
(95% CI)			(1.40, 8.55)	
p-value			0.0073	
Unstratified risk ratio[a]			2.52	
(95% CI)			(1.21, 5.22)	
p-value			0.0131	
Absolute risk reduction			0.23	
(95% CI)			(0.09, 0.37)	
p-value			0.0016	

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Full analysis set includes all randomized subjects analyzed according to their randomized treatment assignment, regardless of the treatment received.
N = Number of subjects in analysis set. n = Number of subjects with observed data. CI = Confidence interval. MRD = Minimal residual disease. NE = Not estimable.
[a] The odds ratio obtained from a logistic regression model with logit link and risk ratio obtained from generalized binomial model with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate/ risk for Blinatumomab relative to SOC Chemotherapy.
[b] p-value is from the test of the interaction term in an unstratified logistic regression model with terms for the covariates and treatment group.
[c] Number of subjects in the full analysis set with at least one evaluable post-baseline disease assessment.
In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.
Age group1, prior salvage therapy and prior alloHSCT are as per randomized strata.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/tables/t-binary-sub-cmrd-fas.sas
Output: t14-04-002-003-binary-sub-cmrd-fas.rtf (Date generated: 22JUN2025:22:27) Source data: adam_fa.adsl, adam_fa.adbase, adam_fa.adrs

Anhang 4-G4.6: Subgruppenanalysen zum Datenschnitt 14. März 2017 (Grafiken)

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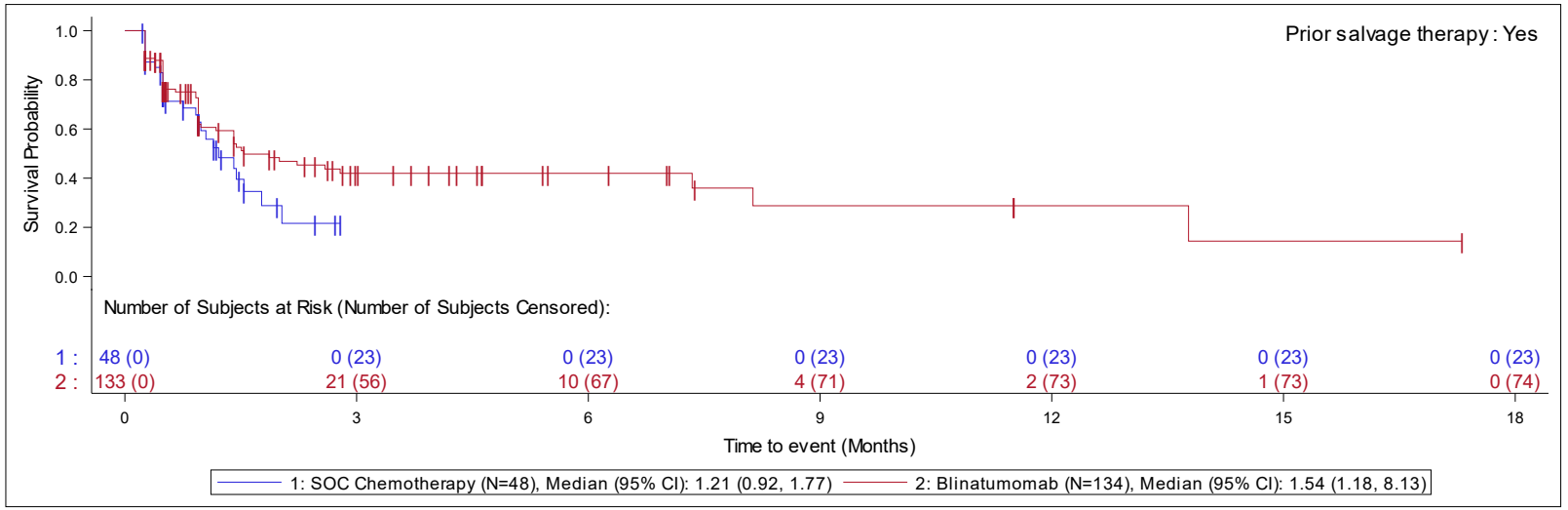
Figure 14-4.4.1. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-allss-ts-allas.sas
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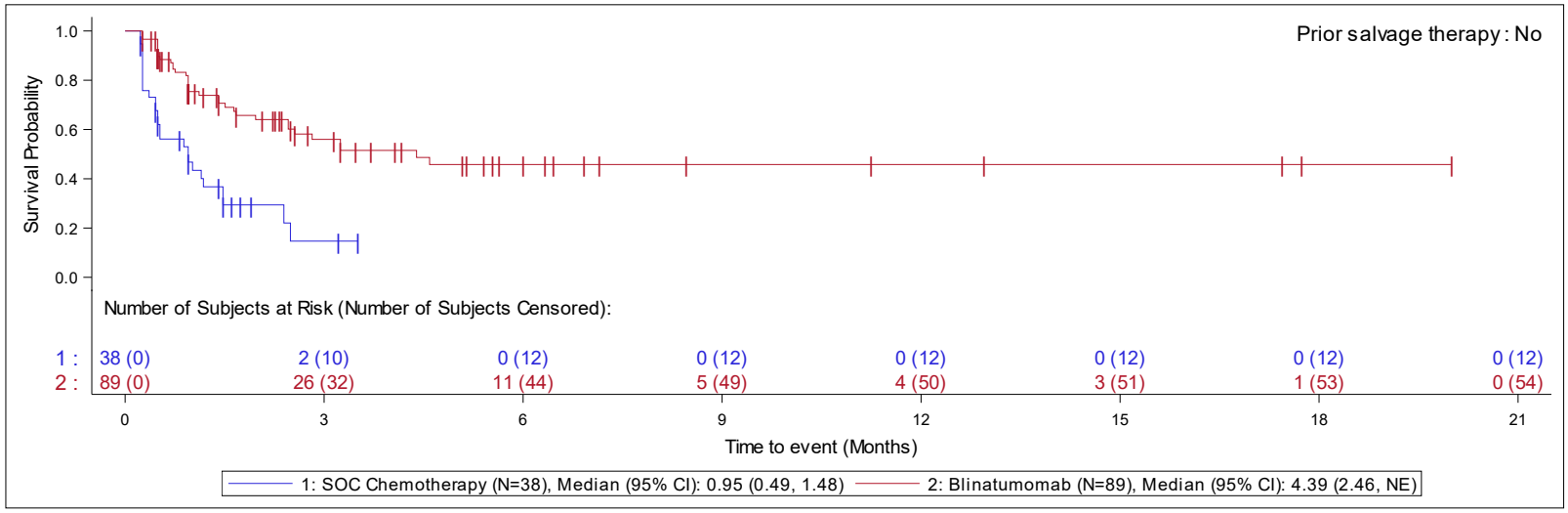
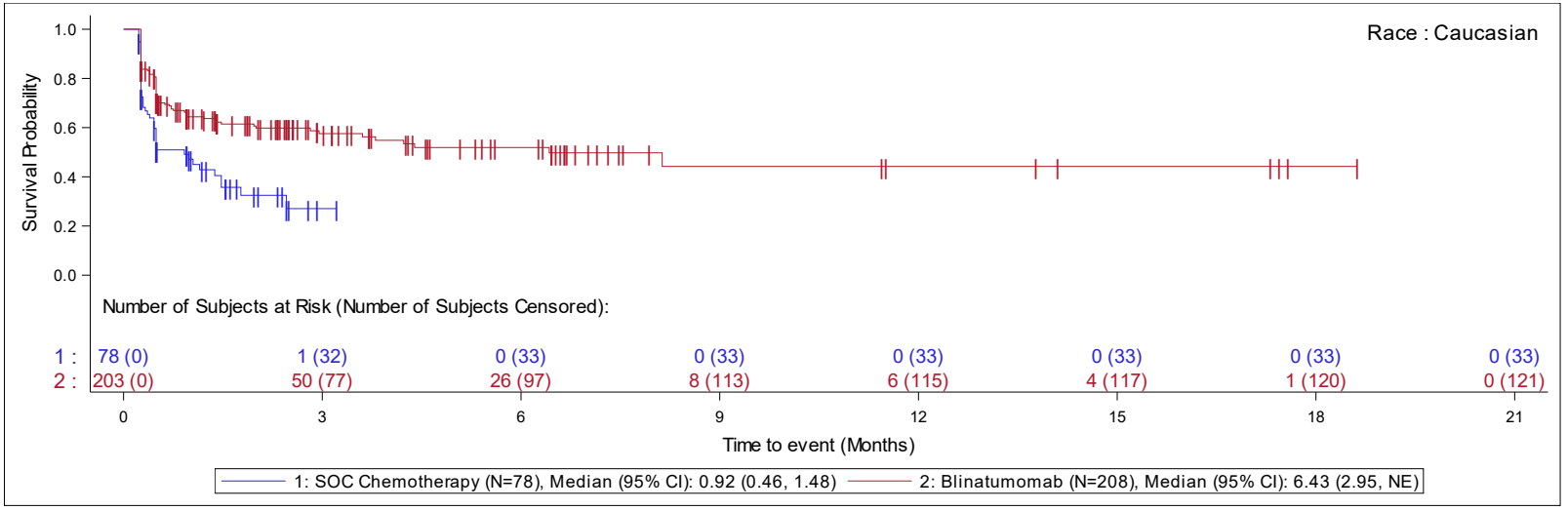
Figure 14-4.4.1. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 7.2 points in Change from Baseline for ALLSS Sum Score (ALLSS Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
ALLSS analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline ALLSS total score.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-allss-ts-allas.sas
Output: f14-04-004-001-km-sub-de-allss-ts-allas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam.adtteqs

Figure 14-4.4.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30
(EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-ghs-eqcas.sas
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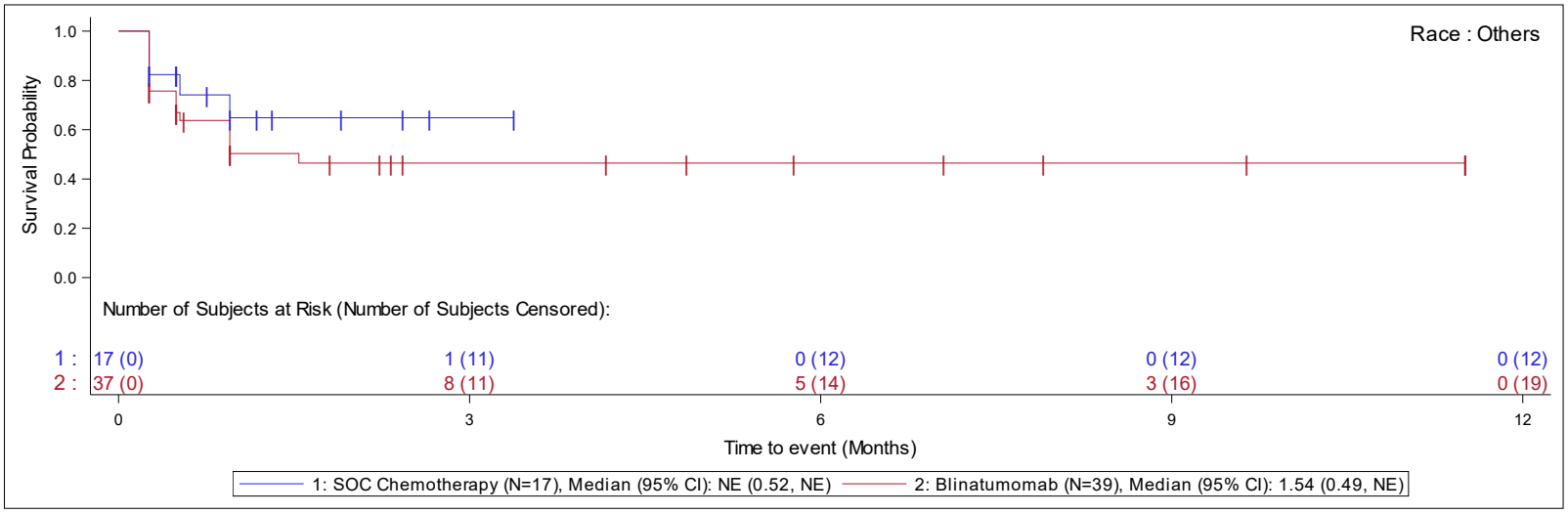
Figure 14-4.4.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Global Health Status or QoL of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-ghs-eqcas.sas
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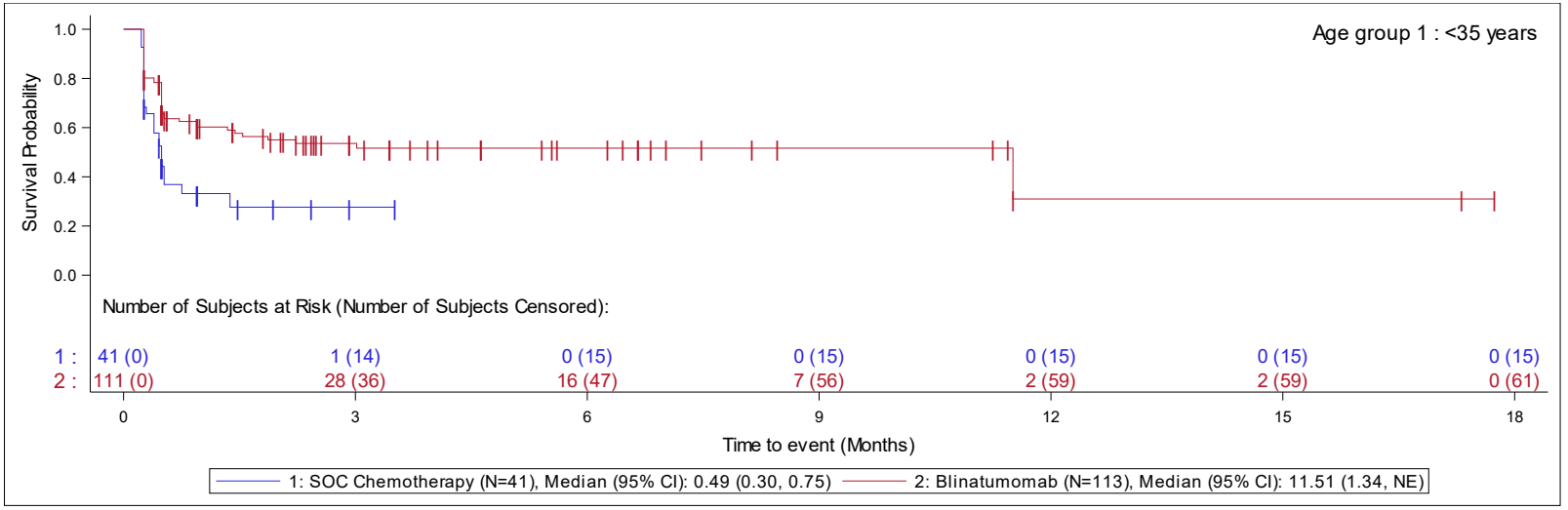
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
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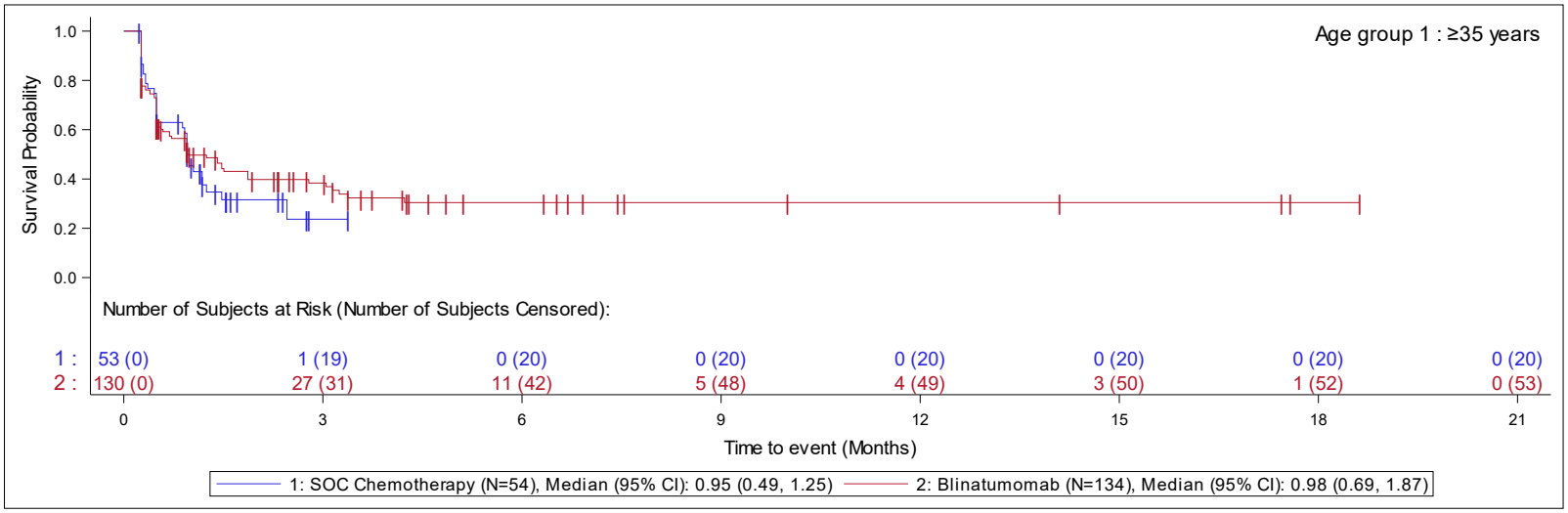
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

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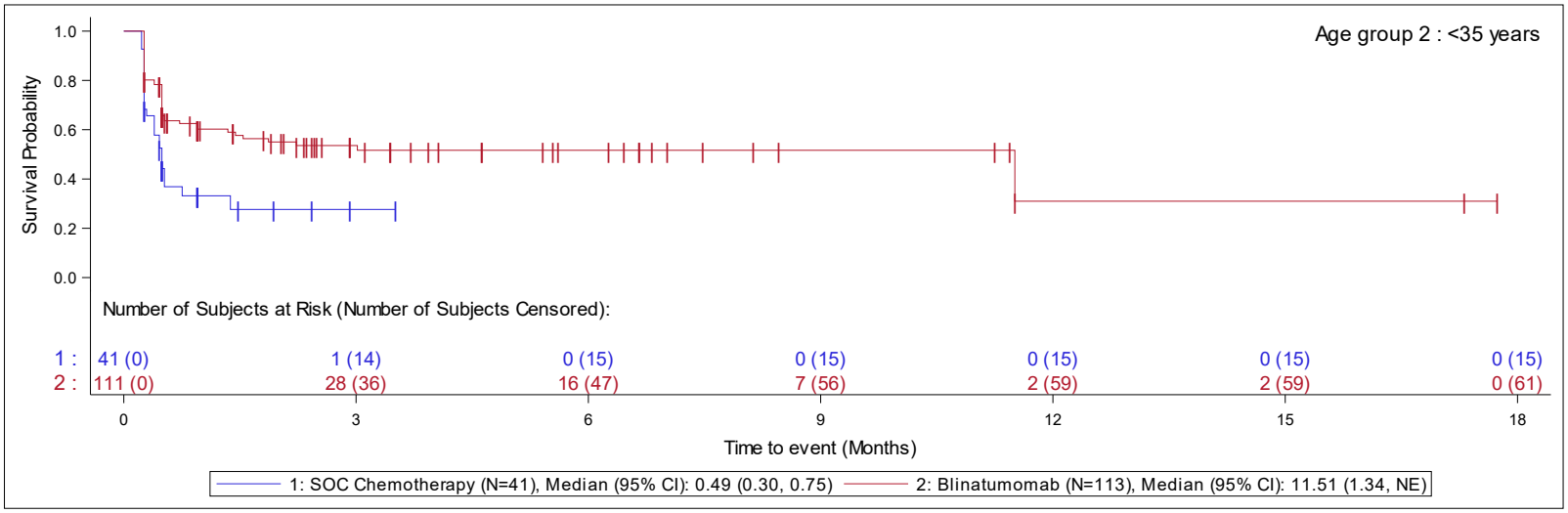
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

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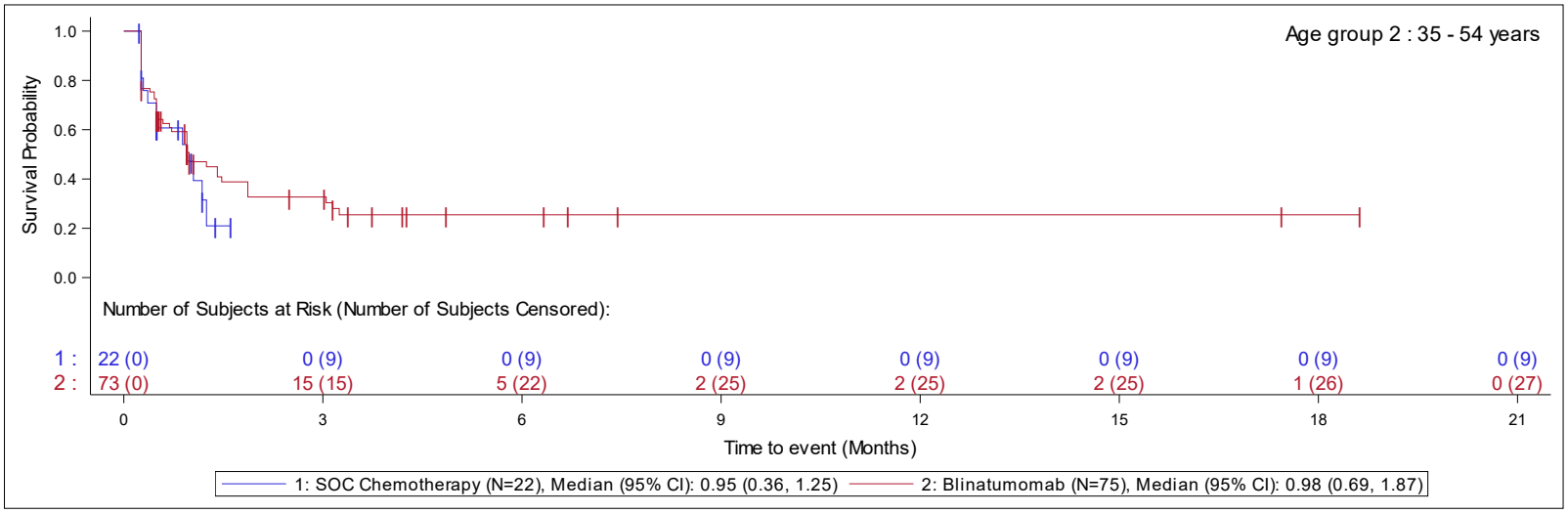
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

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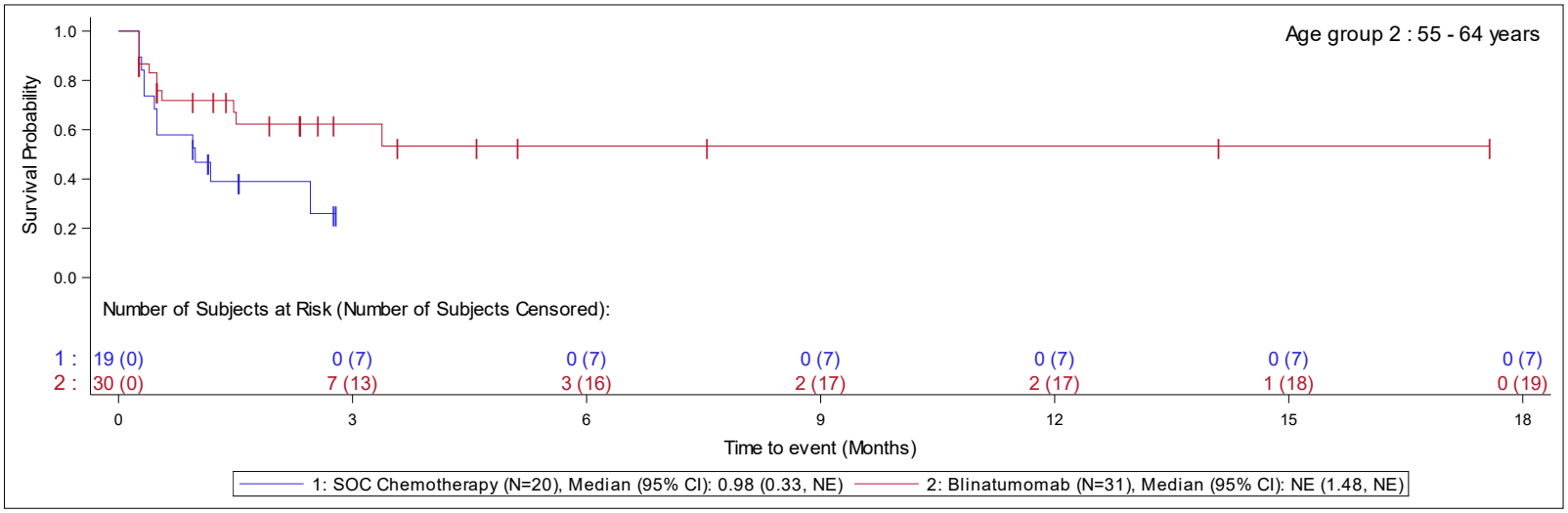
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

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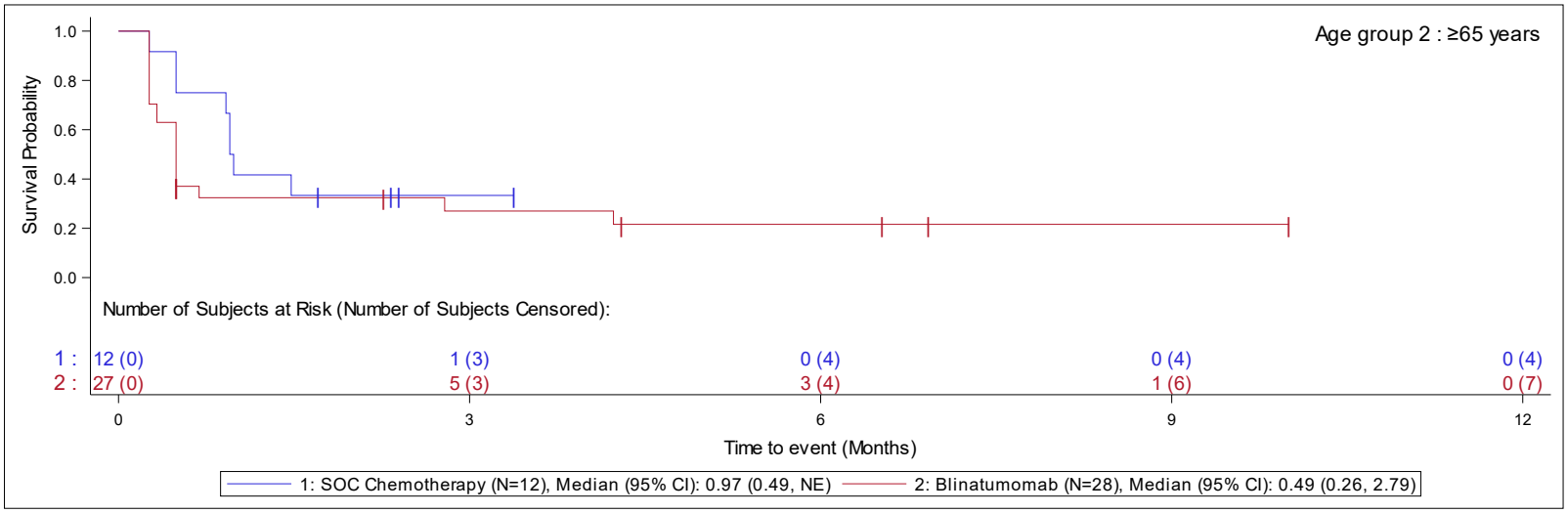
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
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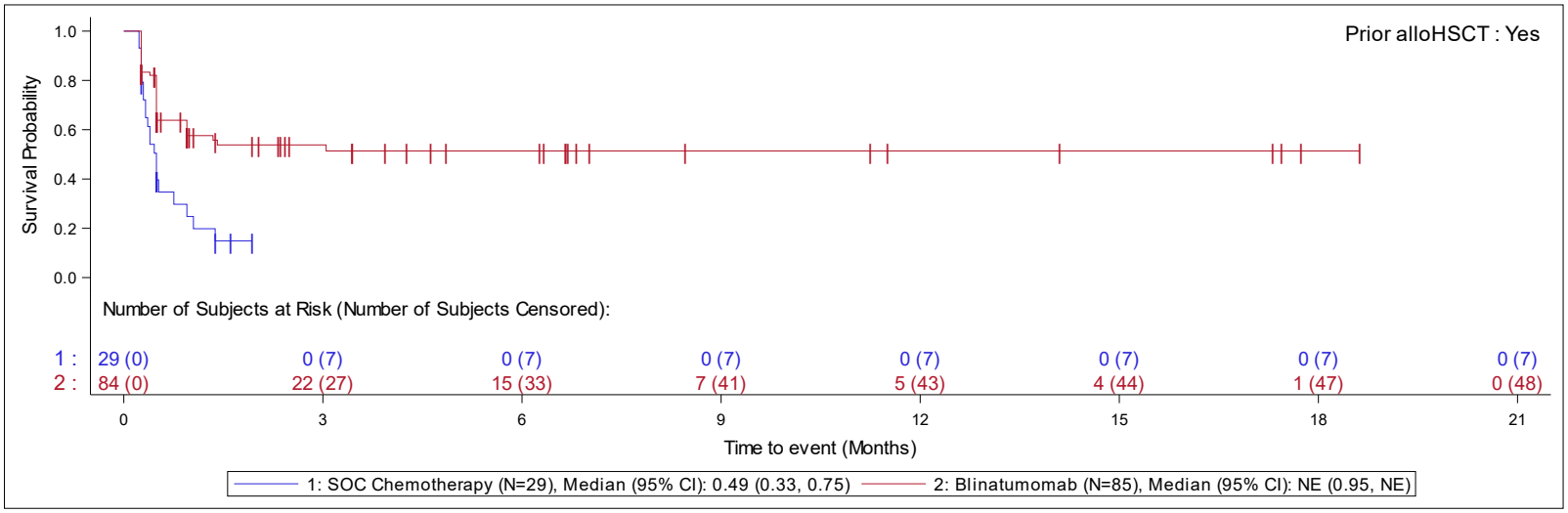
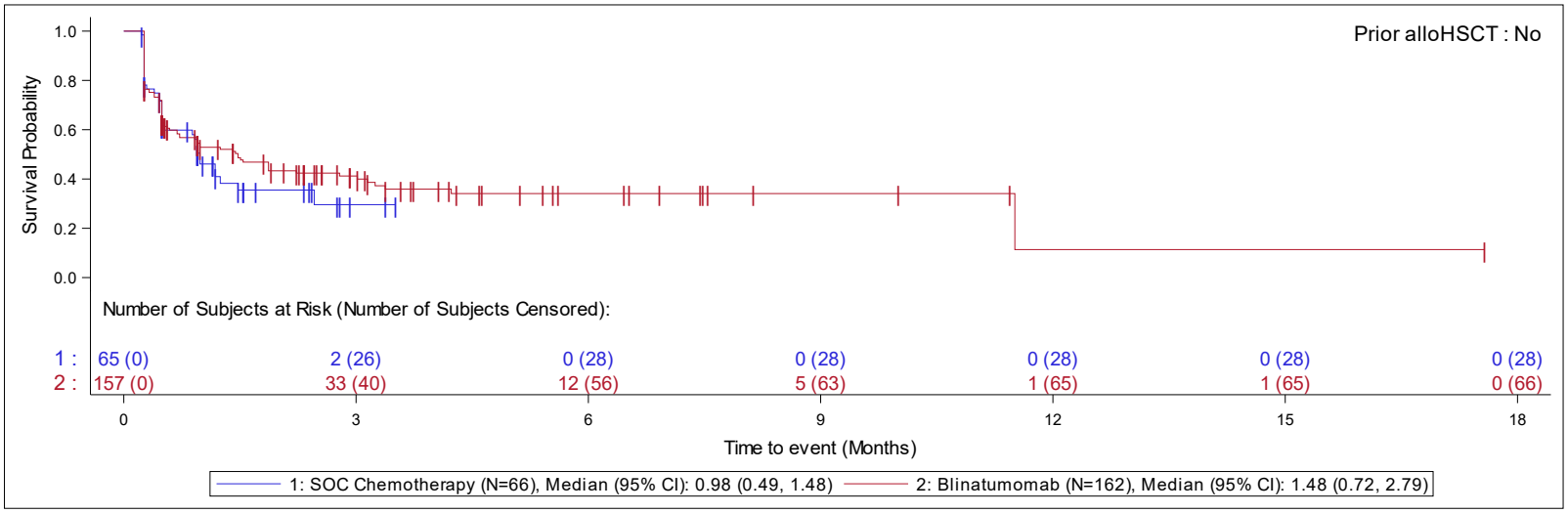
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

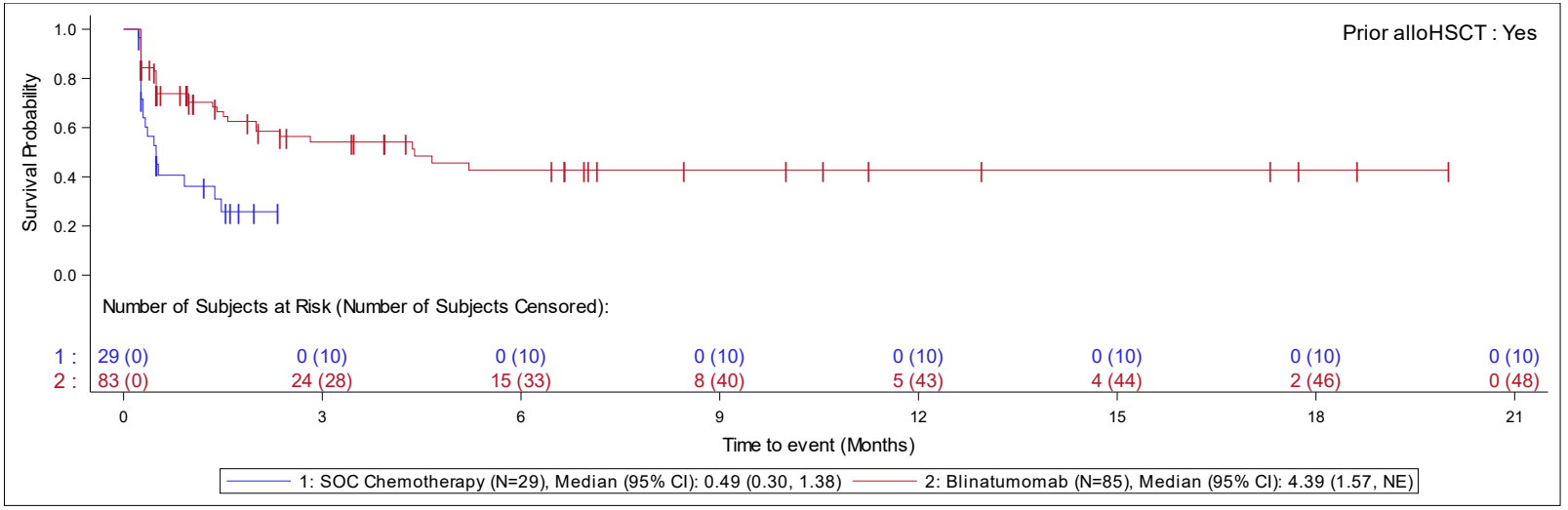
Figure 14-4.4.3. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Physical Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-pf-eqcas.sas
Output: f14-04-004-003-km-sub-de-eortc-pf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

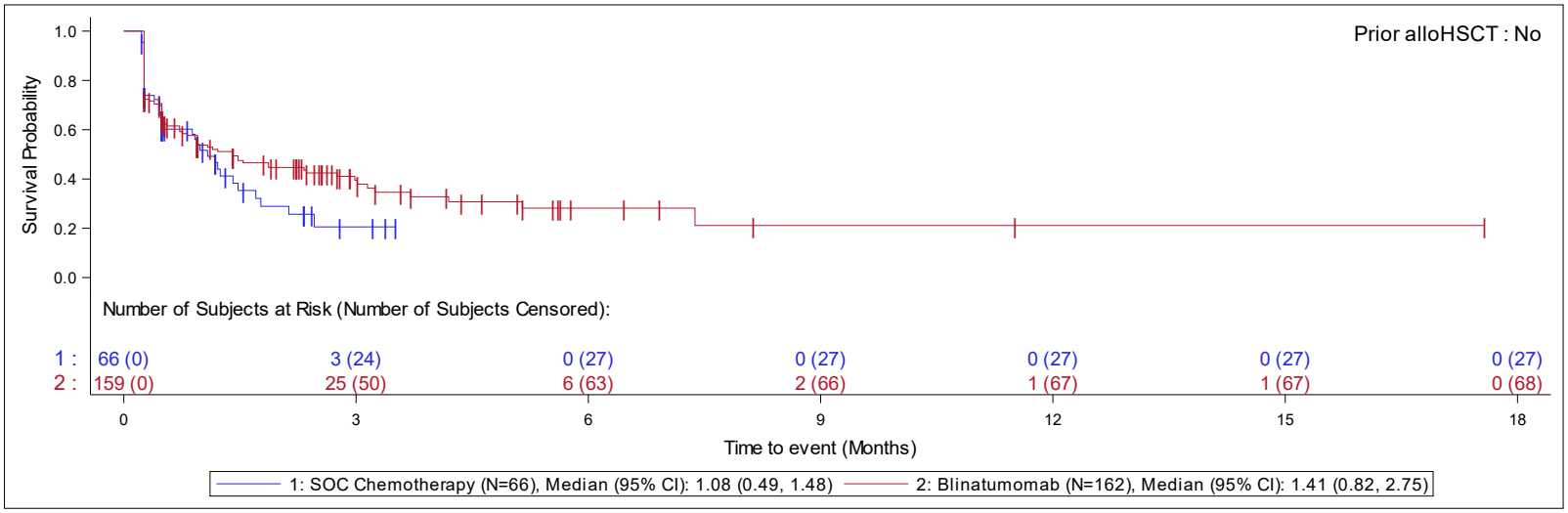
Figure 14-4.4.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-cf-eqcas.sas
Output: f14-04-004-005-km-sub-de-eortc-cf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

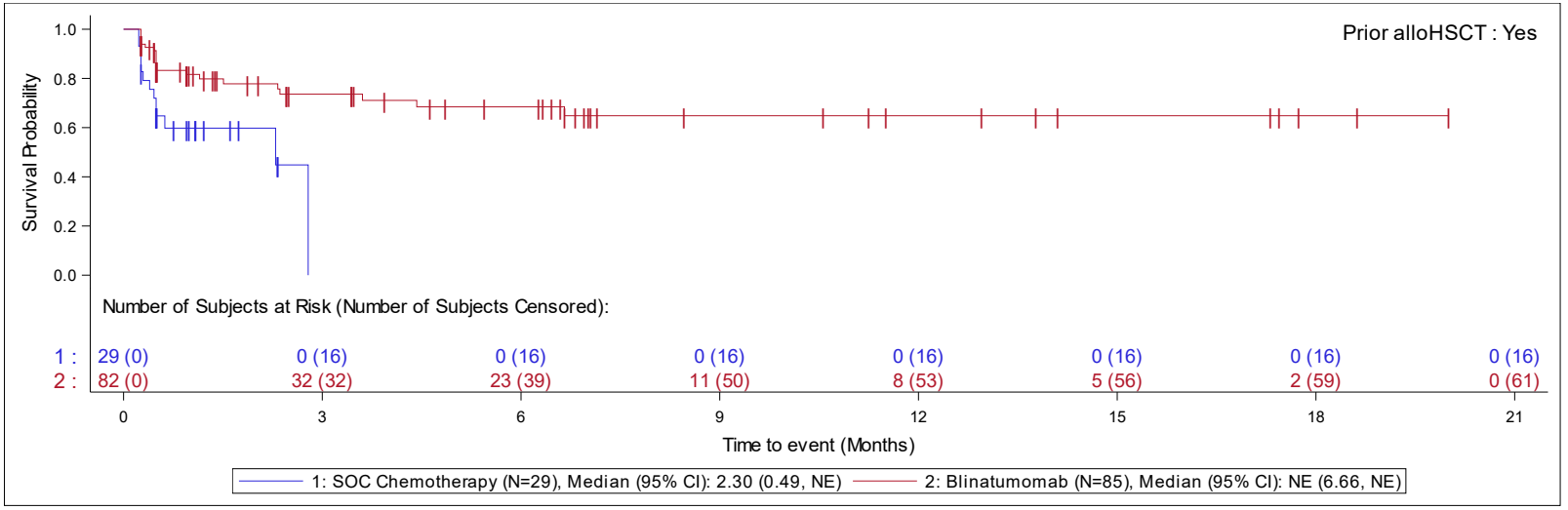
Figure 14-4.4.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Cognitive Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-cf-eqcas.sas
Output: f14-04-004-005-km-sub-de-eortc-cf-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

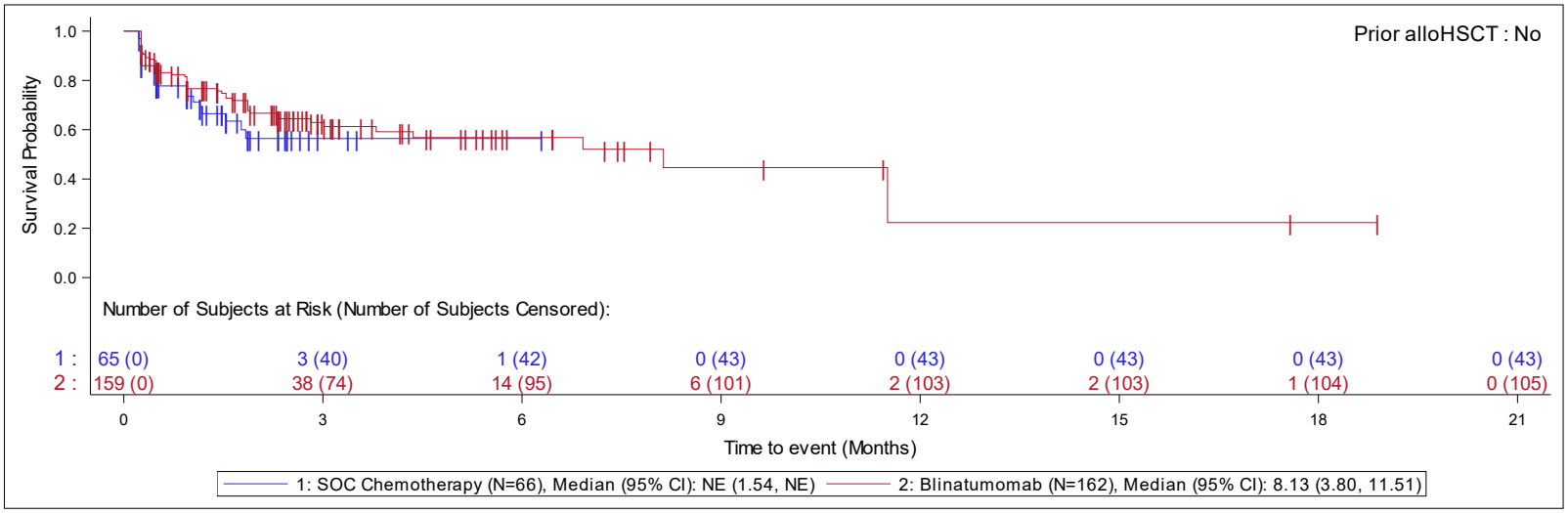
Figure 14-4.4.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-ef-eqcas.sas
Output: f14-04-004-006-km-sub-de-eortc-ef-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

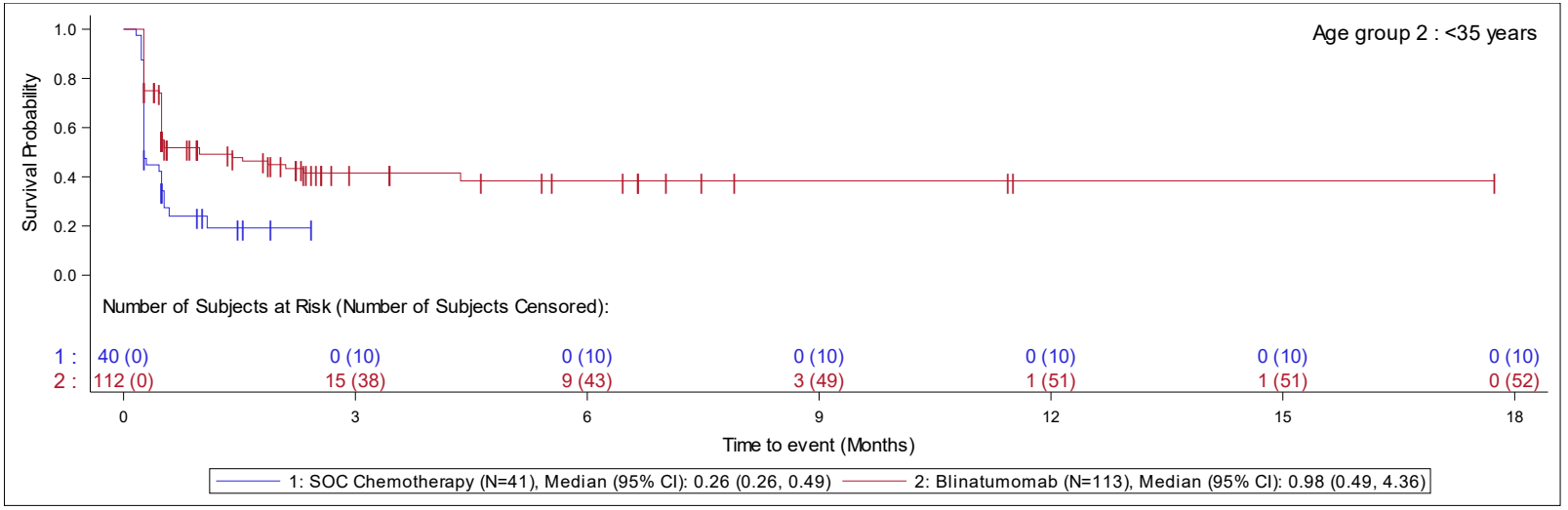
Figure 14-4.4.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Emotional Functioning from Functional Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-ef-eqcas.sas
Output: f14-04-004-006-km-sub-de-eortc-ef-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

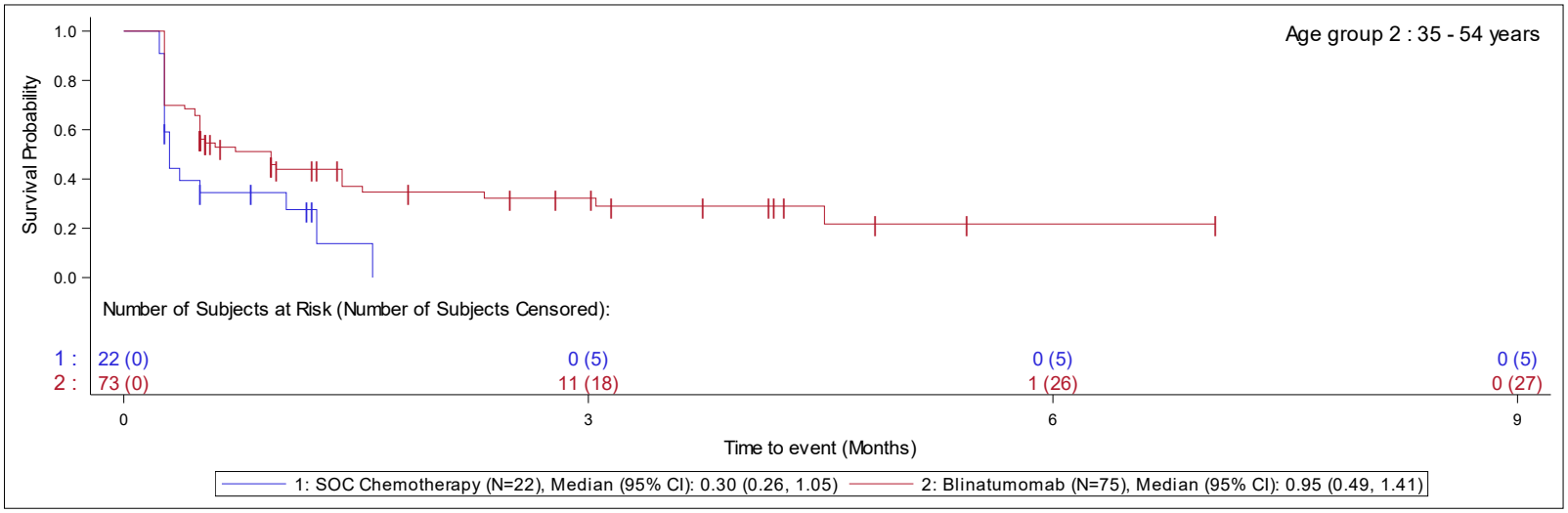
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

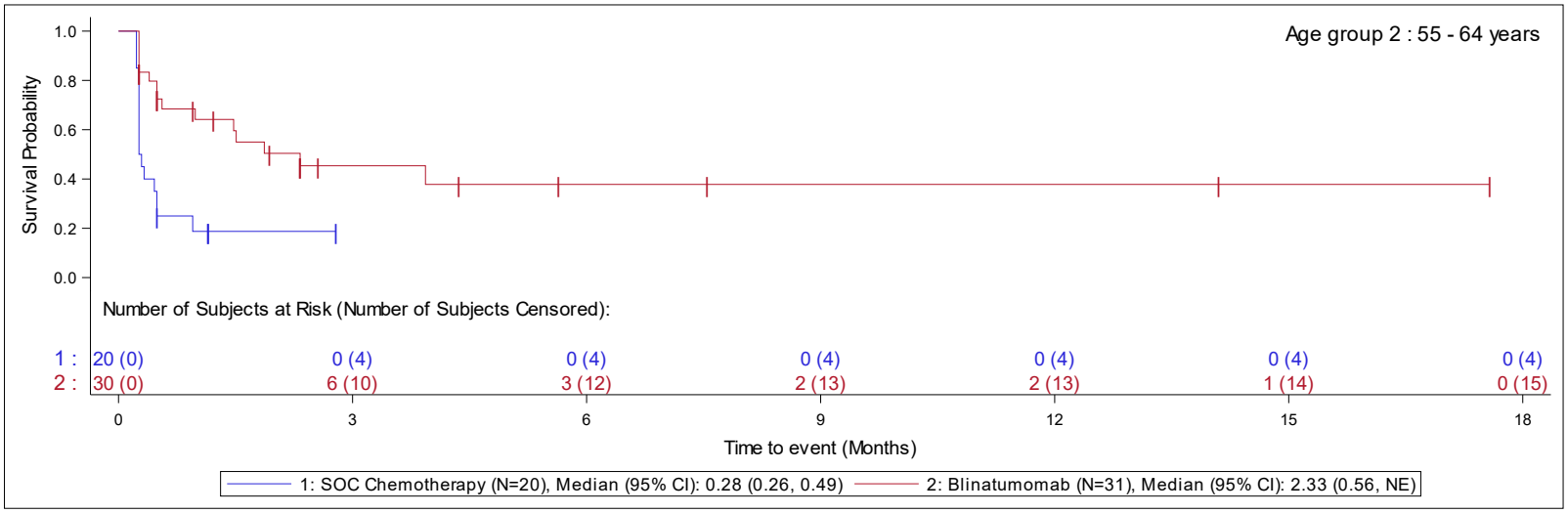
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

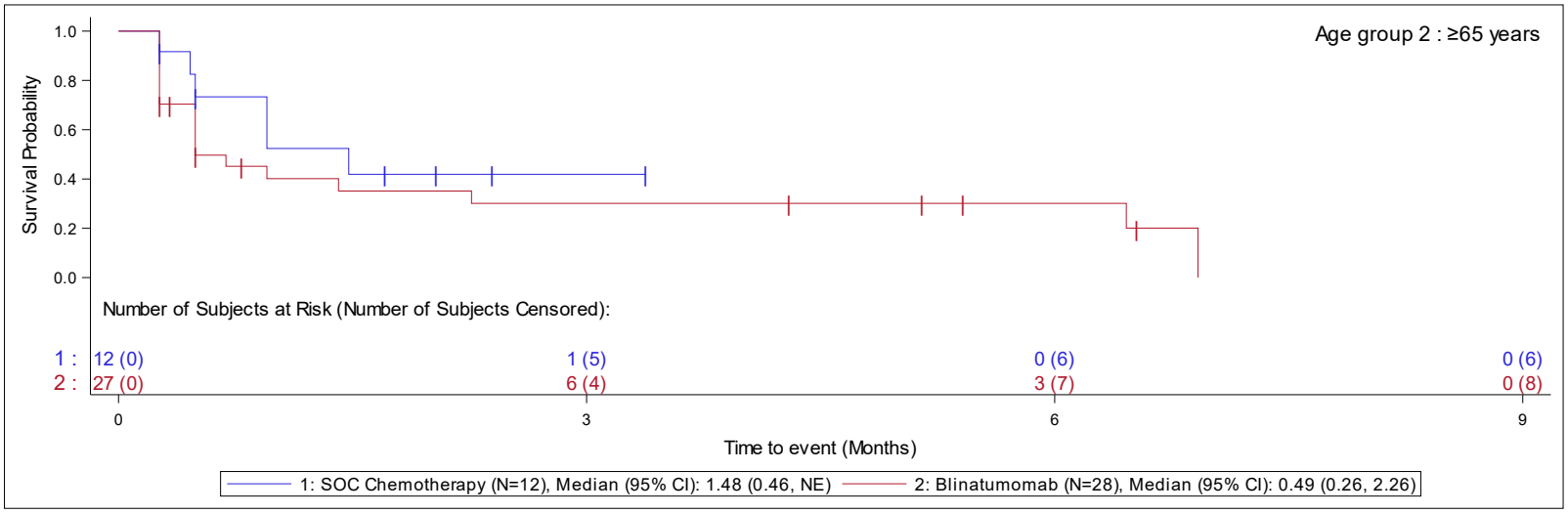
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

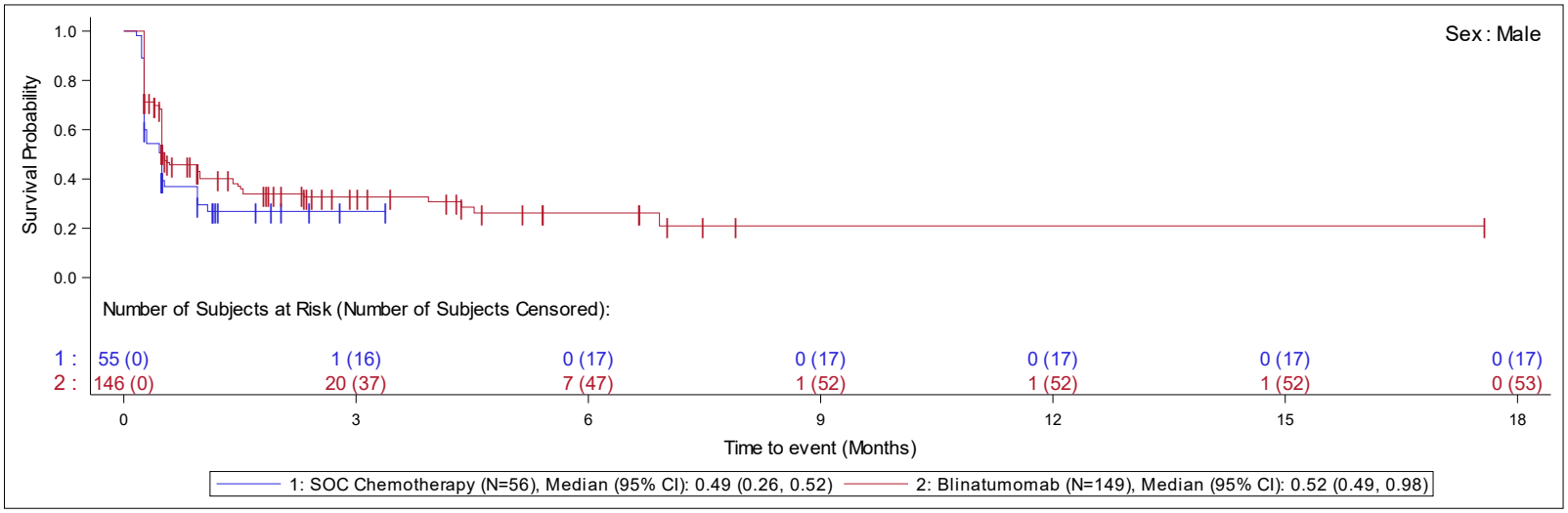
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

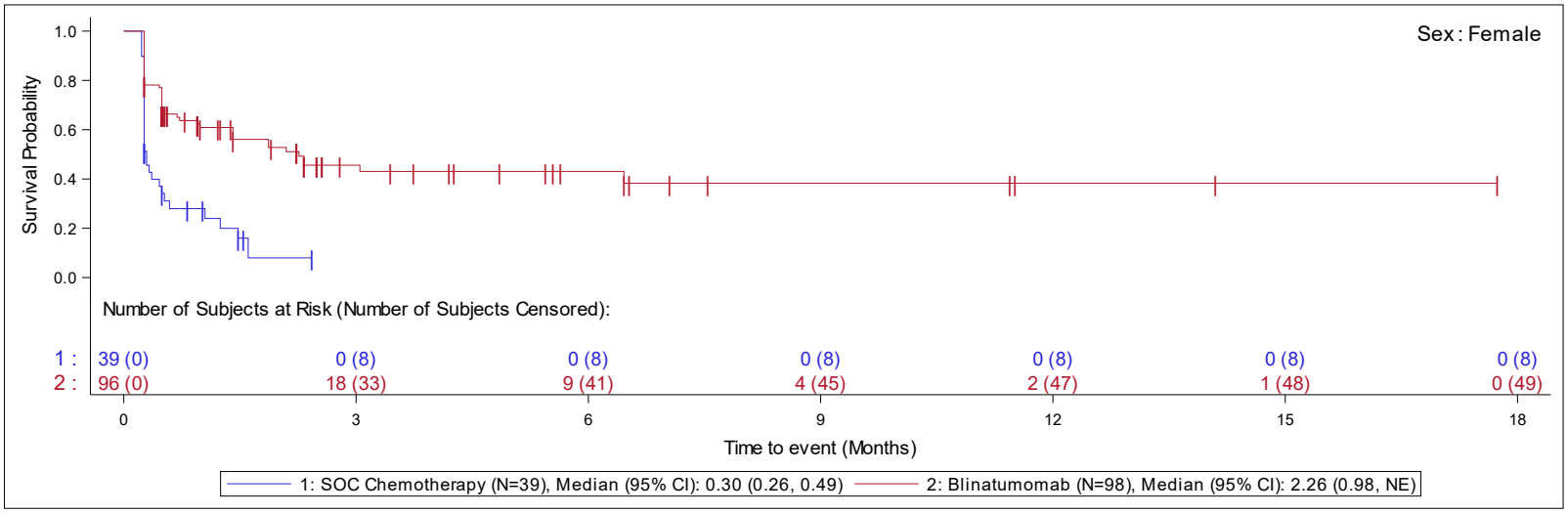
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

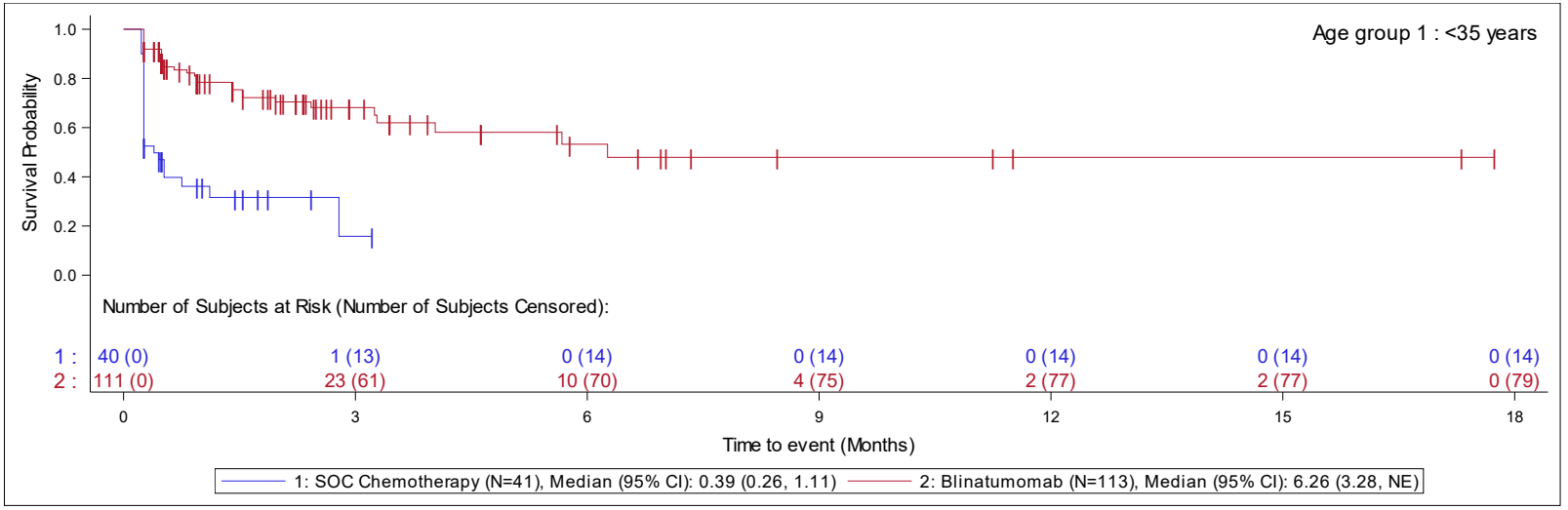
Figure 14-4.4.8. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Fatigue from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-fs-eqcas.sas
Output: f14-04-004-008-km-sub-de-eortc-fs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

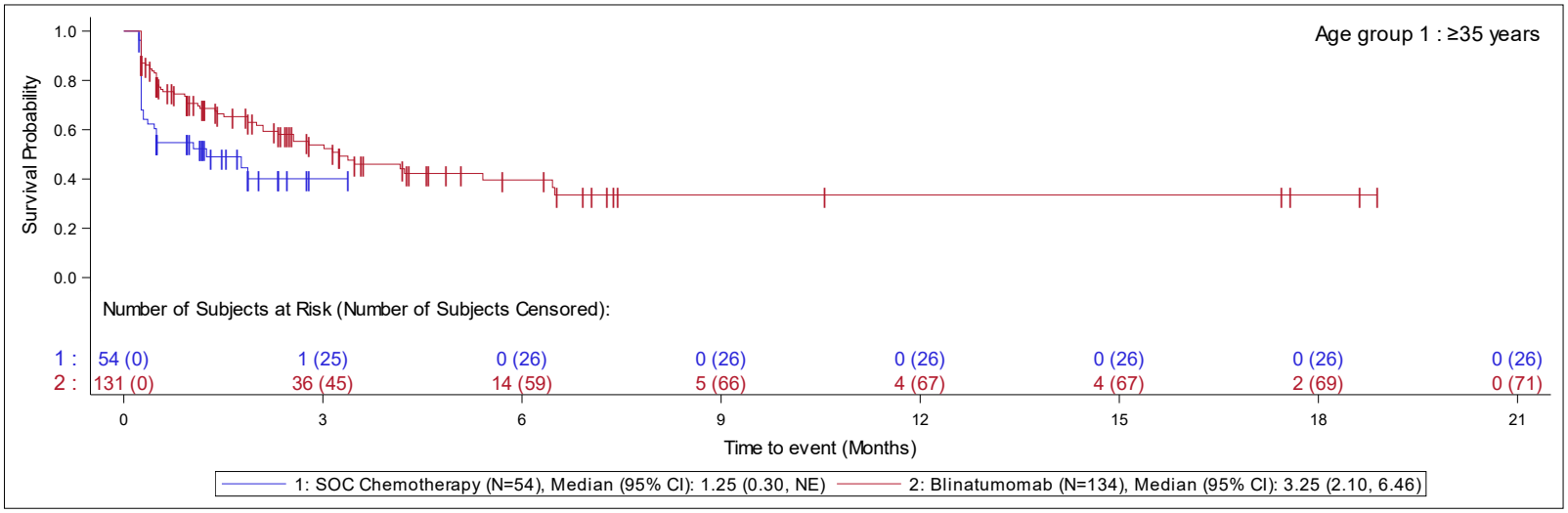
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

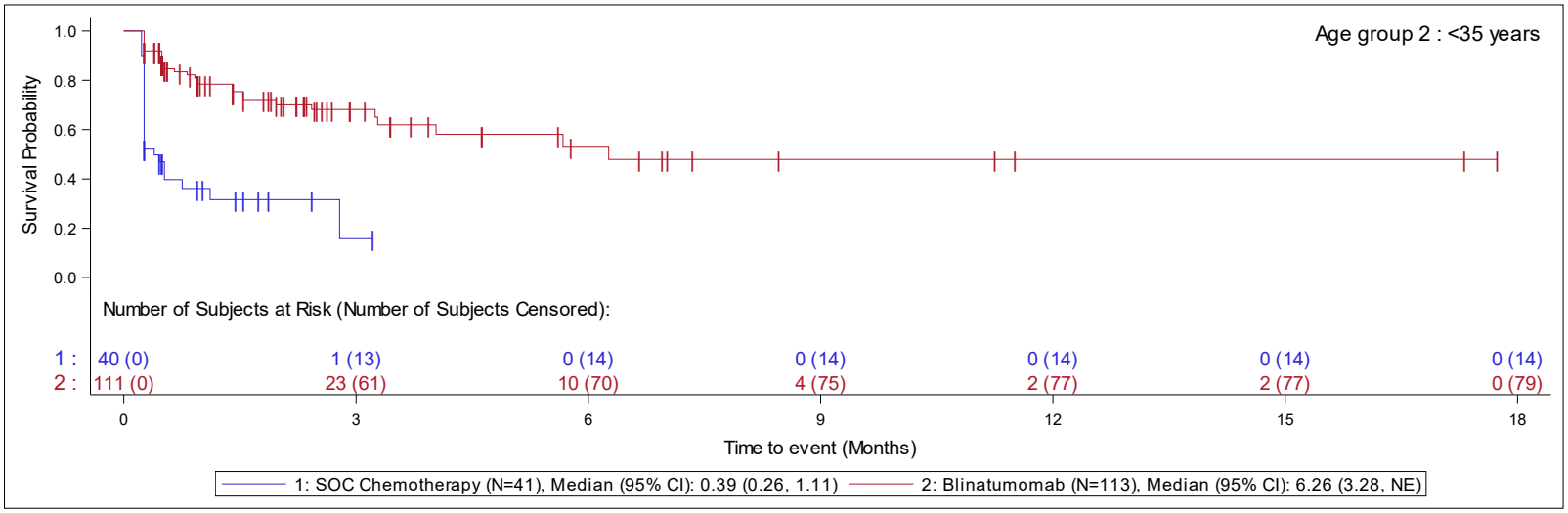
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

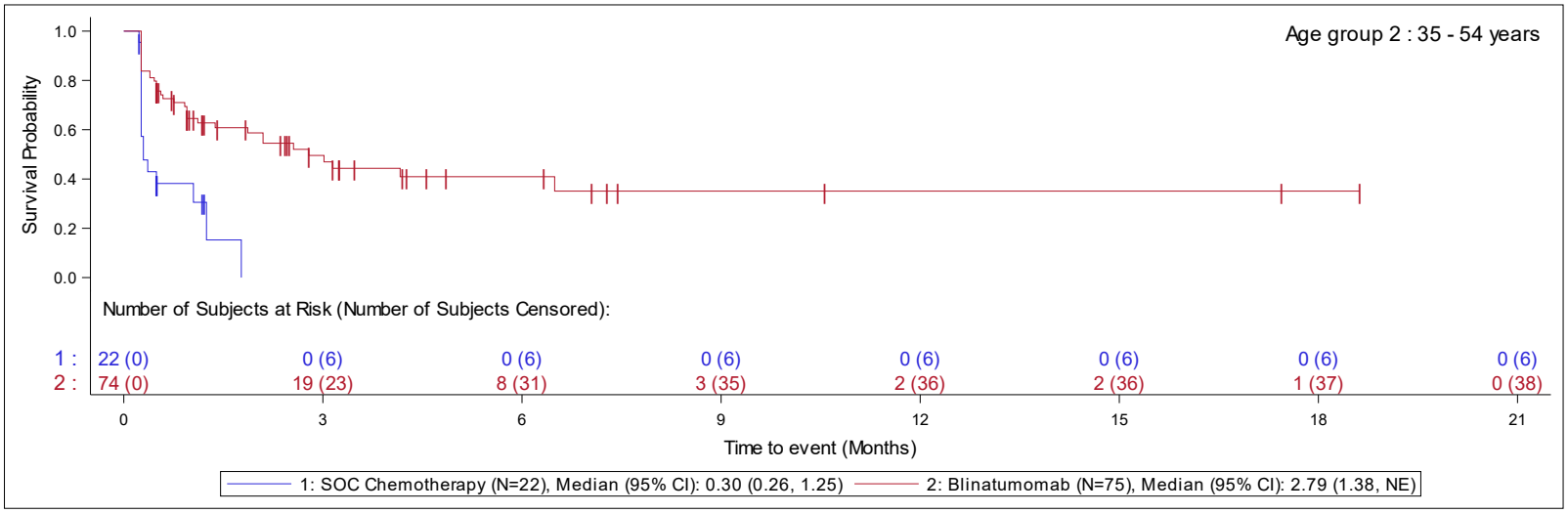
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

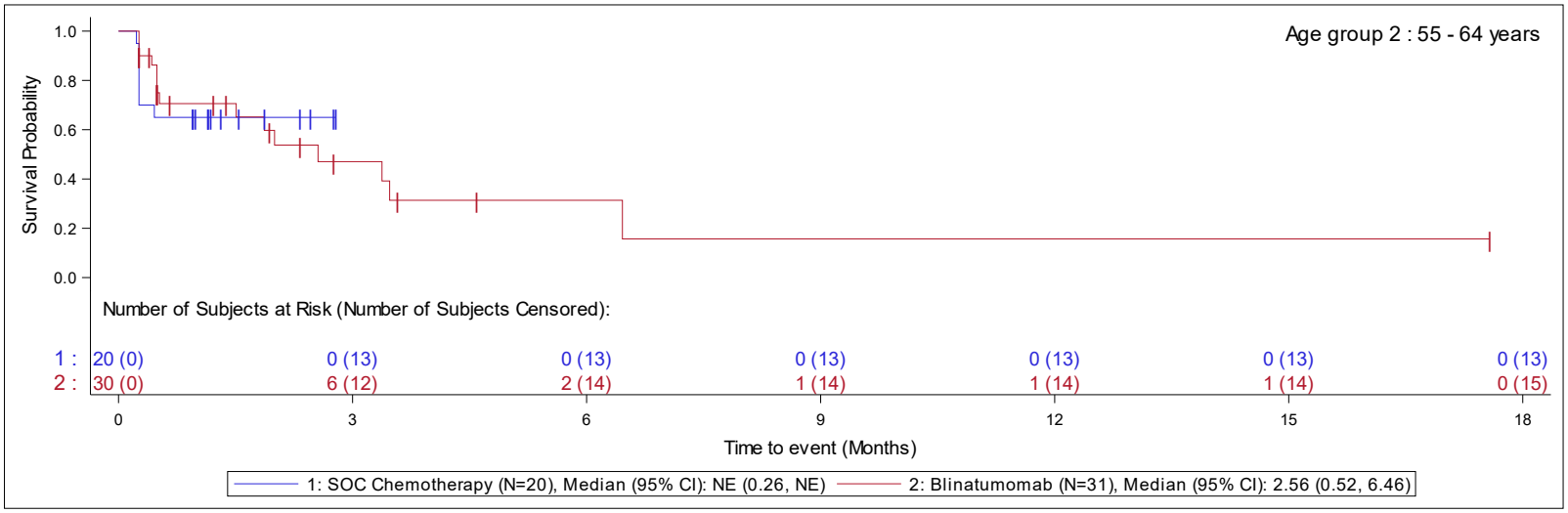
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

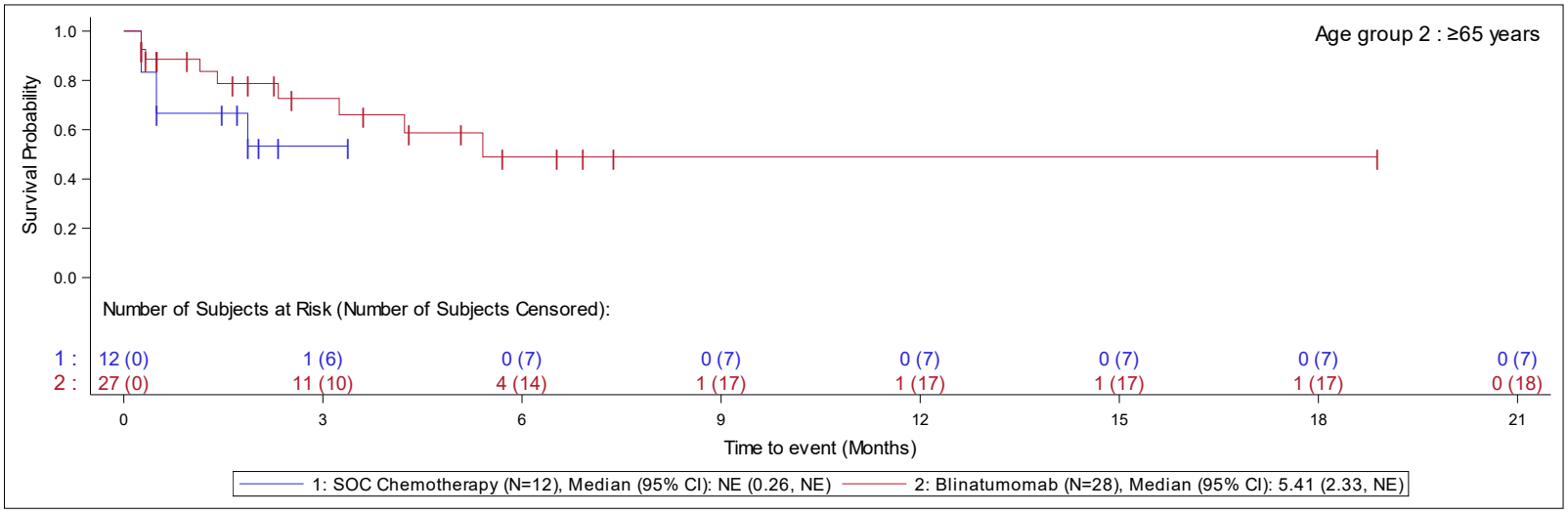
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

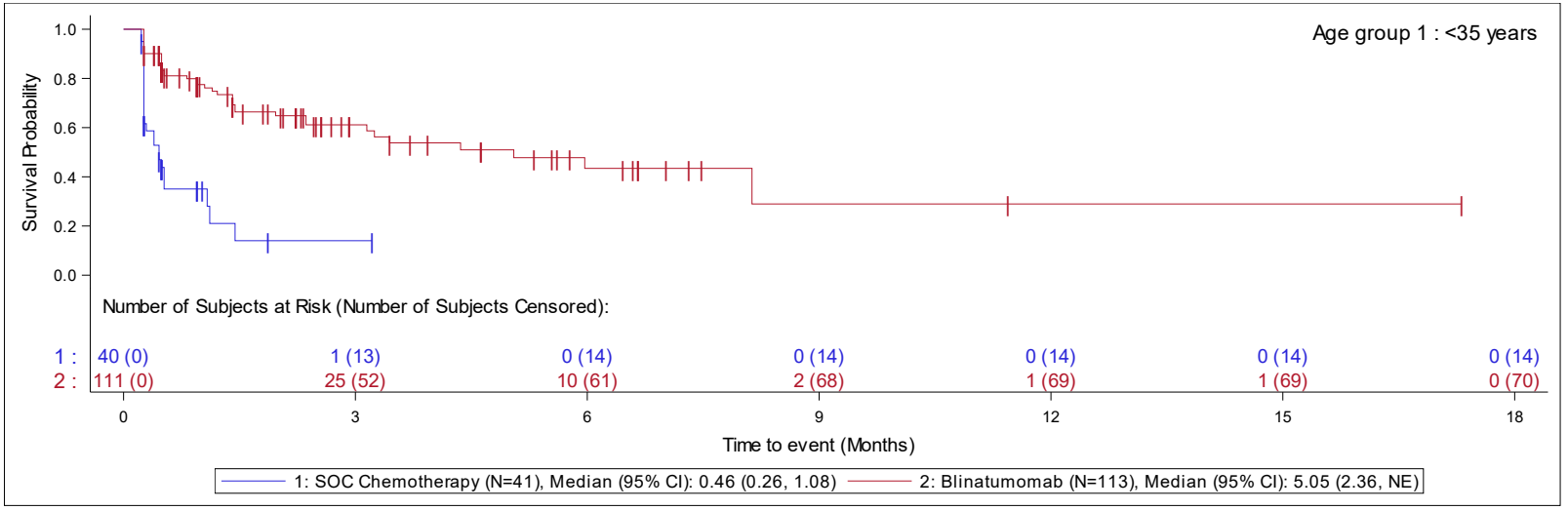
Figure 14-4.4.10. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Nausea and Vomiting from Symptom Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-nvs-eqcas.sas
Output: f14-04-004-010-km-sub-de-eortc-nvs-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

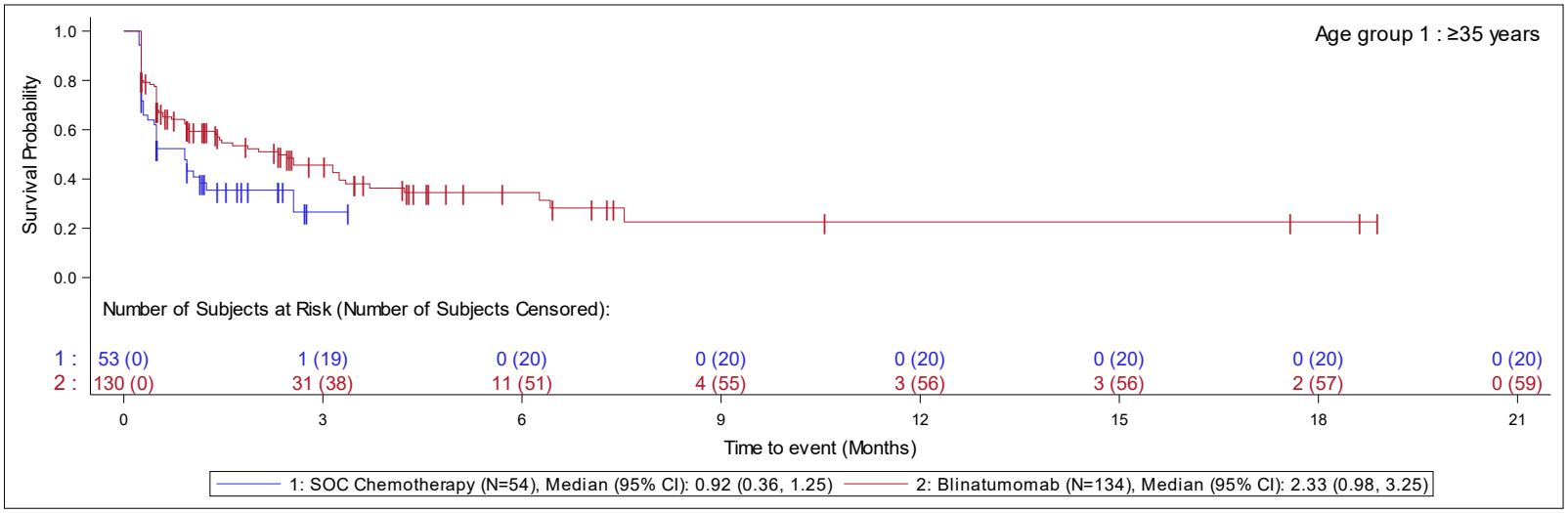
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

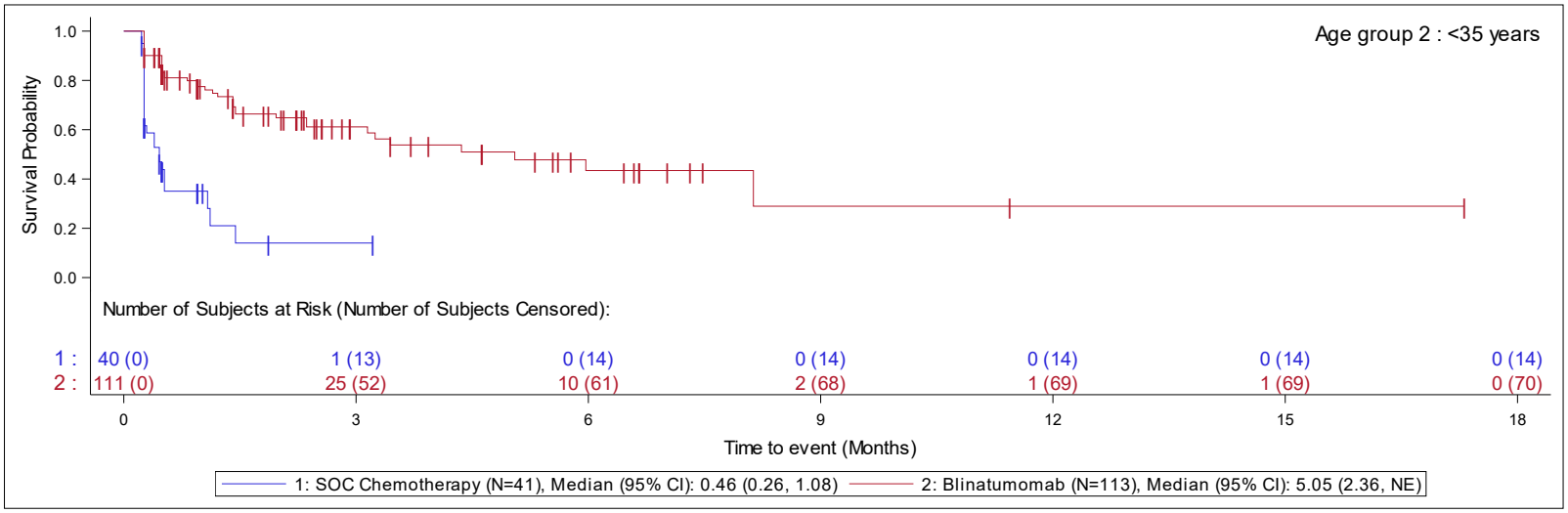
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

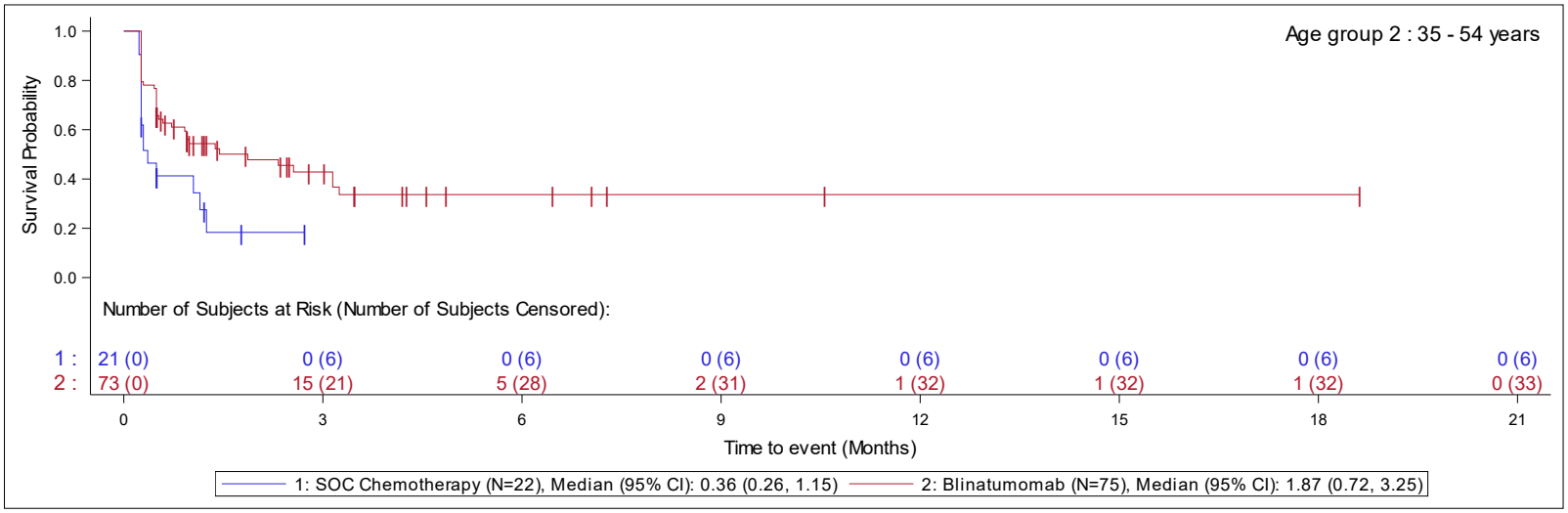
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

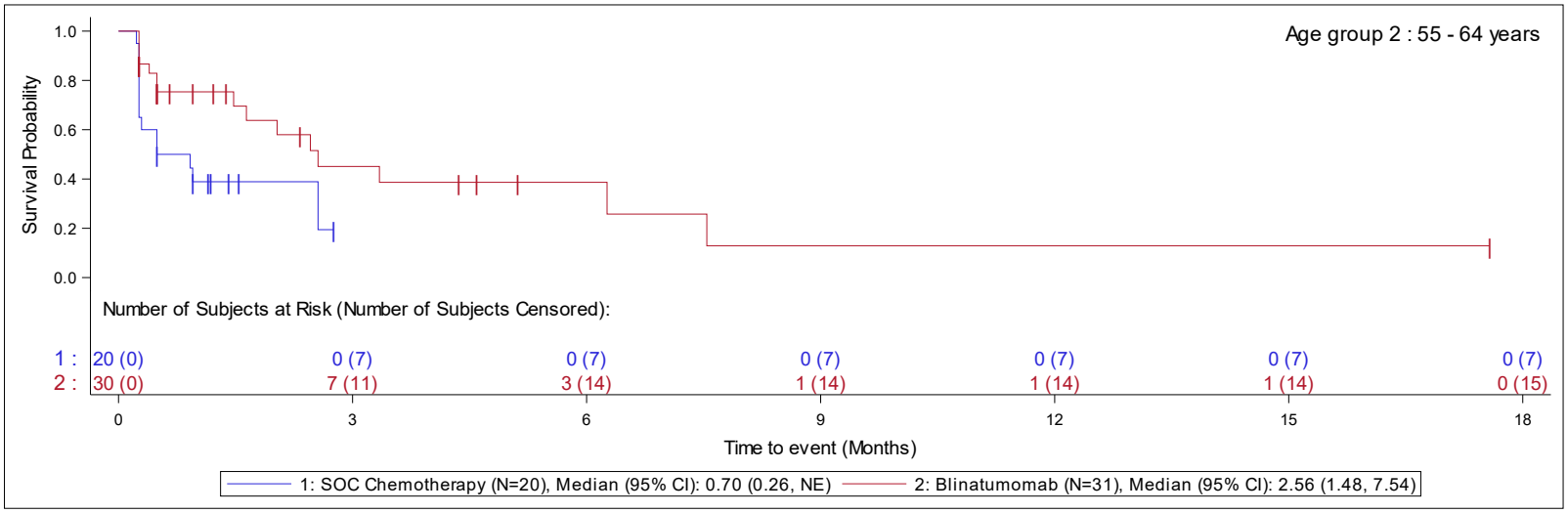
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

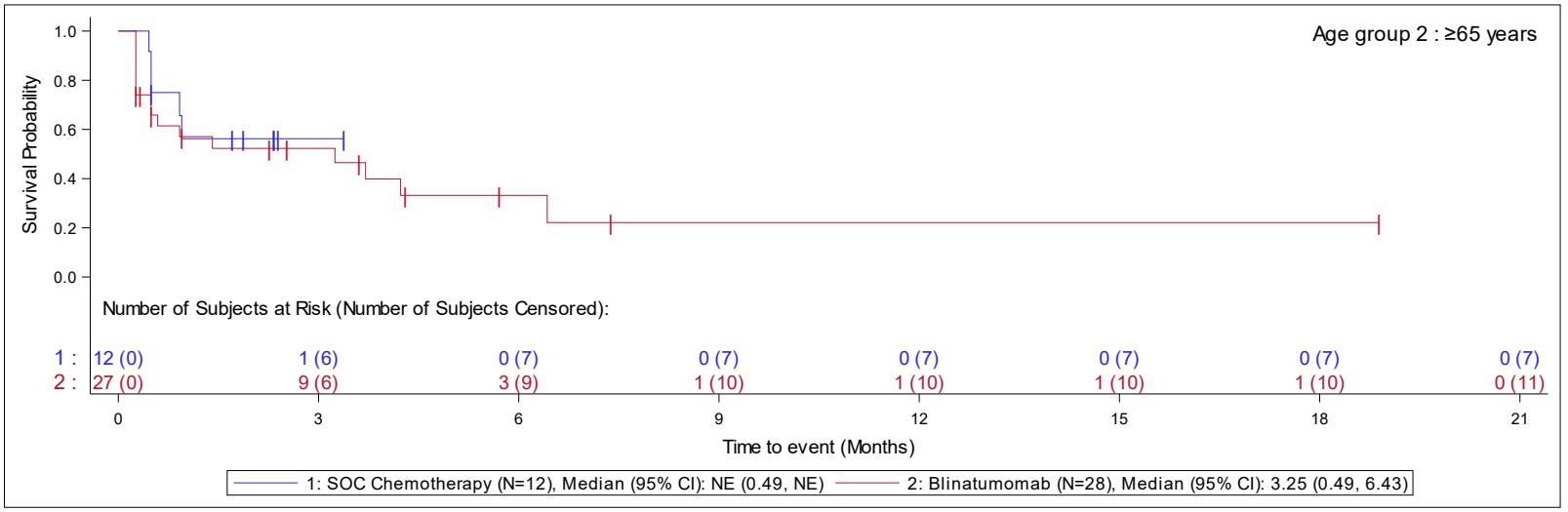
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

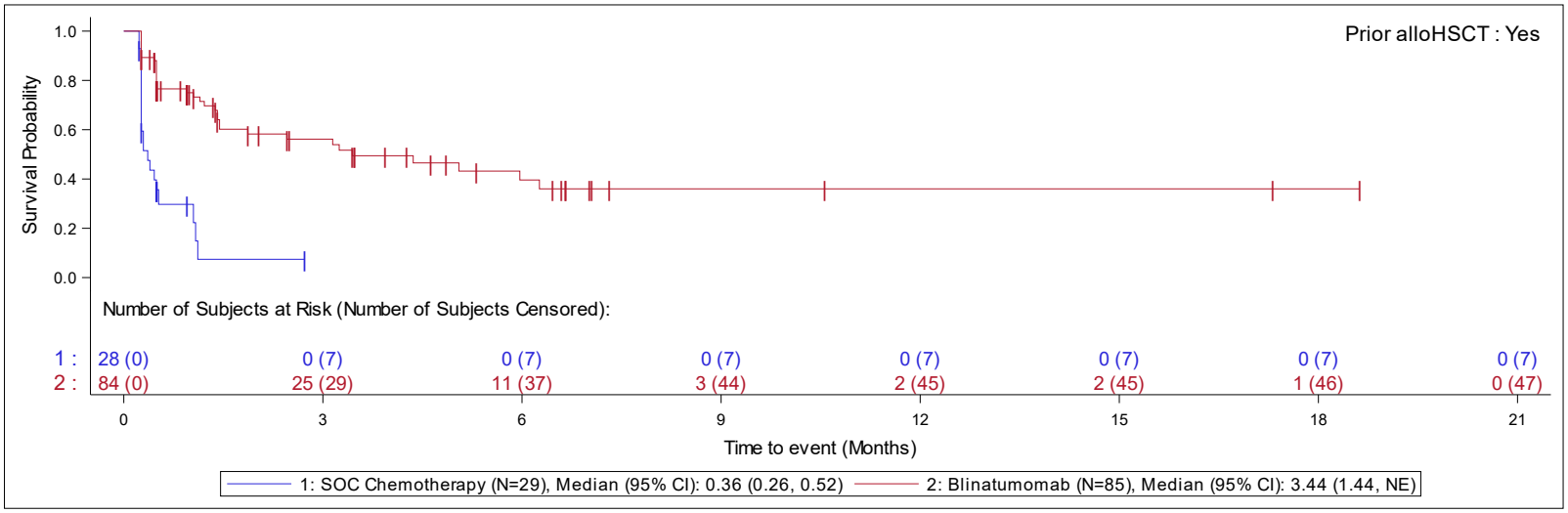
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

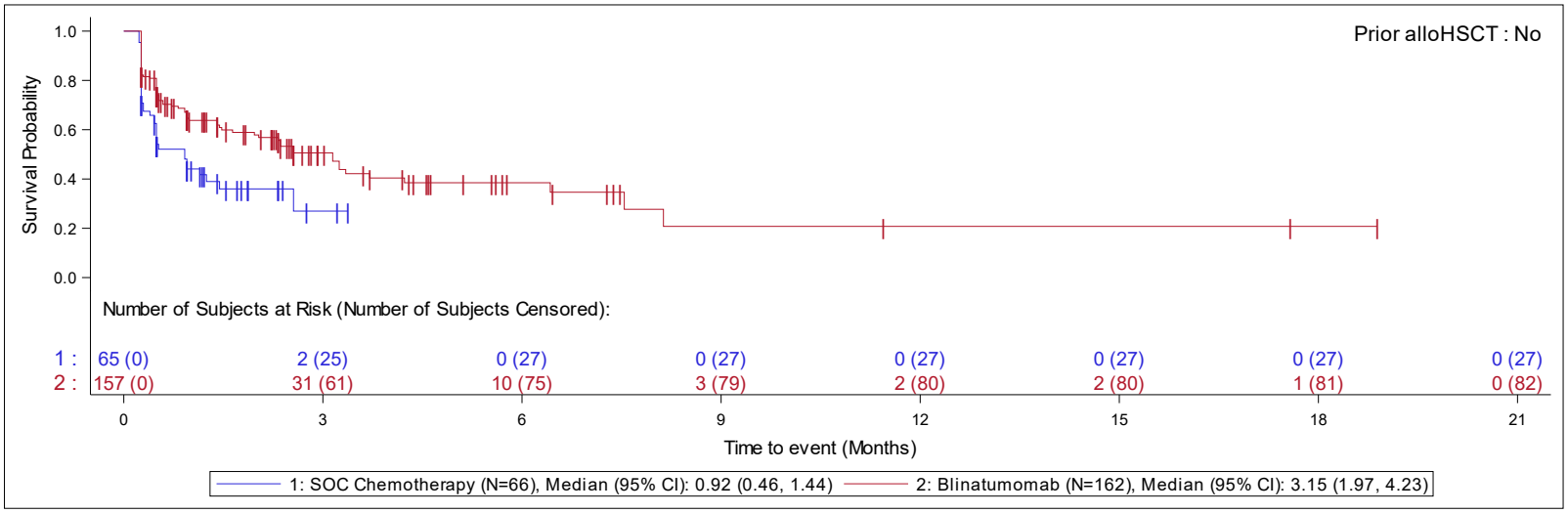
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

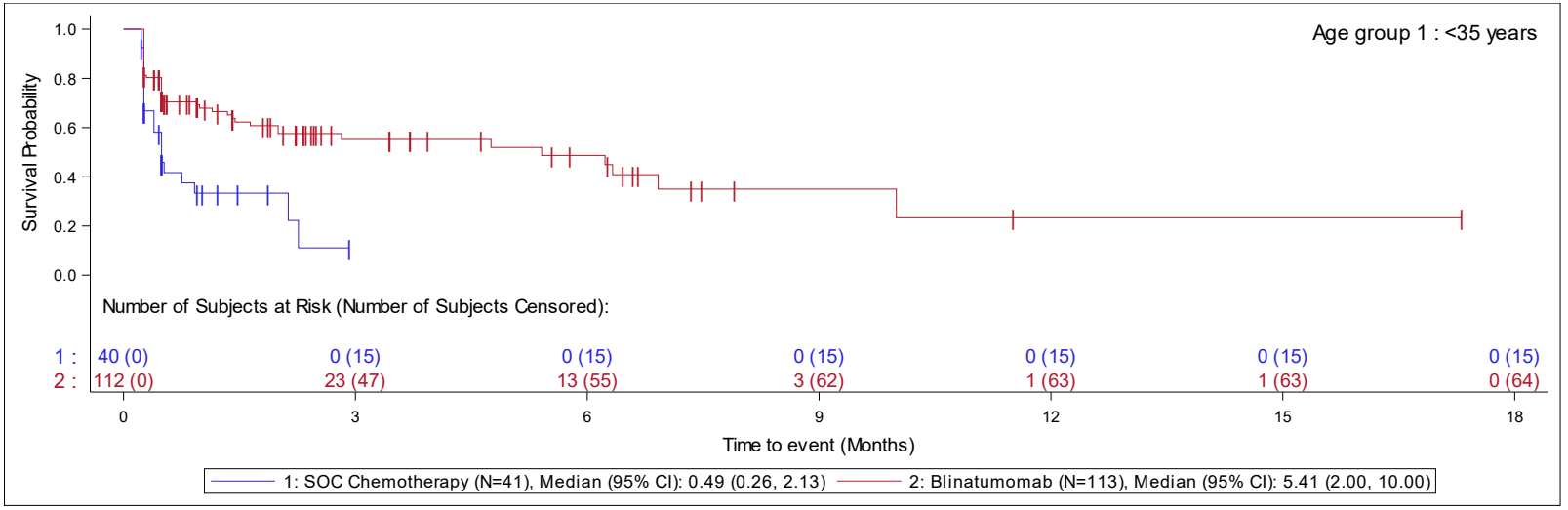
Figure 14-4.4.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Loss of Appetite from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-aps-eqcas.sas
Output: f14-04-004-012-km-sub-de-eortc-aps-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

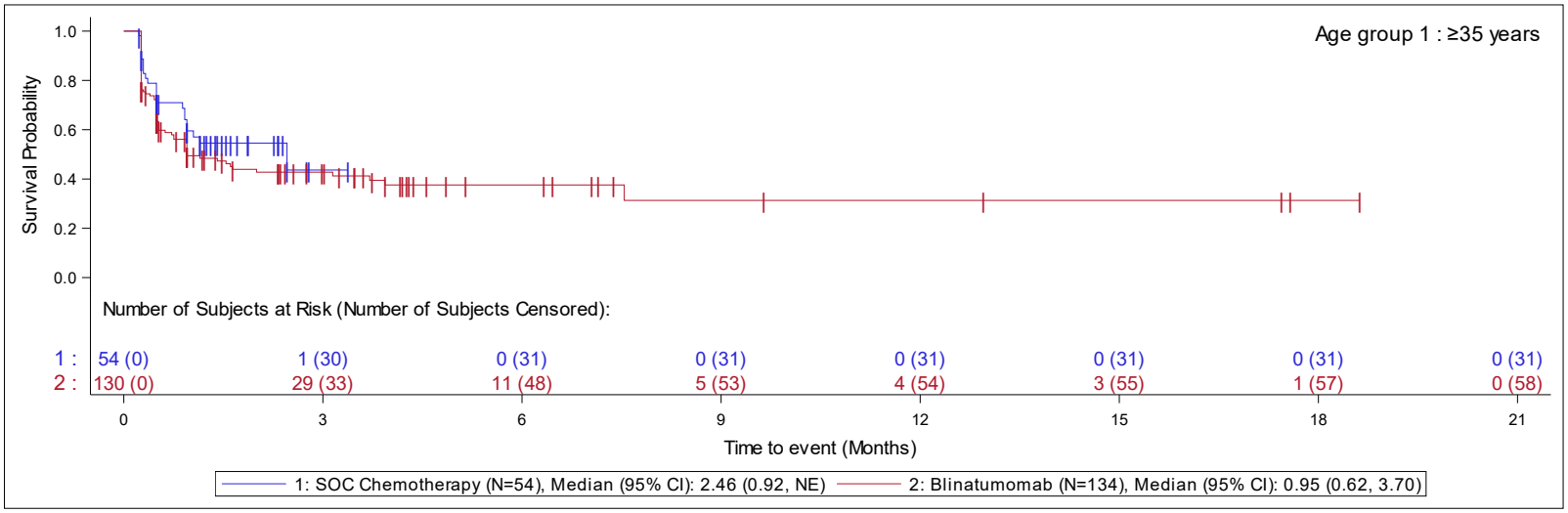
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

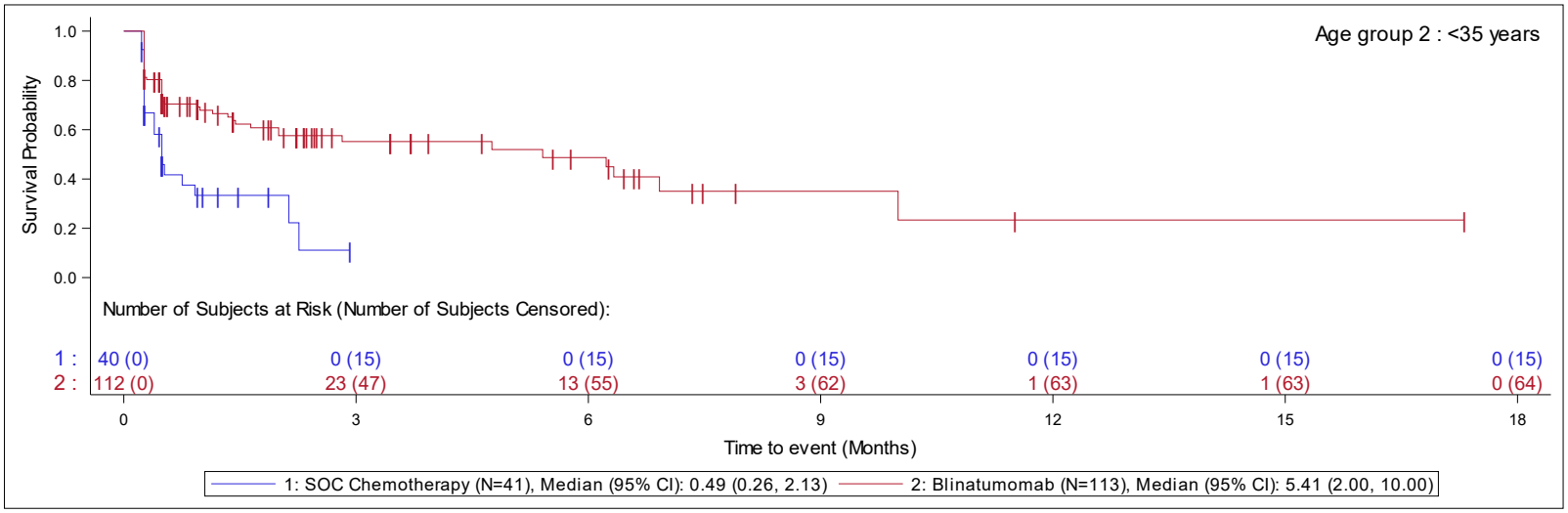
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

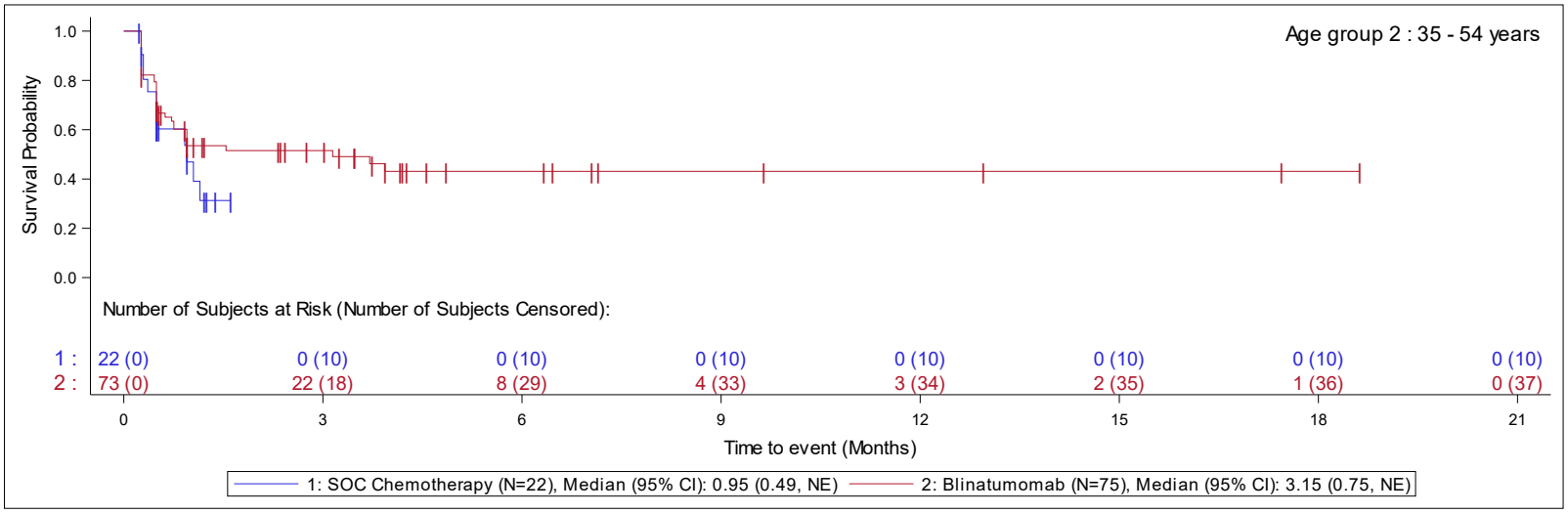
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

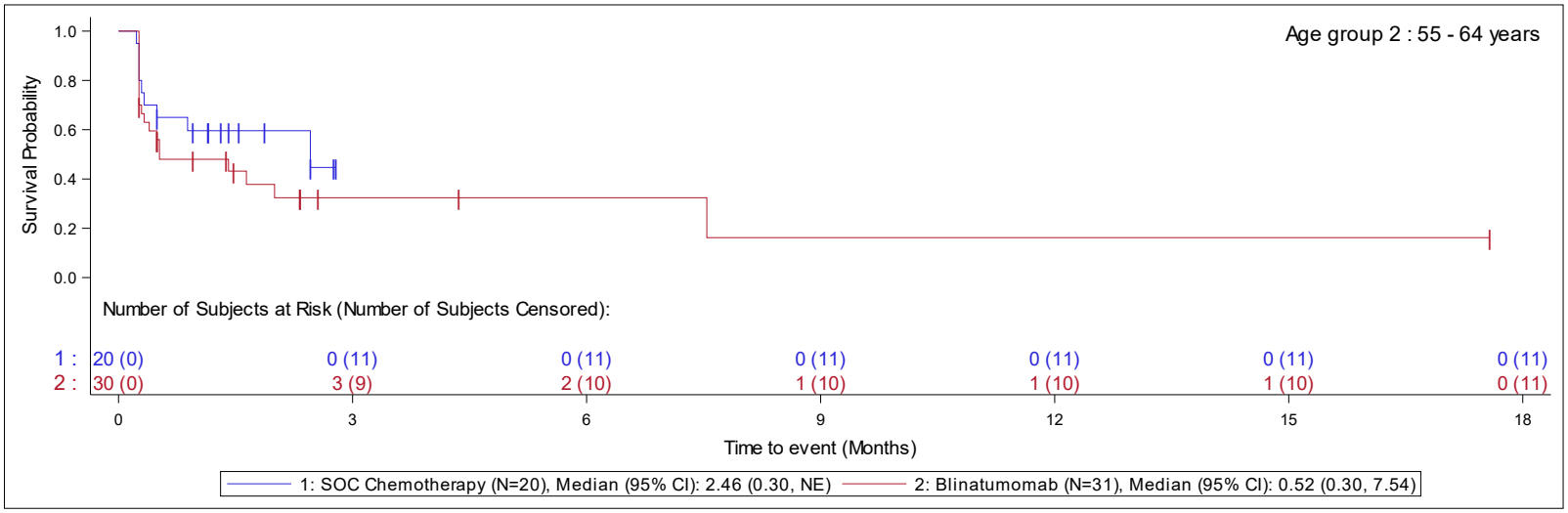
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

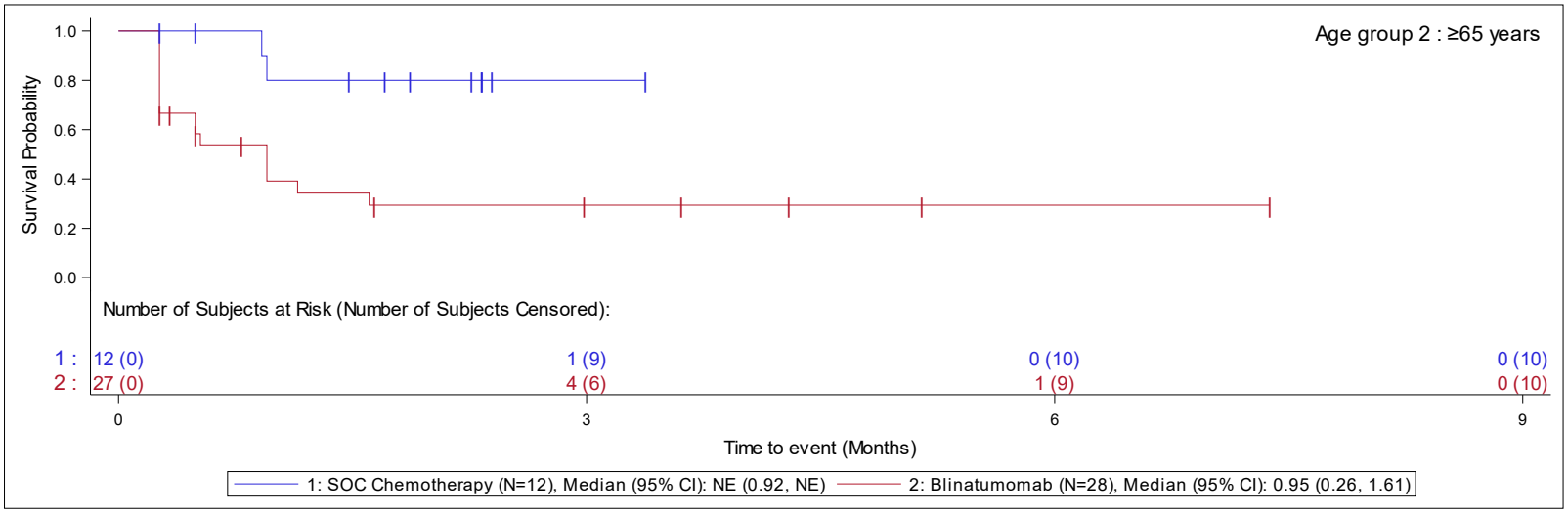
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

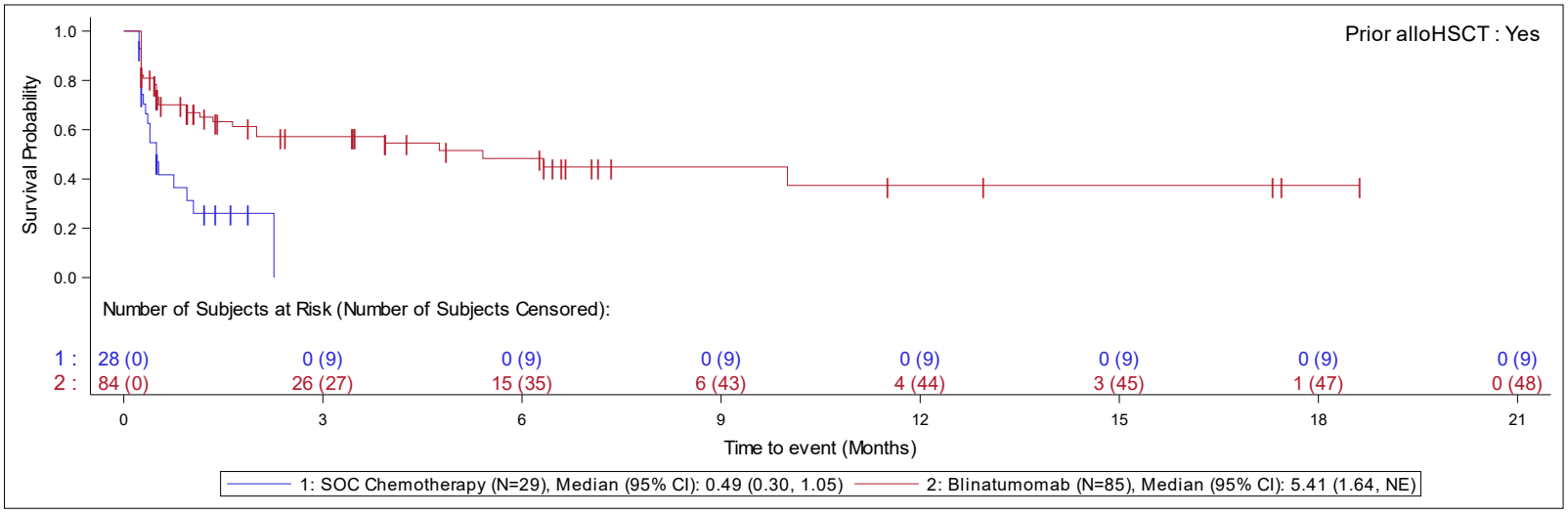
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

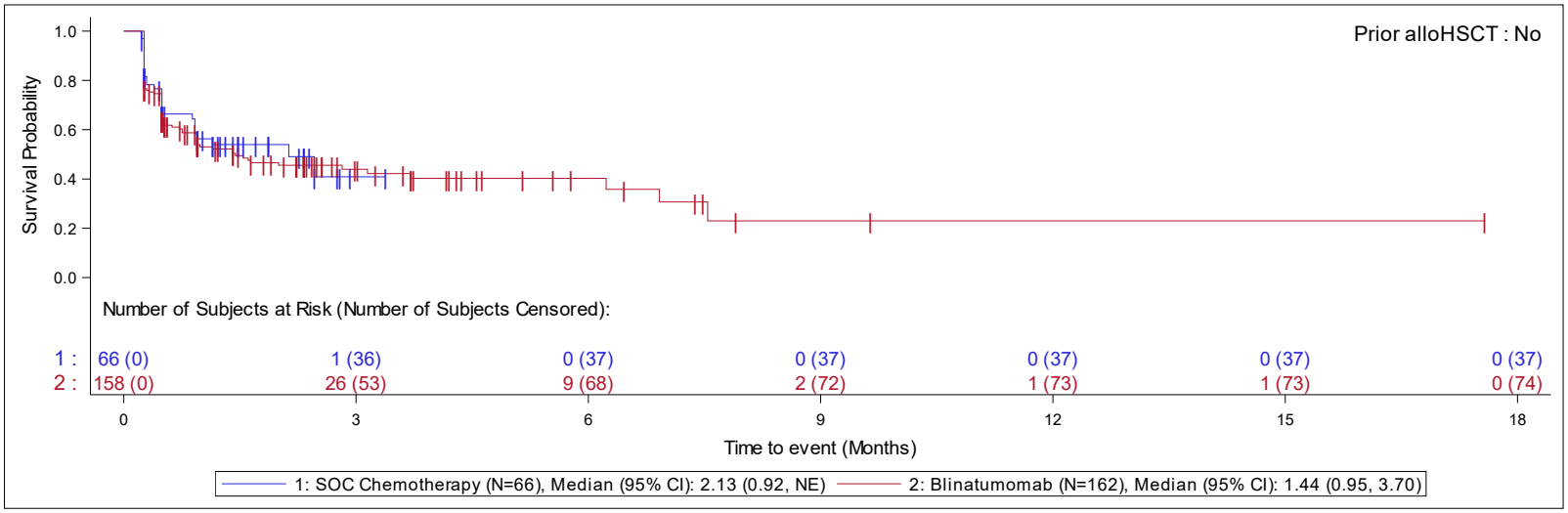
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

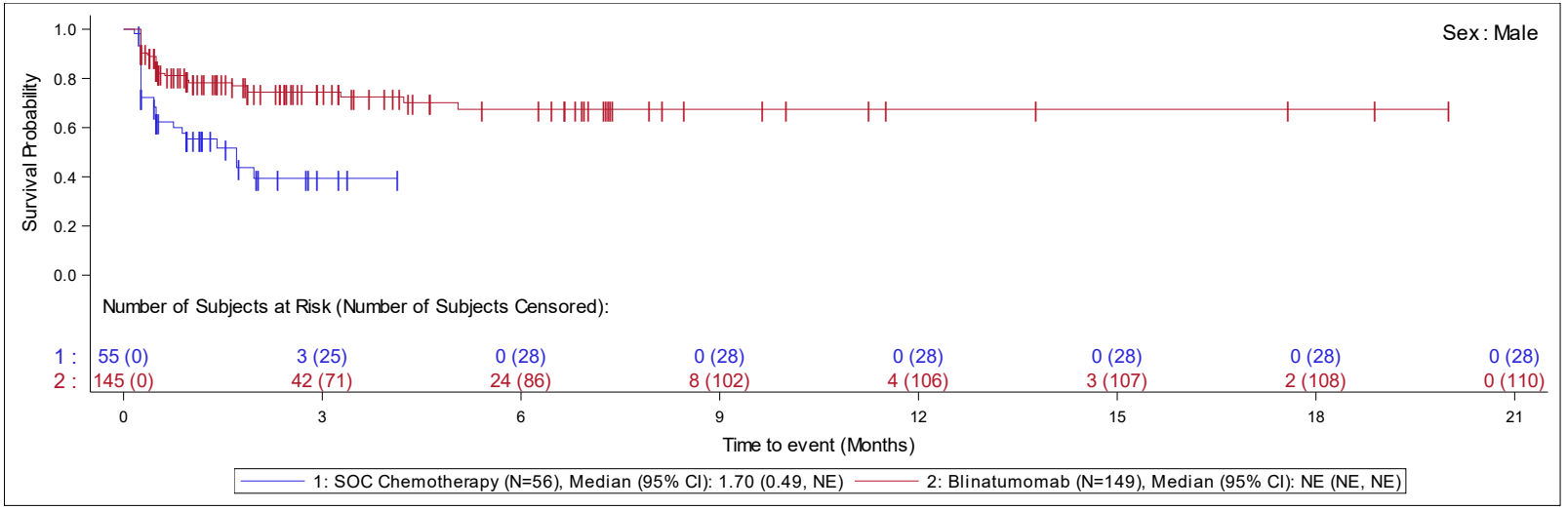
Figure 14-4.4.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Insomnia from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-sls-eqcas.sas
Output: f14-04-004-013-km-sub-de-eortc-sls-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

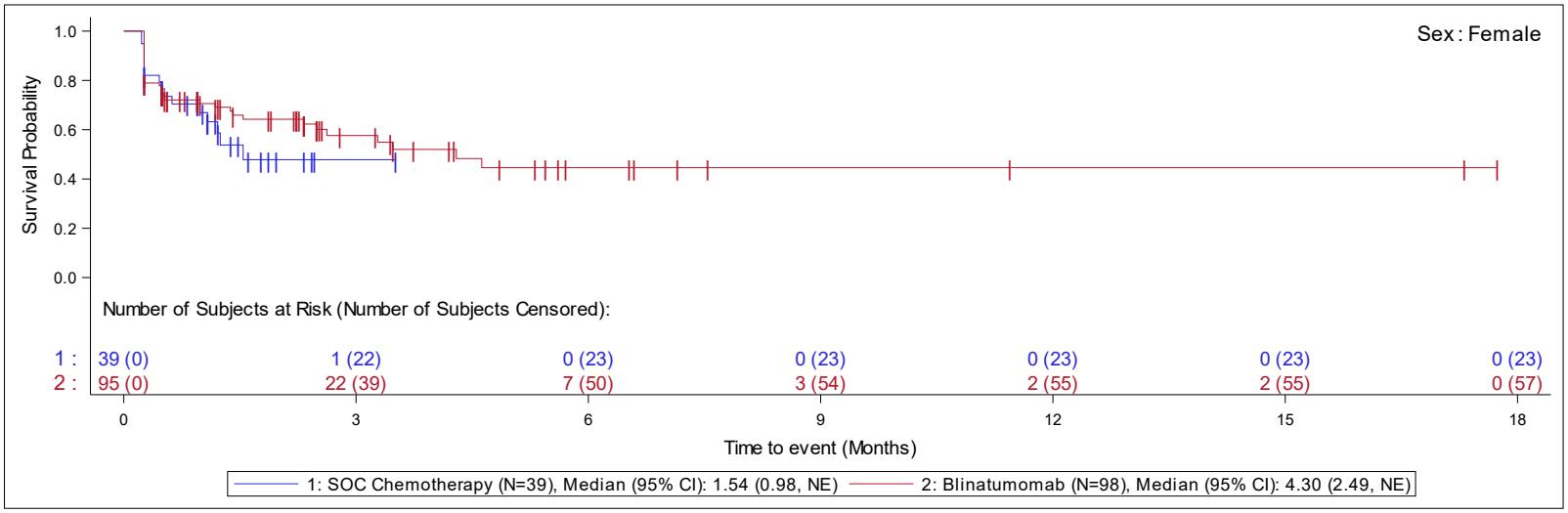
Figure 14-4.4.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-cos-eqcas.sas
Output: f14-04-004-014-km-sub-de-eortc-cos-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

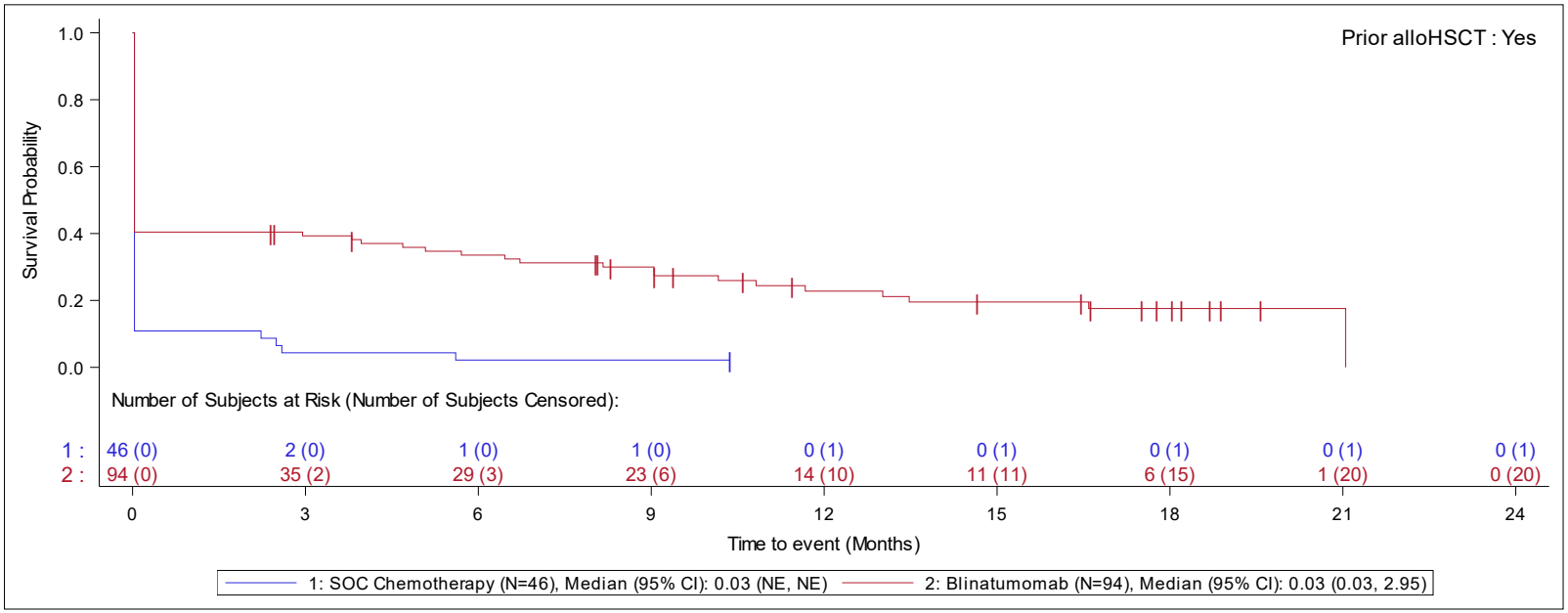
Figure 14-4.4.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Deterioration of at least 10 points - Constipation from Individual Item Subscales of EORTC QLQ - C30 (EORTC QLQ - C30 Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
EORTC QLQ-C30 analysis set will include all randomized subjects with a non-missing baseline and at least 1 non-missing post-baseline result of any EORTC QLQ-C30 scales/item.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-de-eortc-cos-eqcas.sas
Output: f14-04-004-014-km-sub-de-eortc-cos-eqcas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adqs, adam_fa.adtteqs

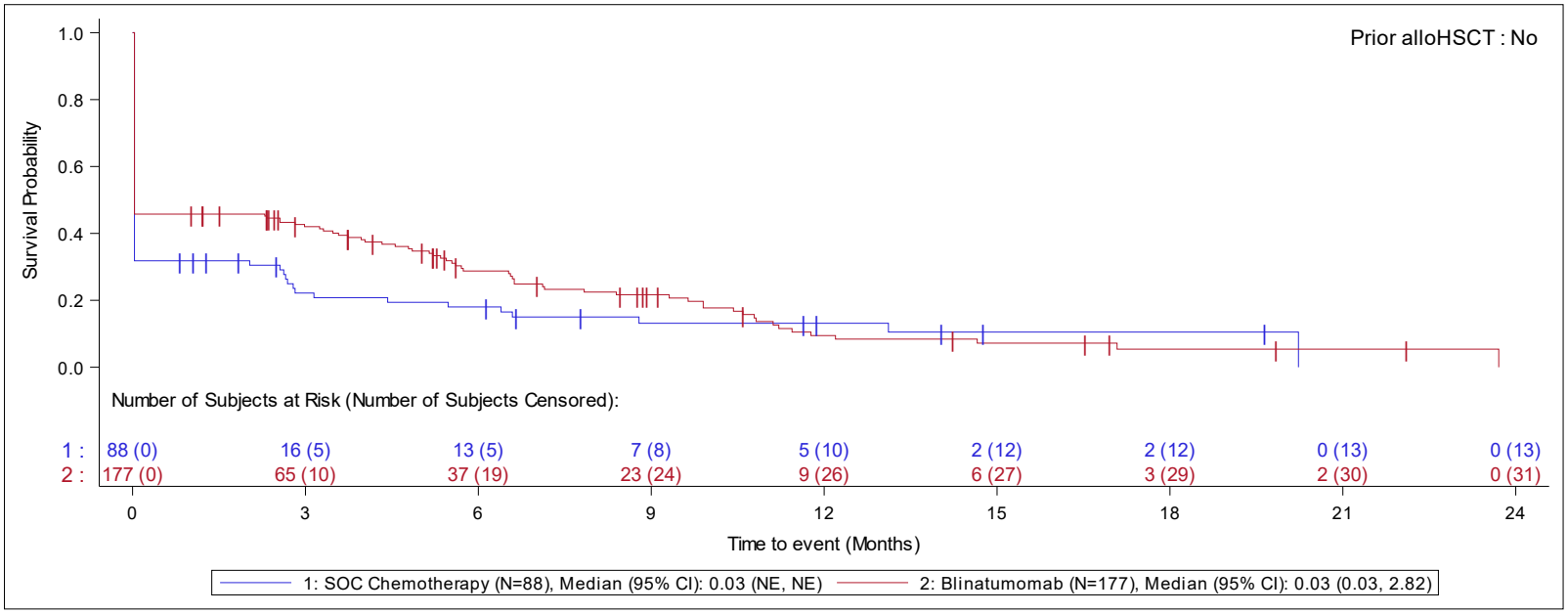
Figure 14-4.5.2. Kaplan-Meier plot for Event Free Survival - Subgroup Analysis (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-efs-fas.sas
Output: f14-04-005-002-km-sub-efs-fas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

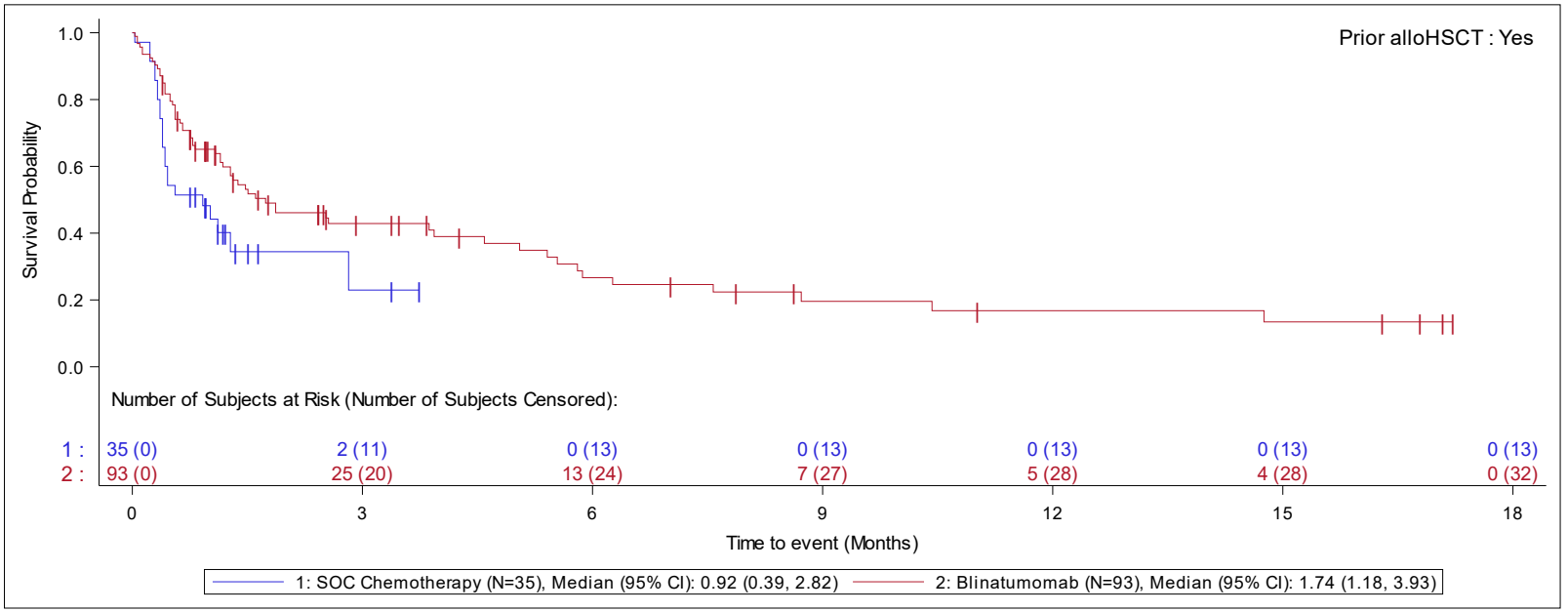
Figure 14-4.5.2. Kaplan-Meier plot for Event Free Survival - Subgroup Analysis (Full Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-efs-fas.sas
Output: f14-04-005-002-km-sub-efs-fas.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam_fa.adtteeff

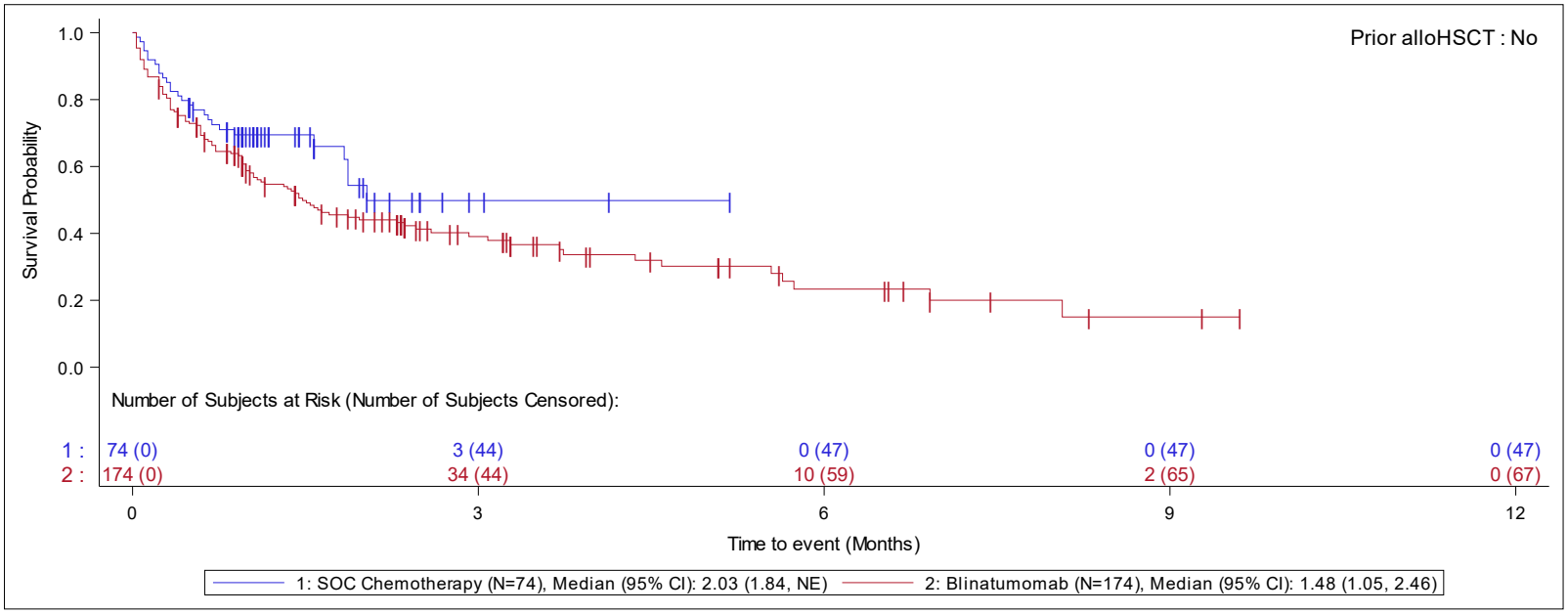
Figure 14-6.2.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-ser-teae-saf.sas
Output: f14-06-002-002-km-sub-ser-teae-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

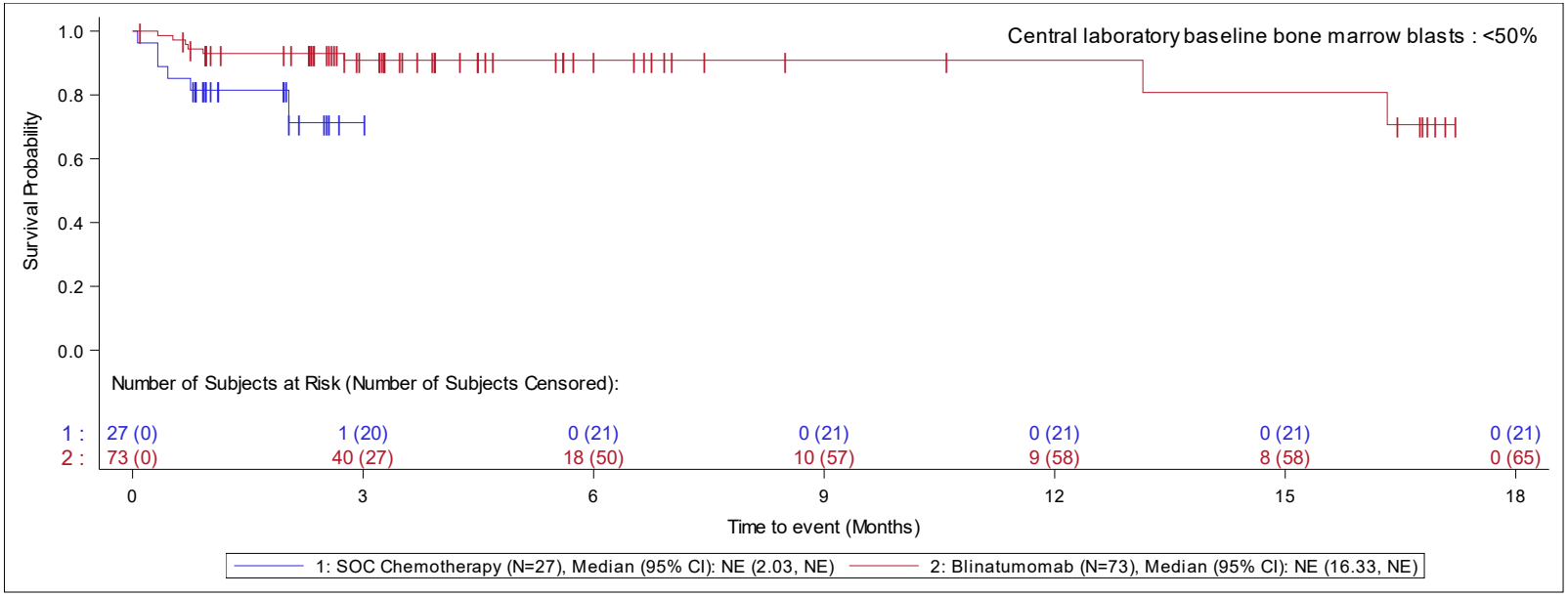
Figure 14-6.2.2. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-ser-teae-saf.sas
Output: f14-06-002-002-km-sub-ser-teae-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

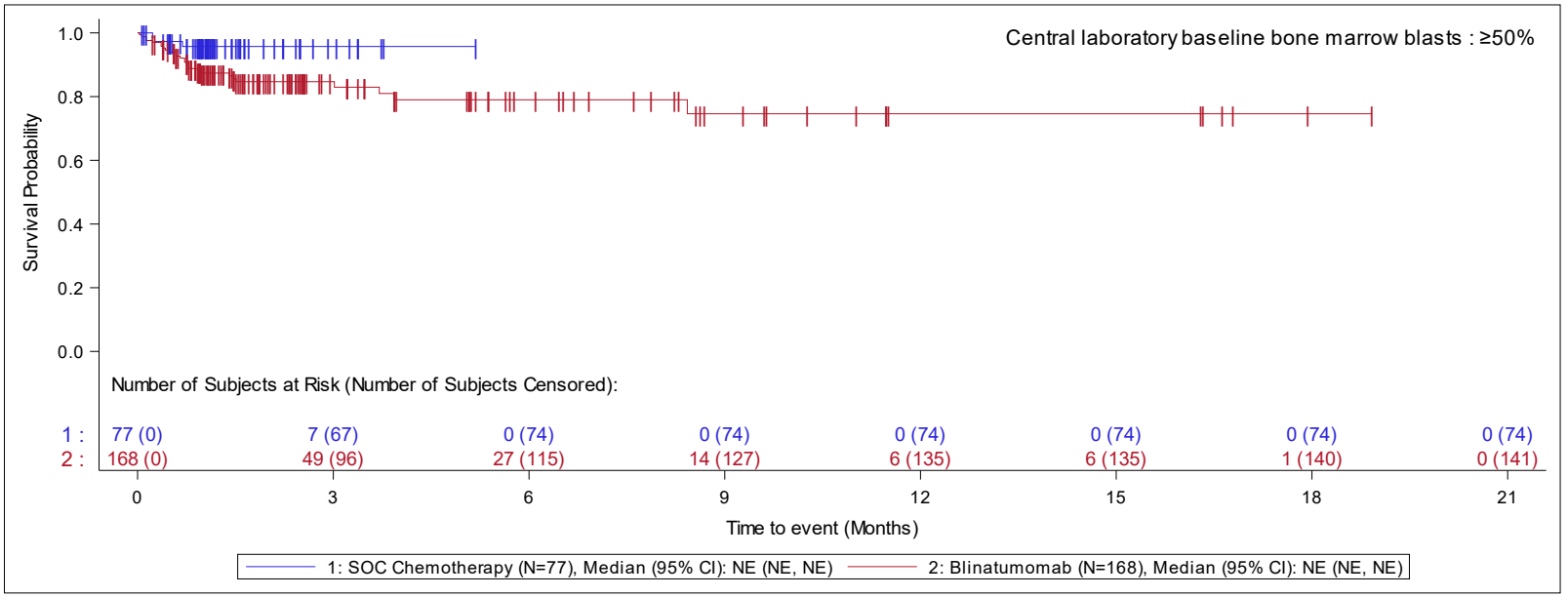
Figure 14-6.2.4. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-teae-trt-disc-saf.sas
Output: f14-06-002-004-km-sub-teae-trt-disc-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

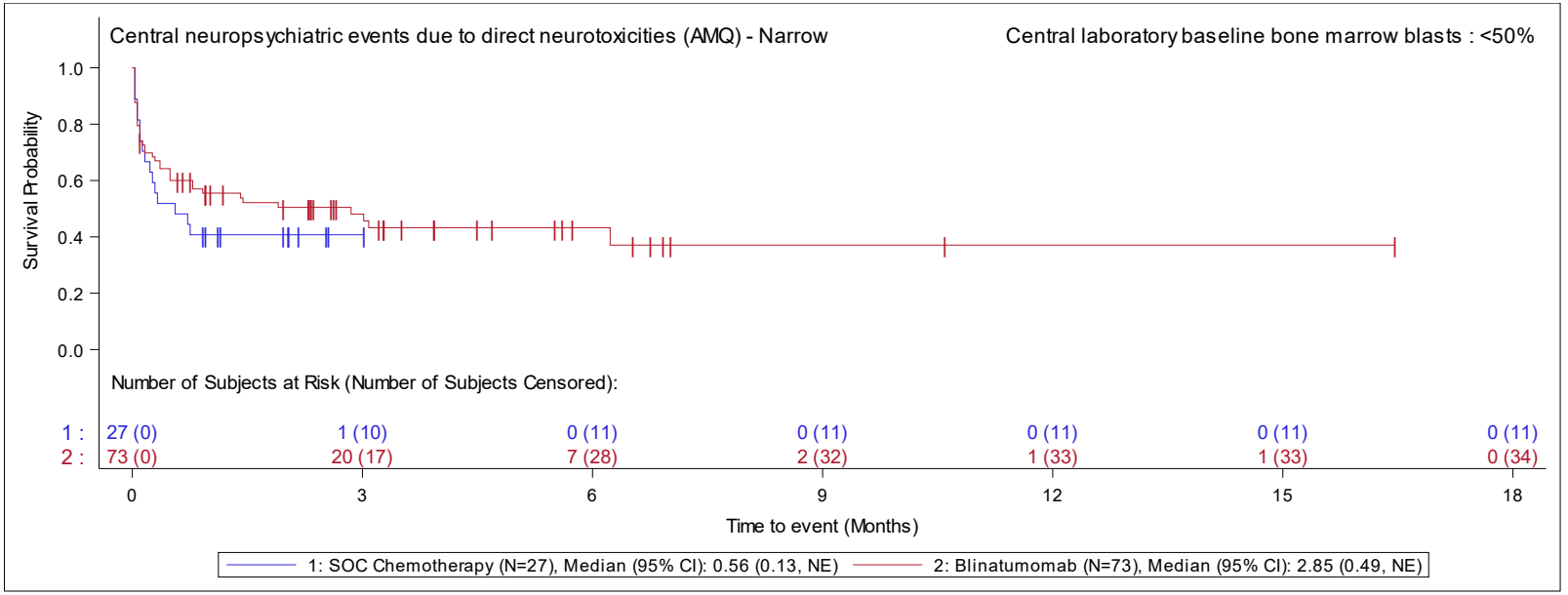
Figure 14-6.2.4. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-teae-trt-disc-saf.sas
Output: f14-06-002-004-km-sub-teae-trt-disc-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

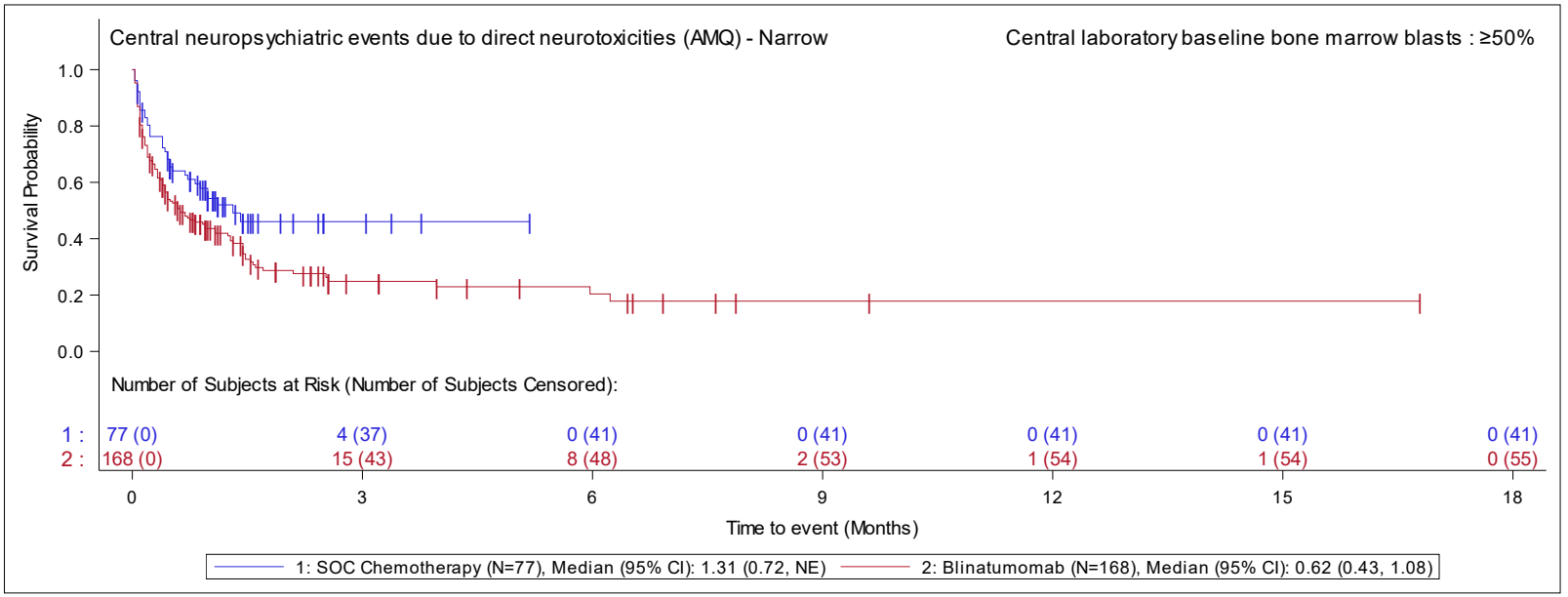
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-teae-aesi-saf.sas
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

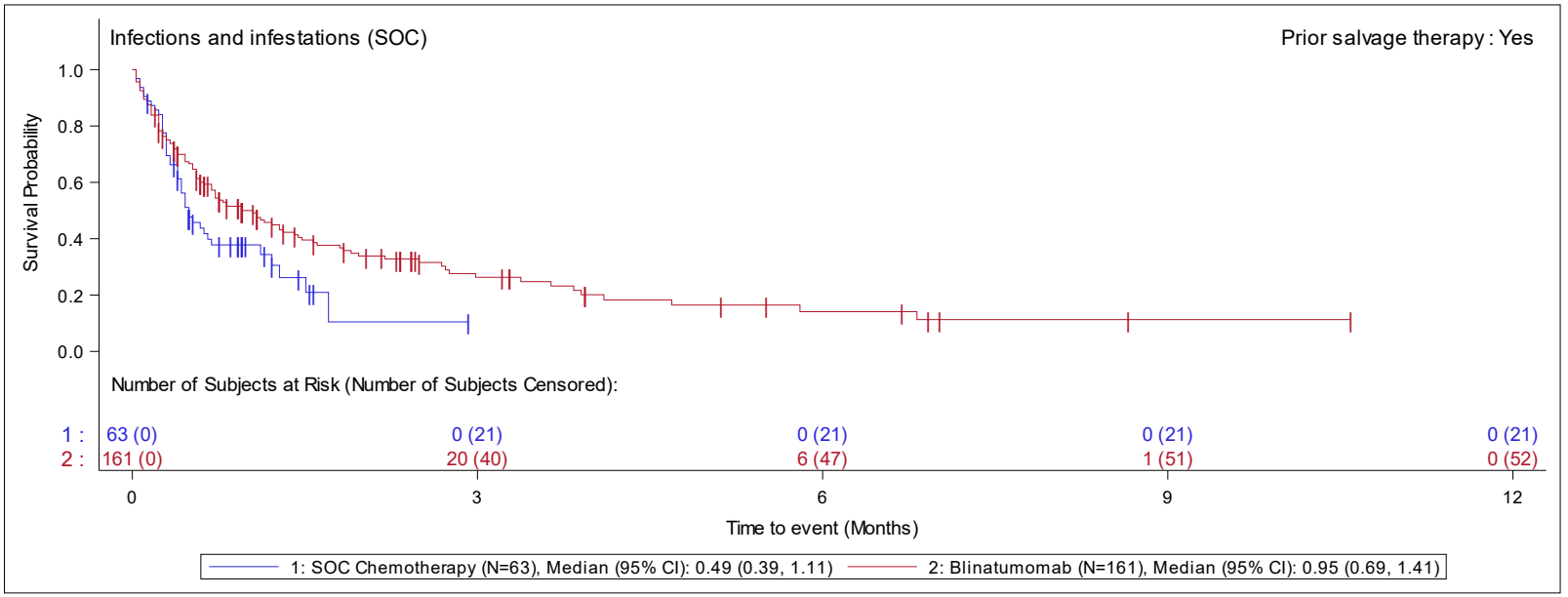
Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-teae-aesi-saf.sas
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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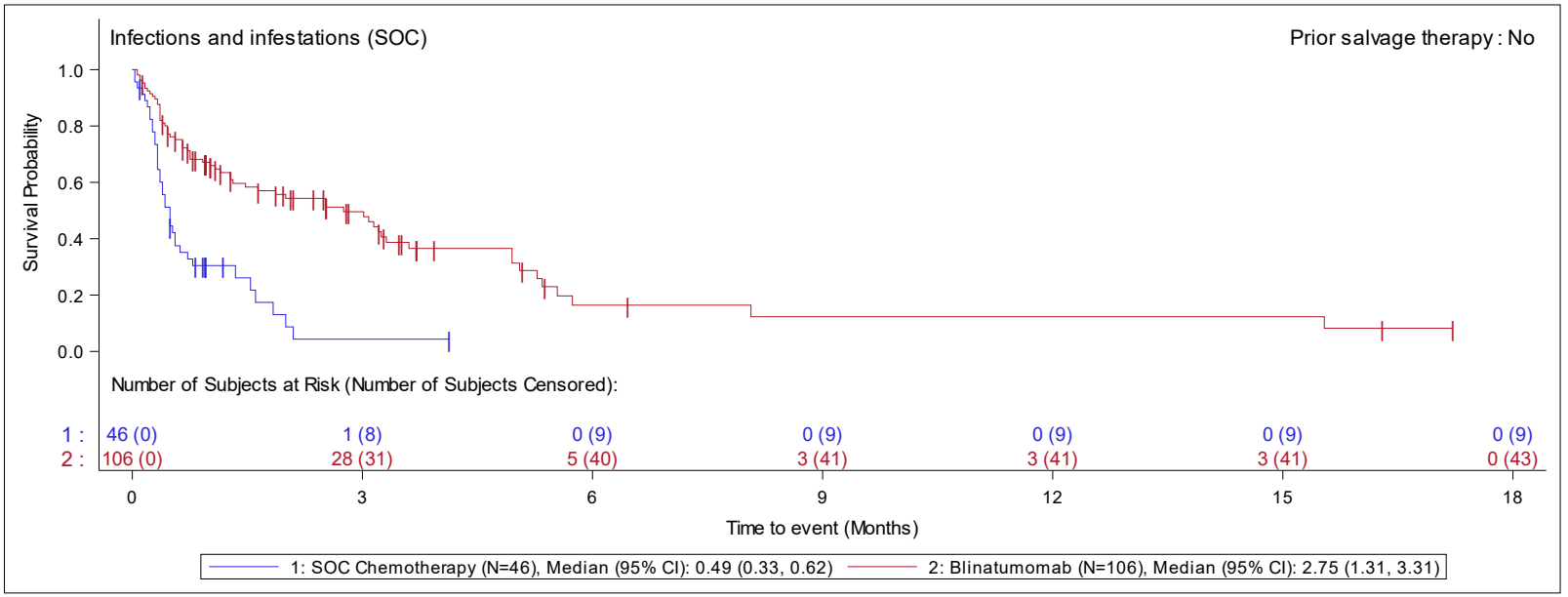
Output: f14-06-002-005-km-sub-teae-aesi-saf.rtf (Date Generated: 23OCT25 00:29) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Figure 14-6.2.5. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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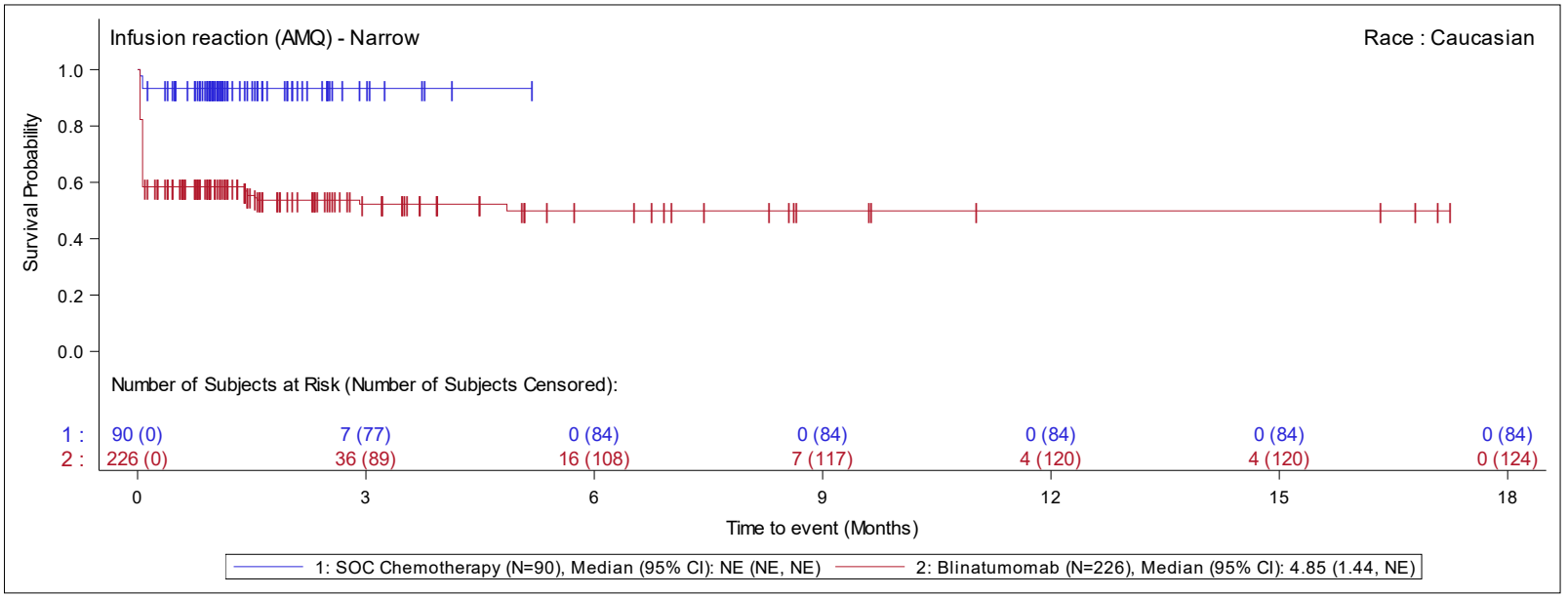

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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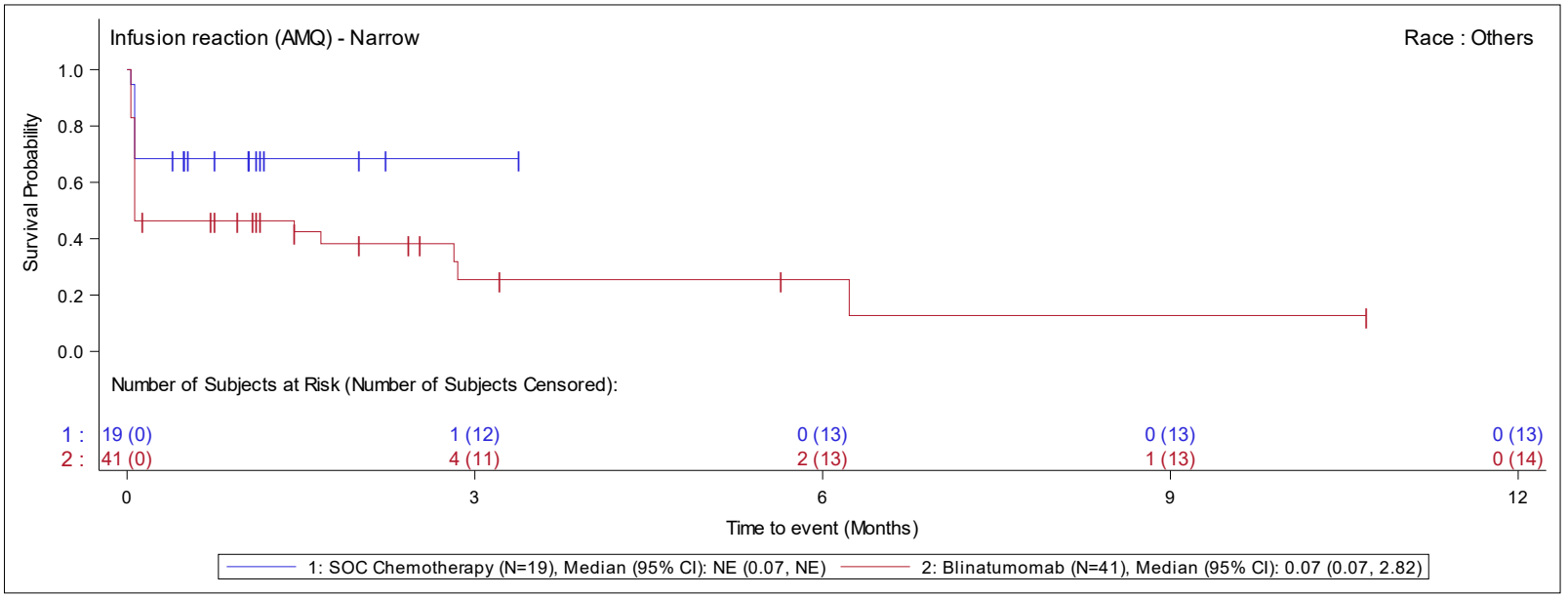

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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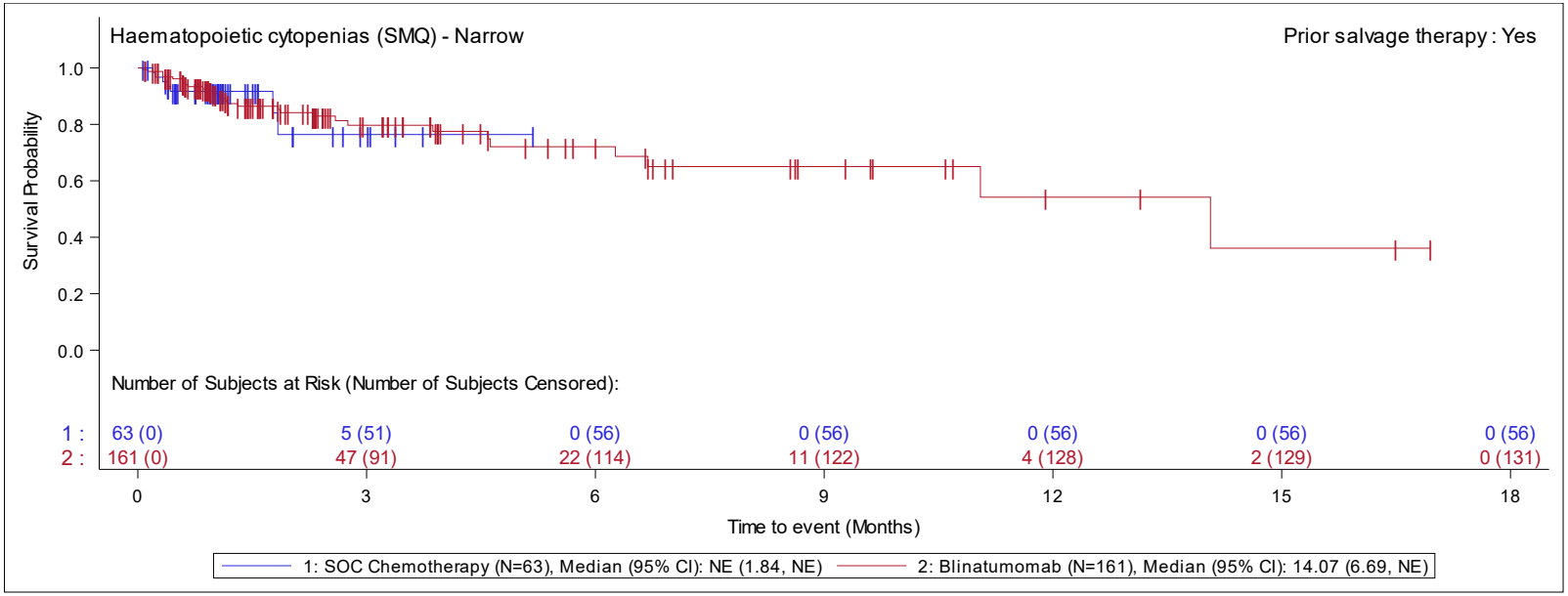
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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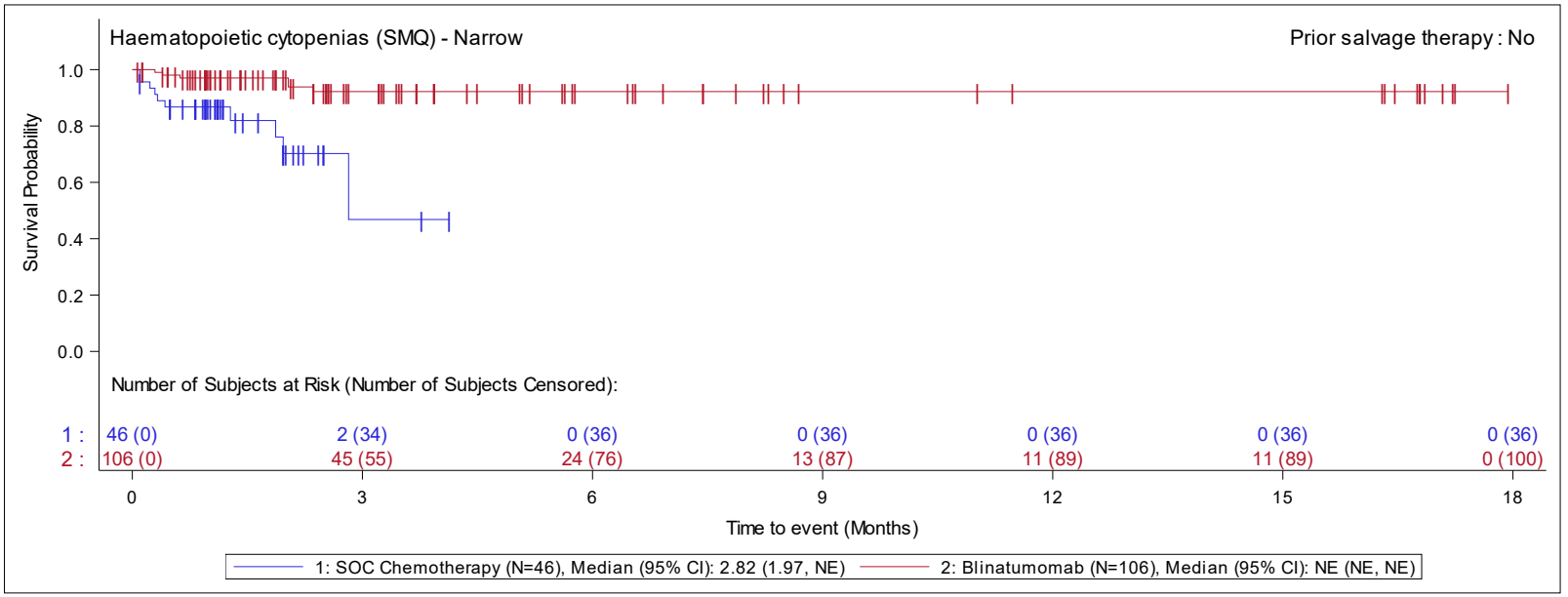
Figure 14-6.2.6. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Prior Defined Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



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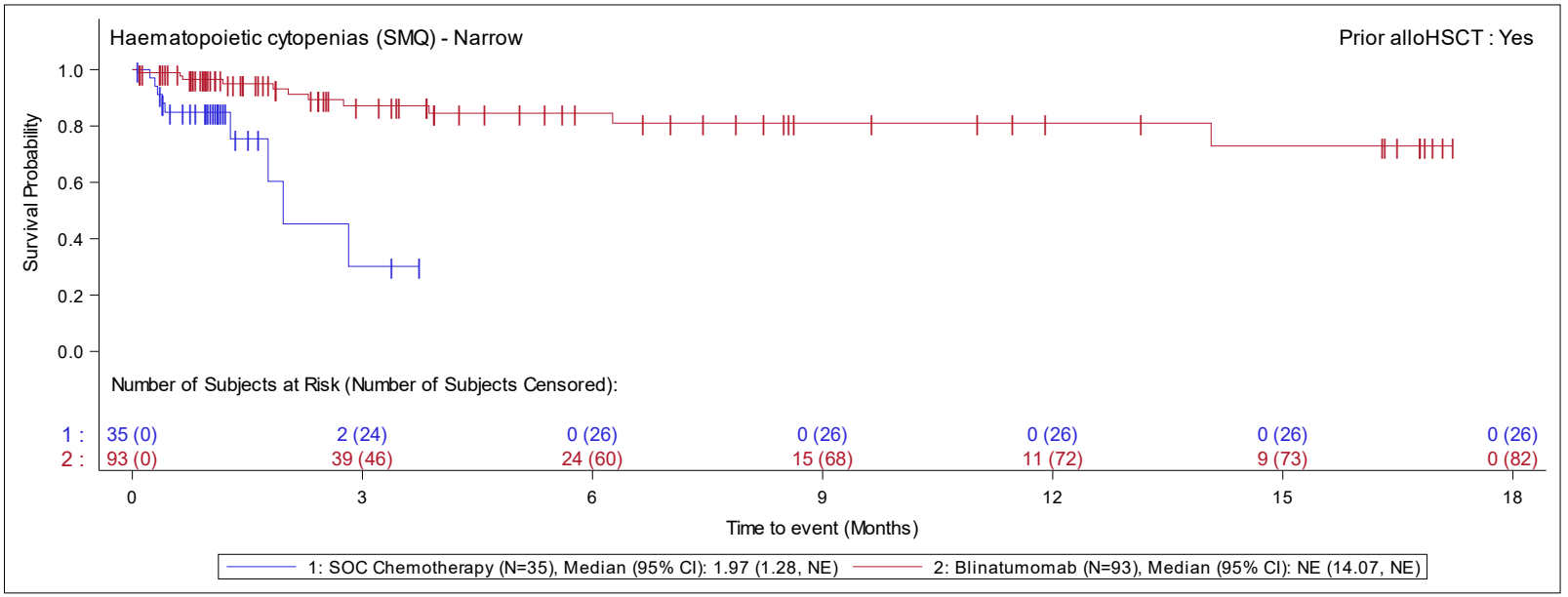

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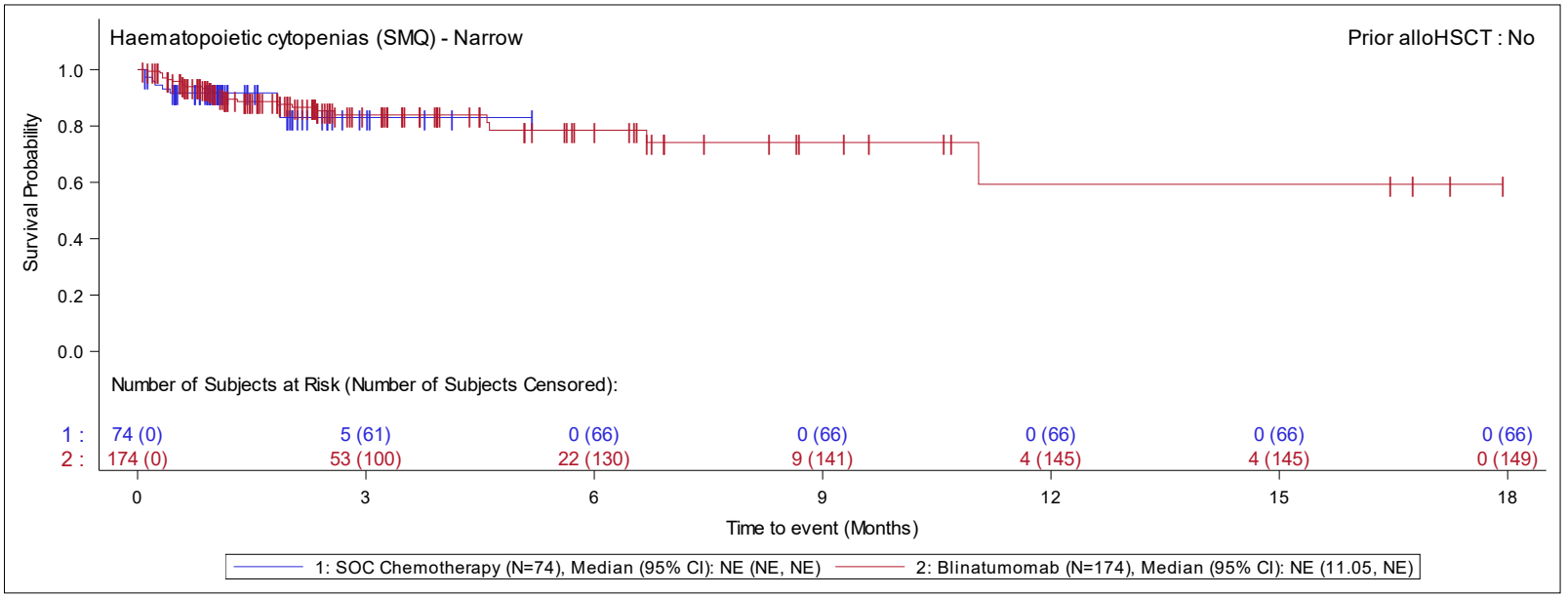

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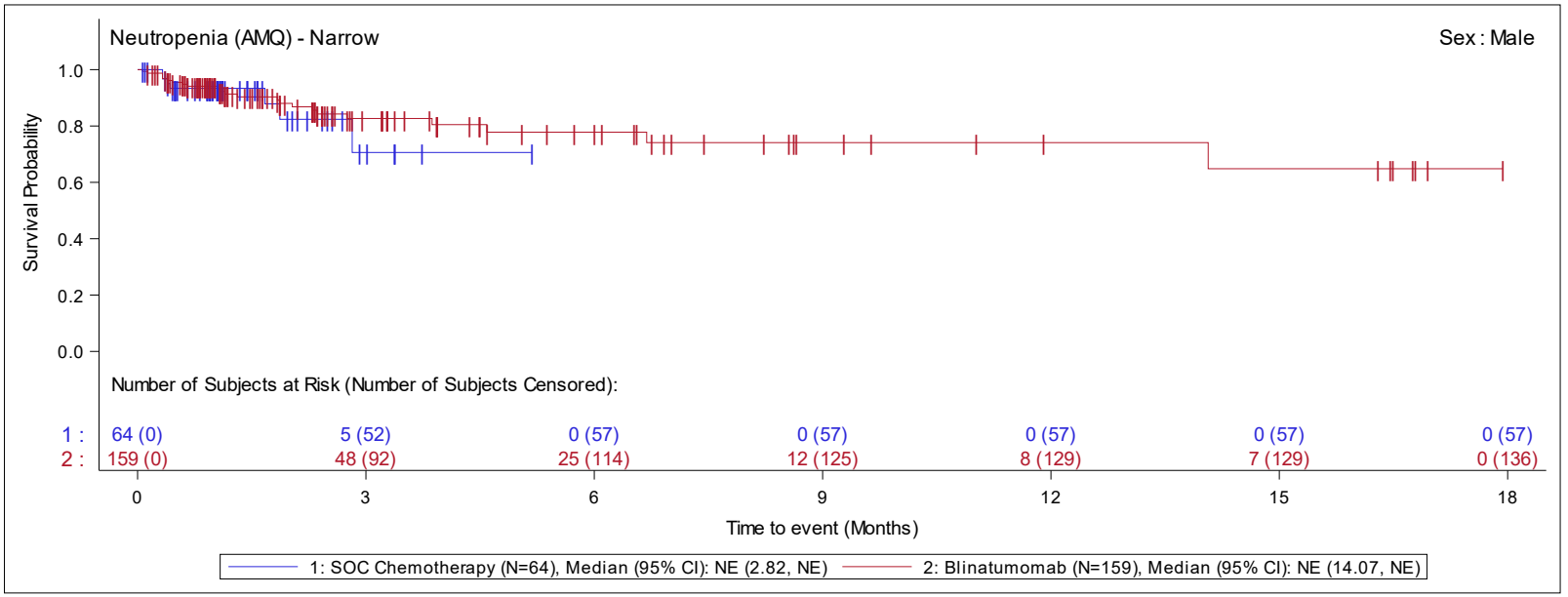

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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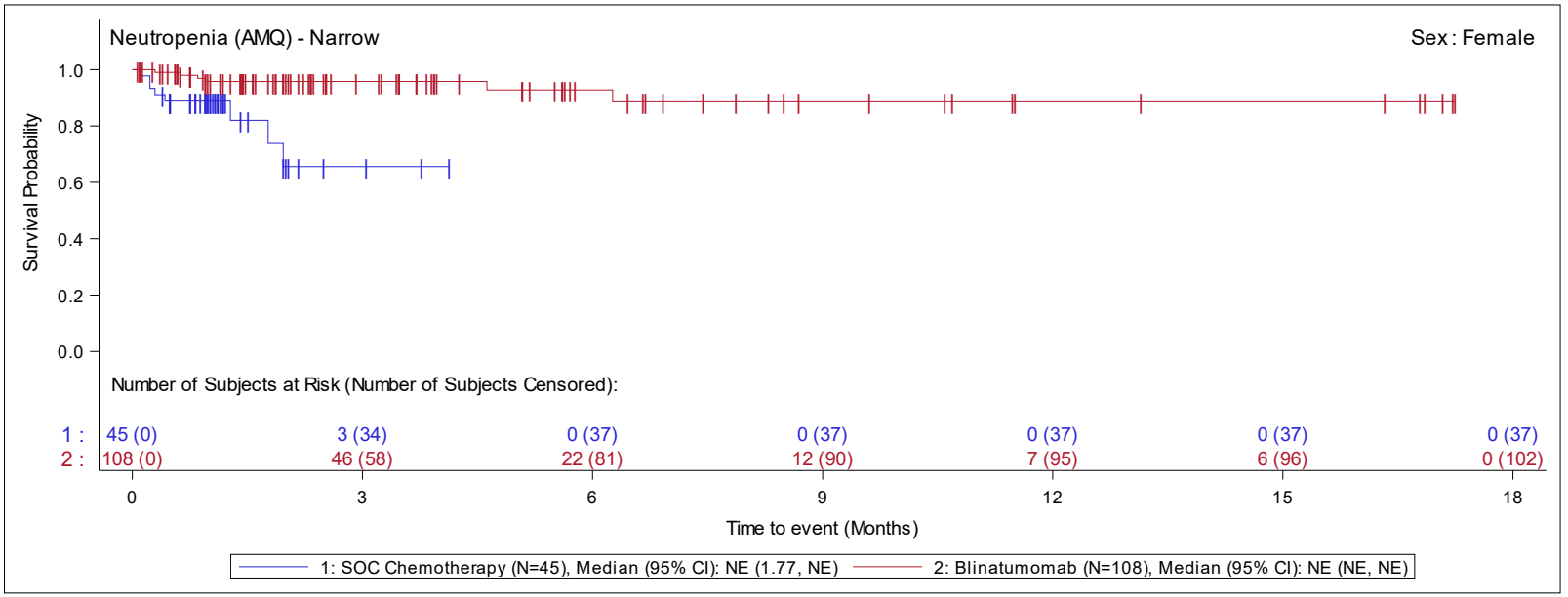

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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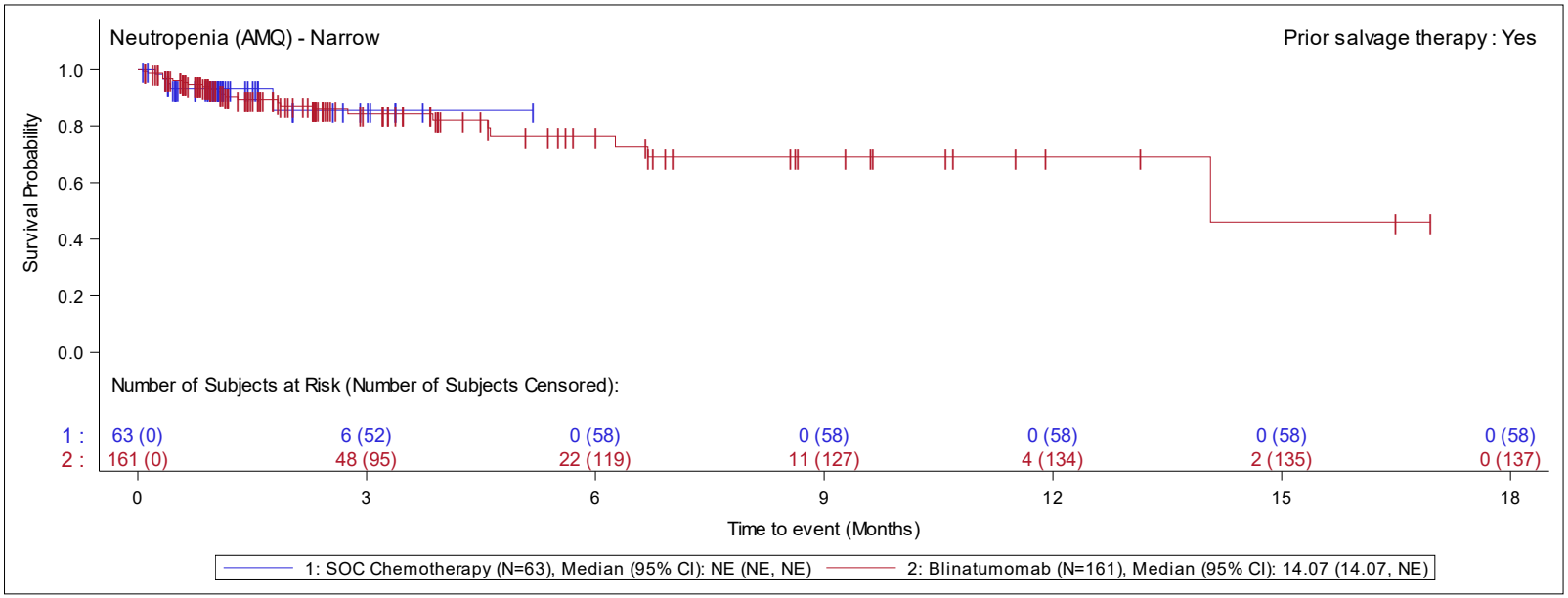

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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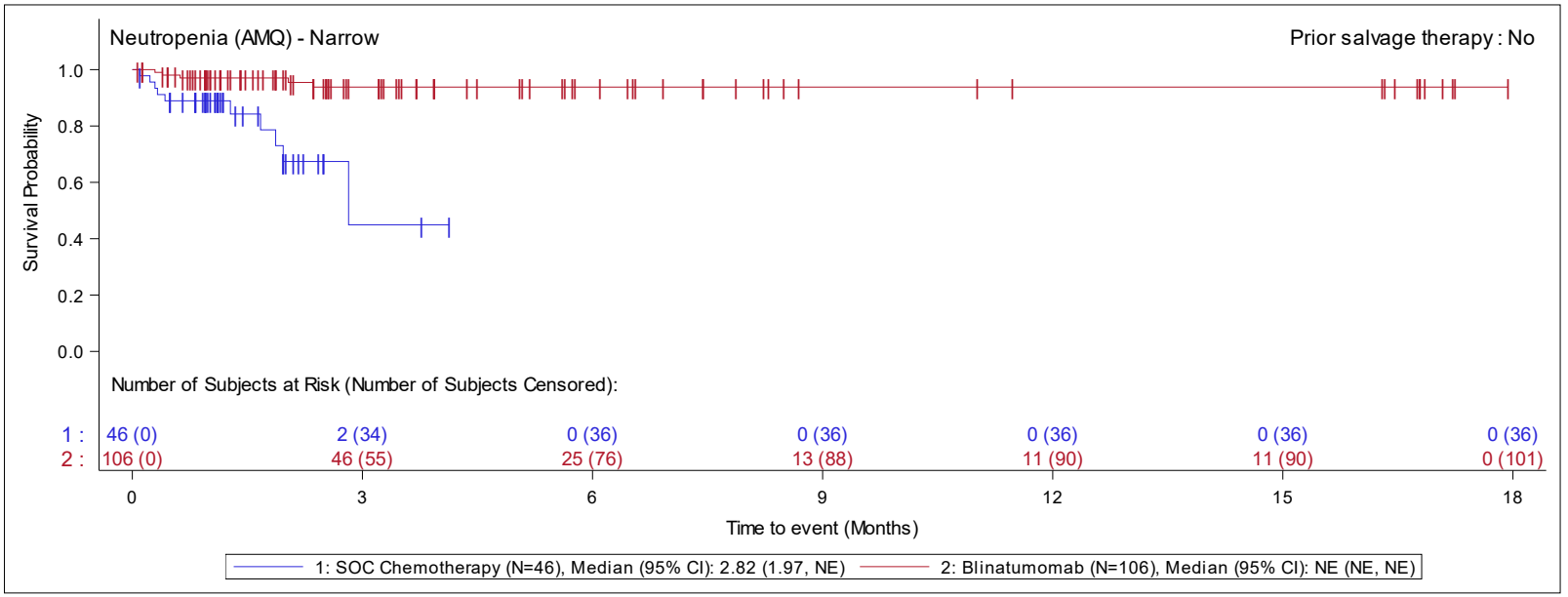

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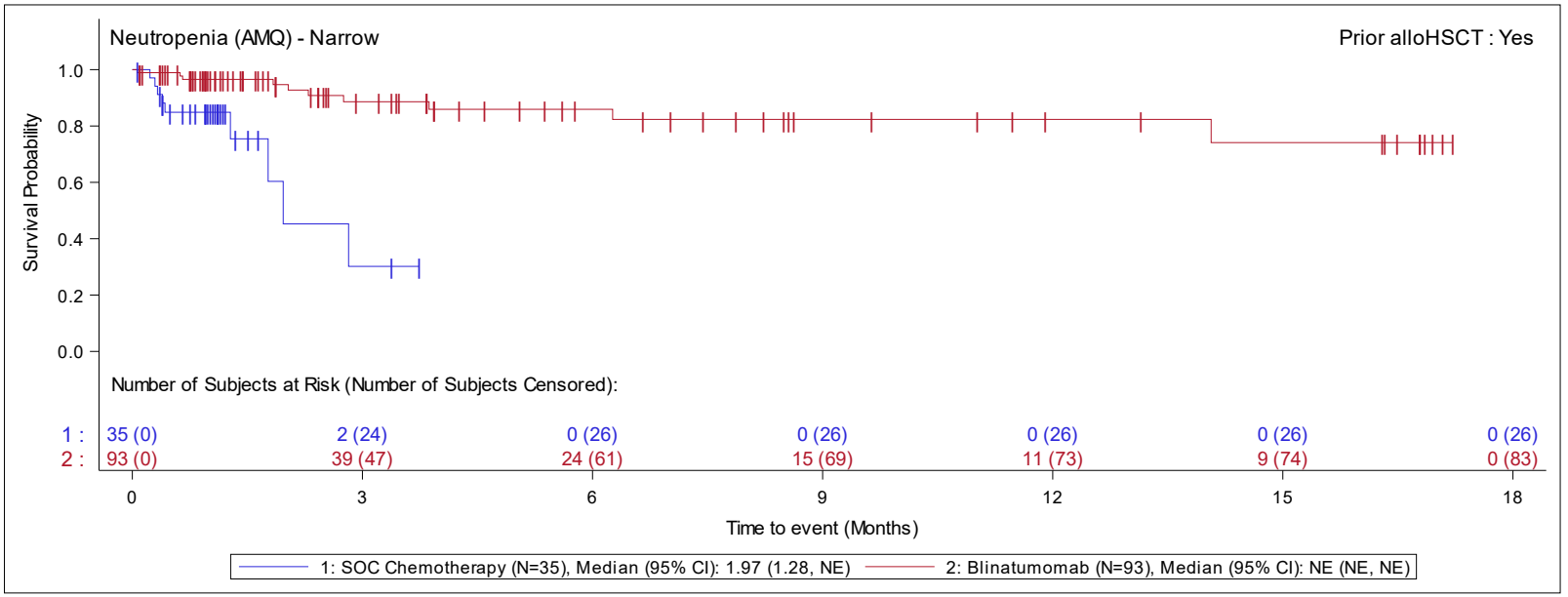

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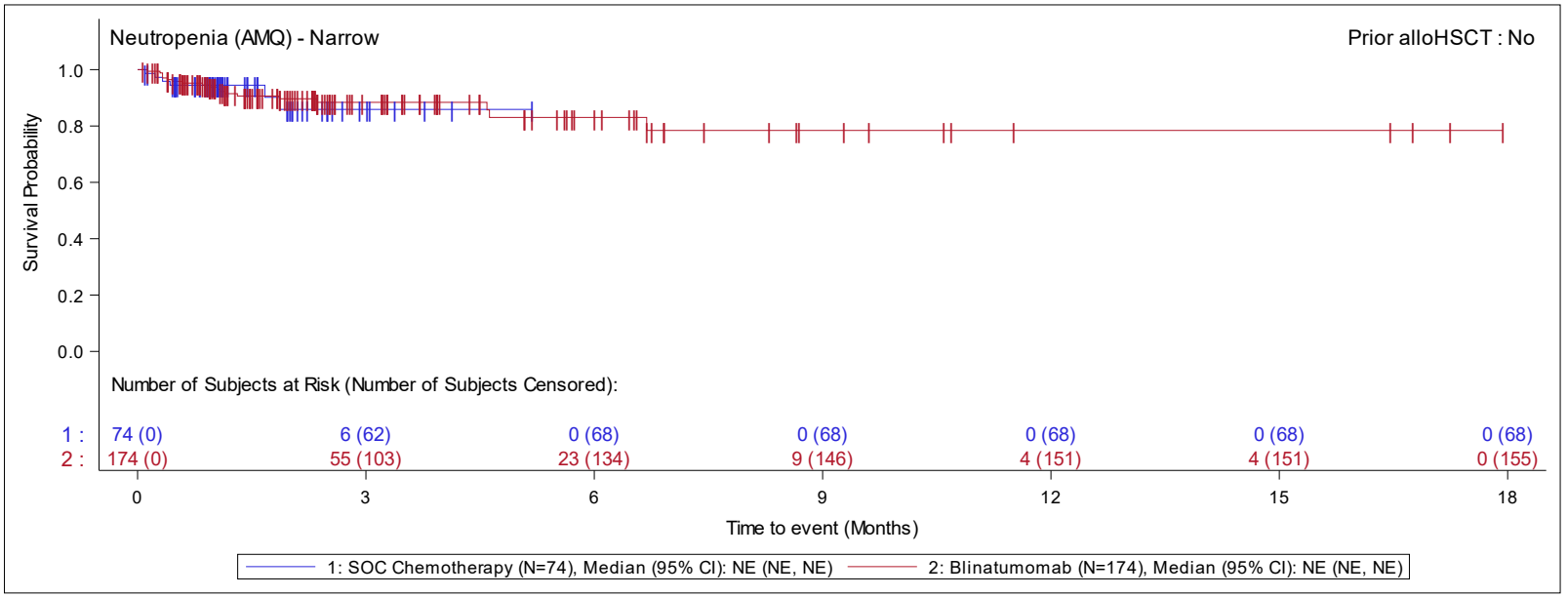

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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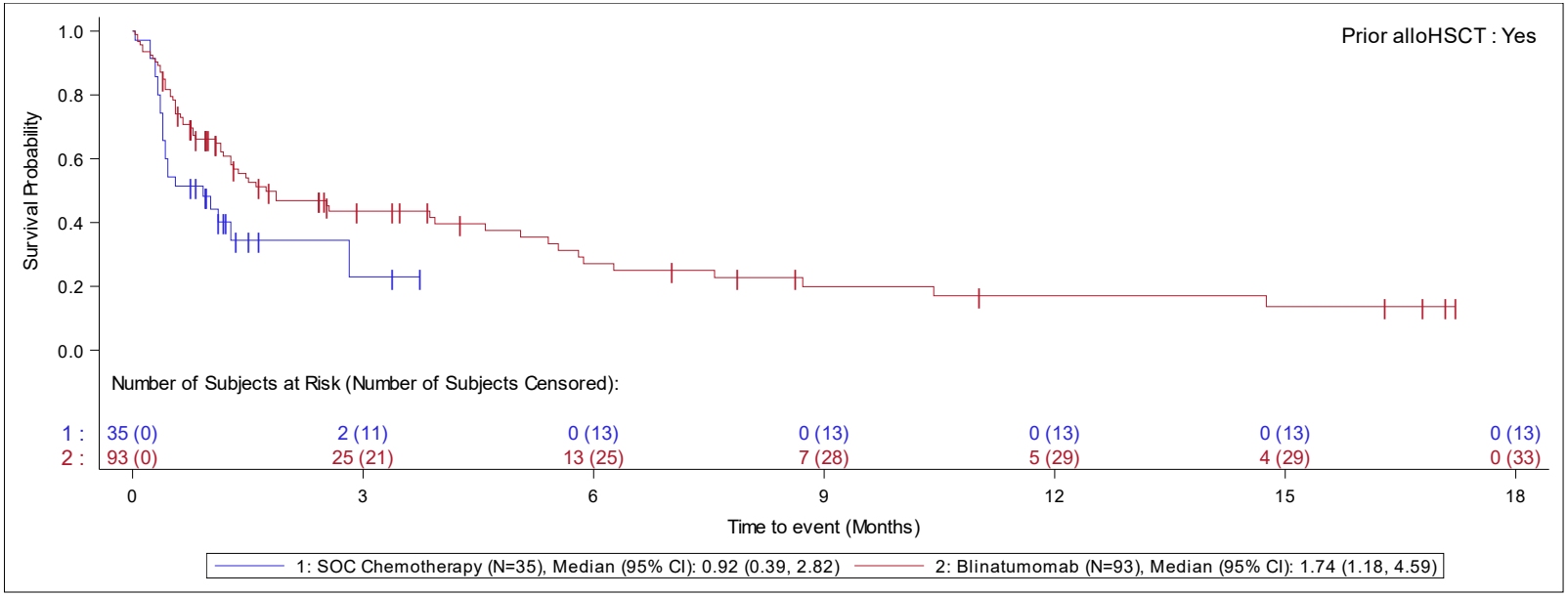
Figure 14-6.2.9. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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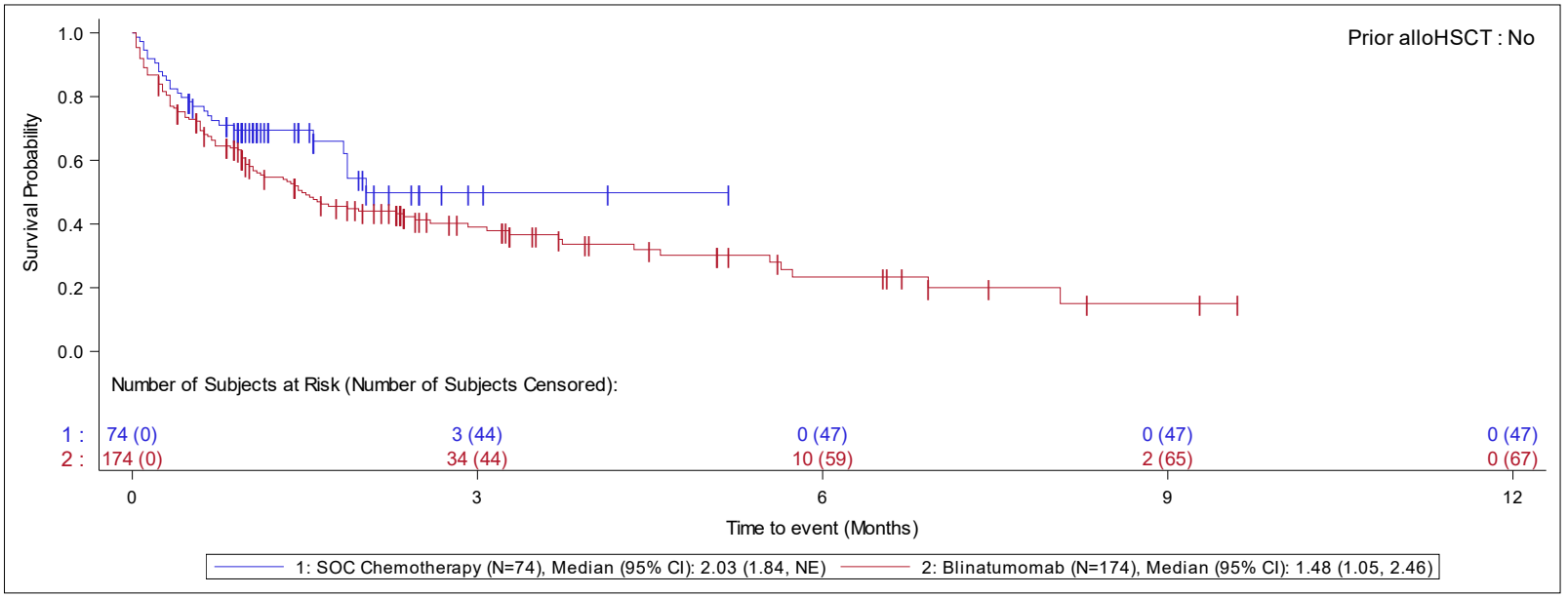
Figure 14-6.2.9. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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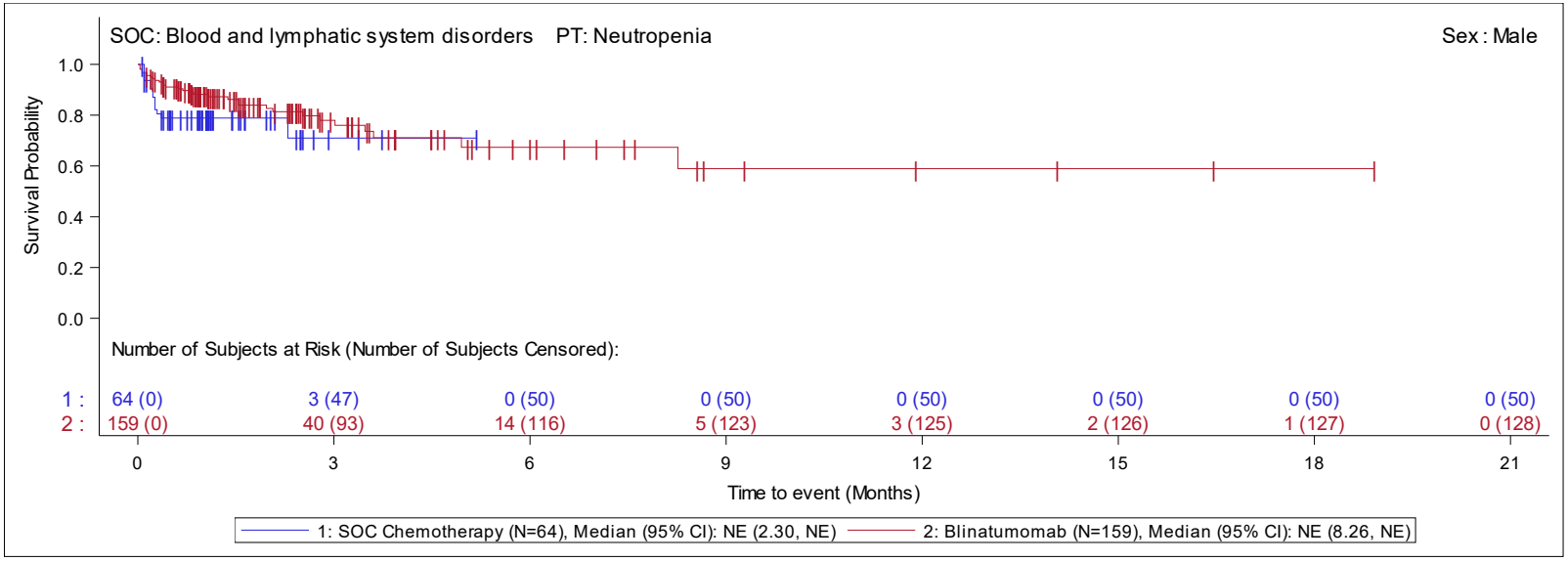
Output: f14-06-002-009-km-sub-ser-teae-edp-saf.rtf (Date Generated: 23OCT25 00:28) Source Data: adam_fa.adsl, adam_fa.adbase, adam.adtteae

Figure 14-6.2.11. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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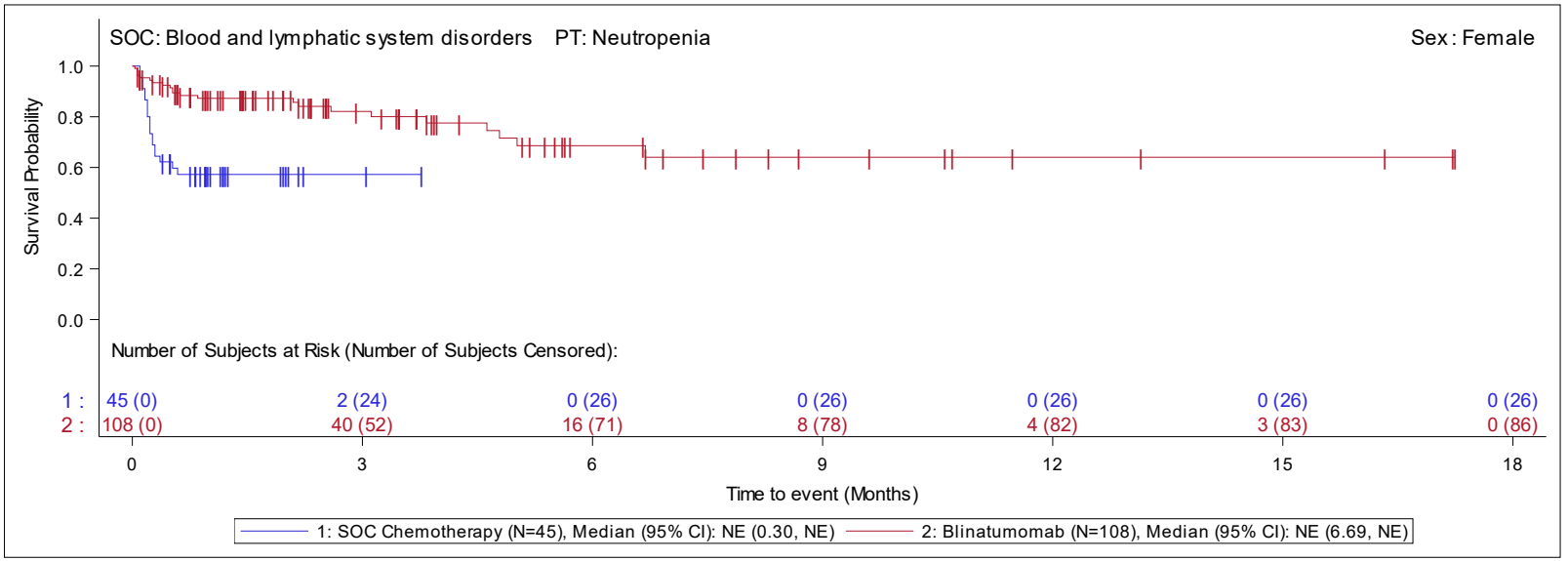
Figure 14-6.2.11. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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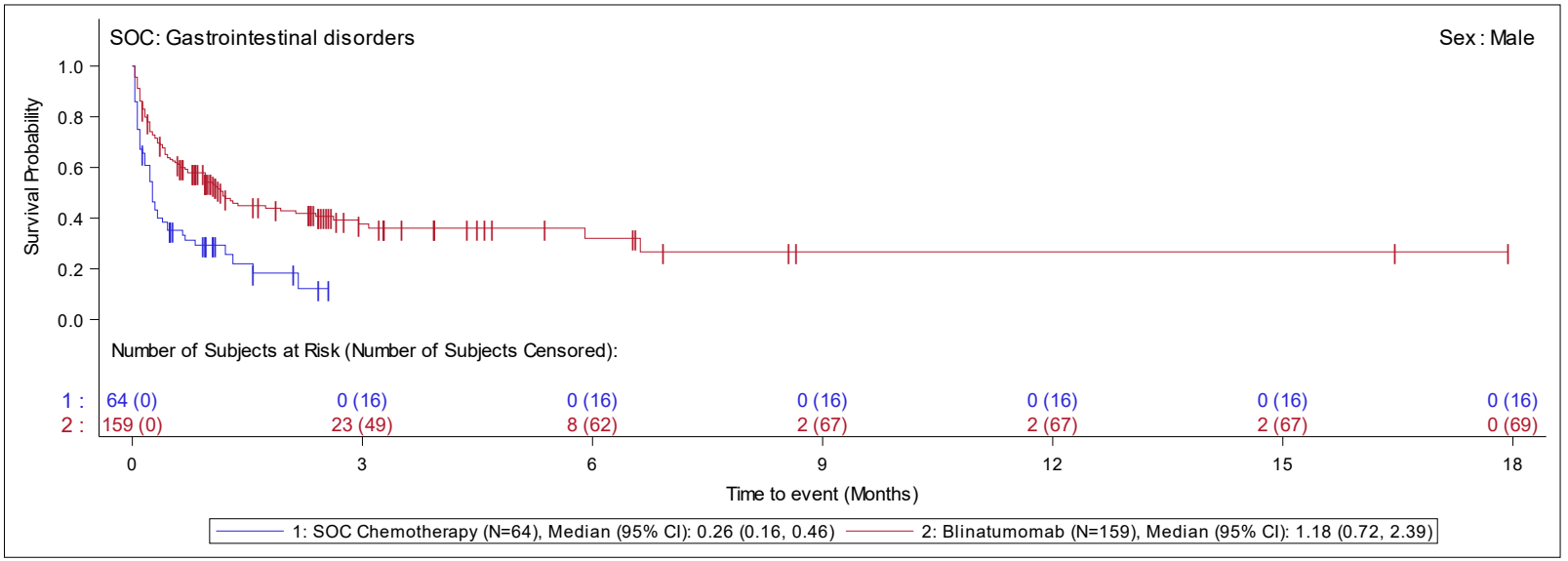

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Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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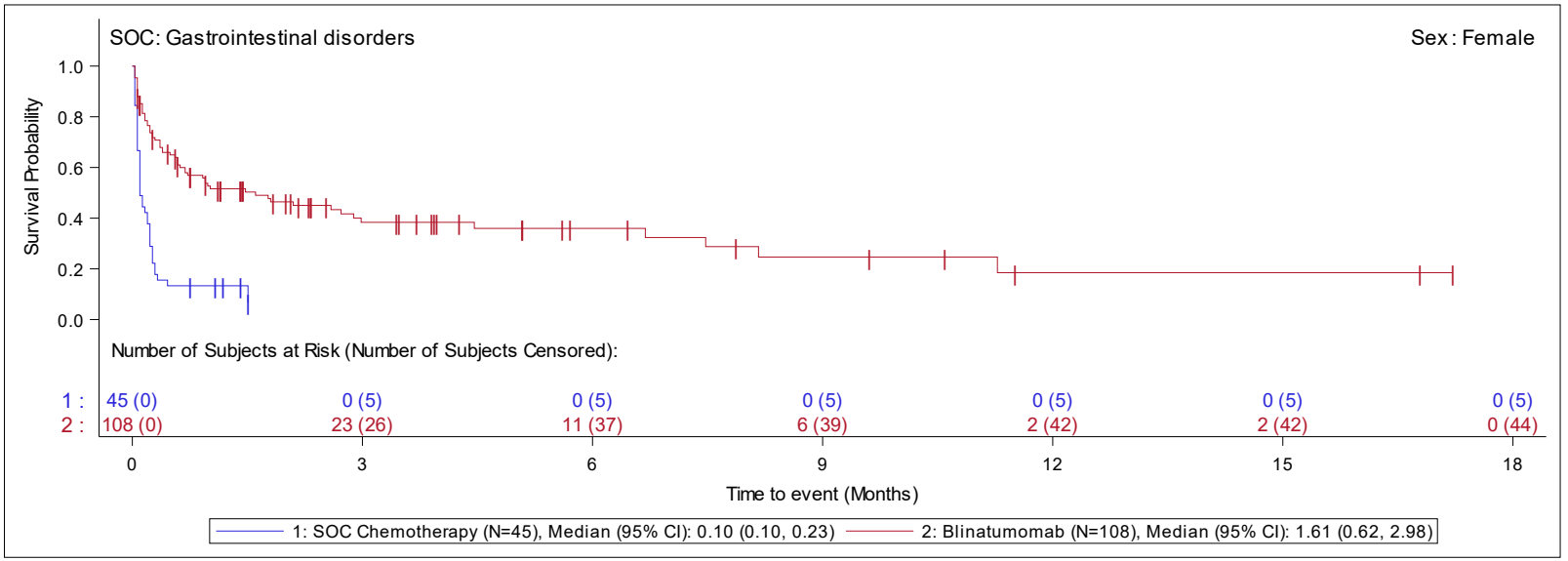

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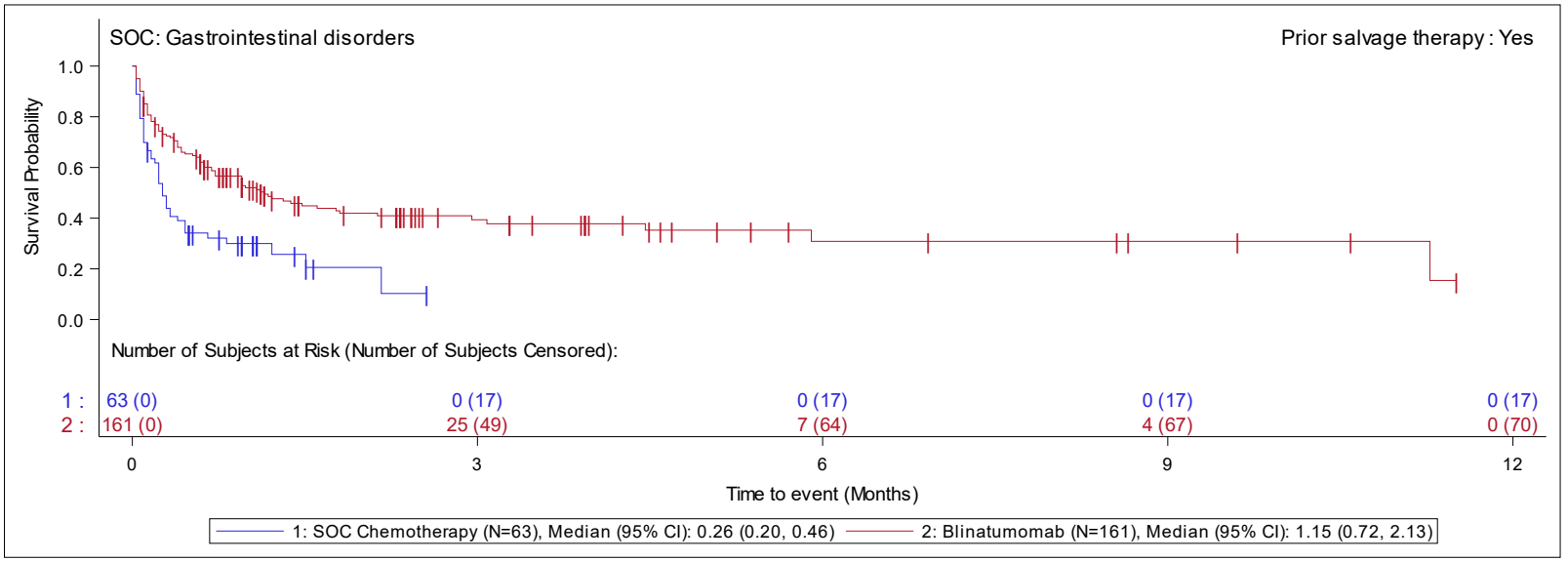

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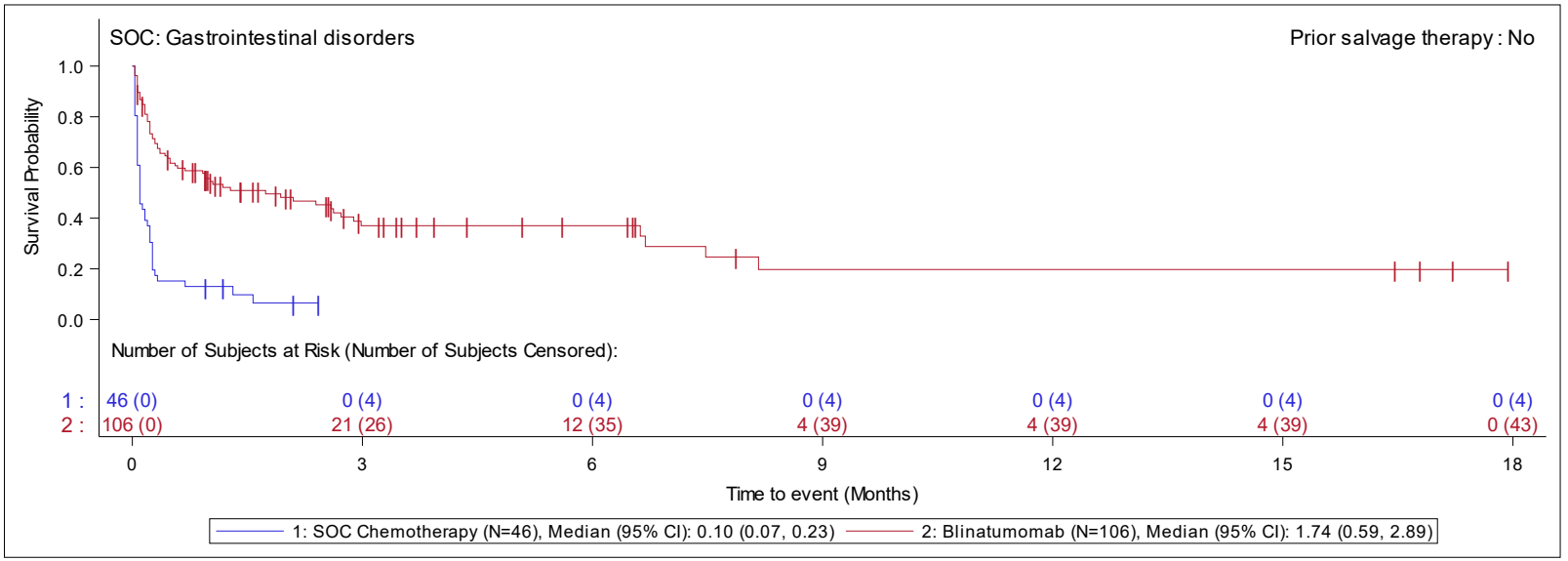

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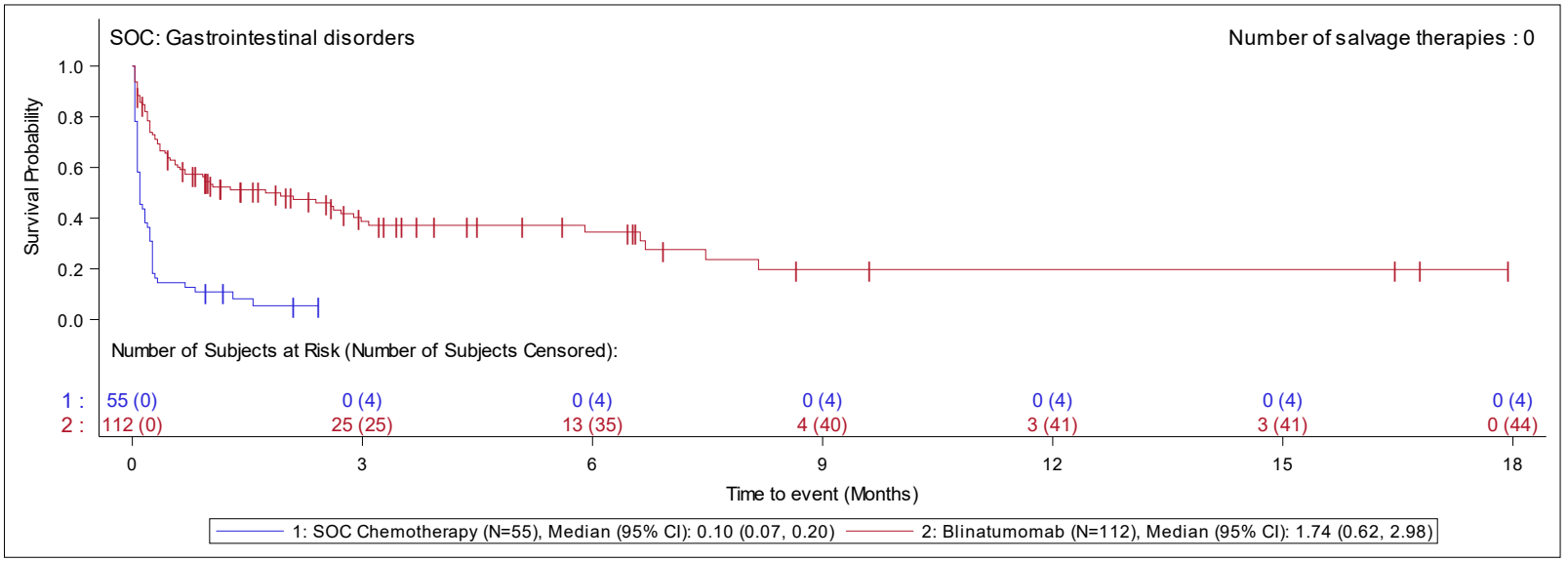

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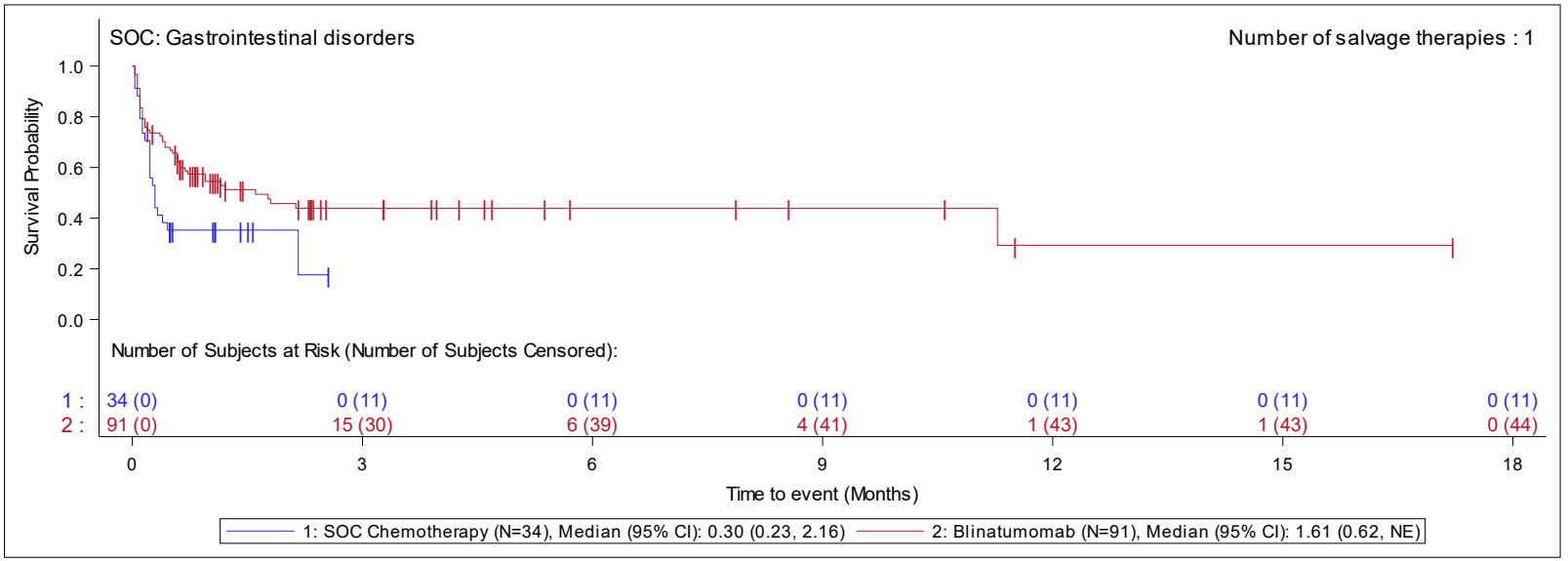

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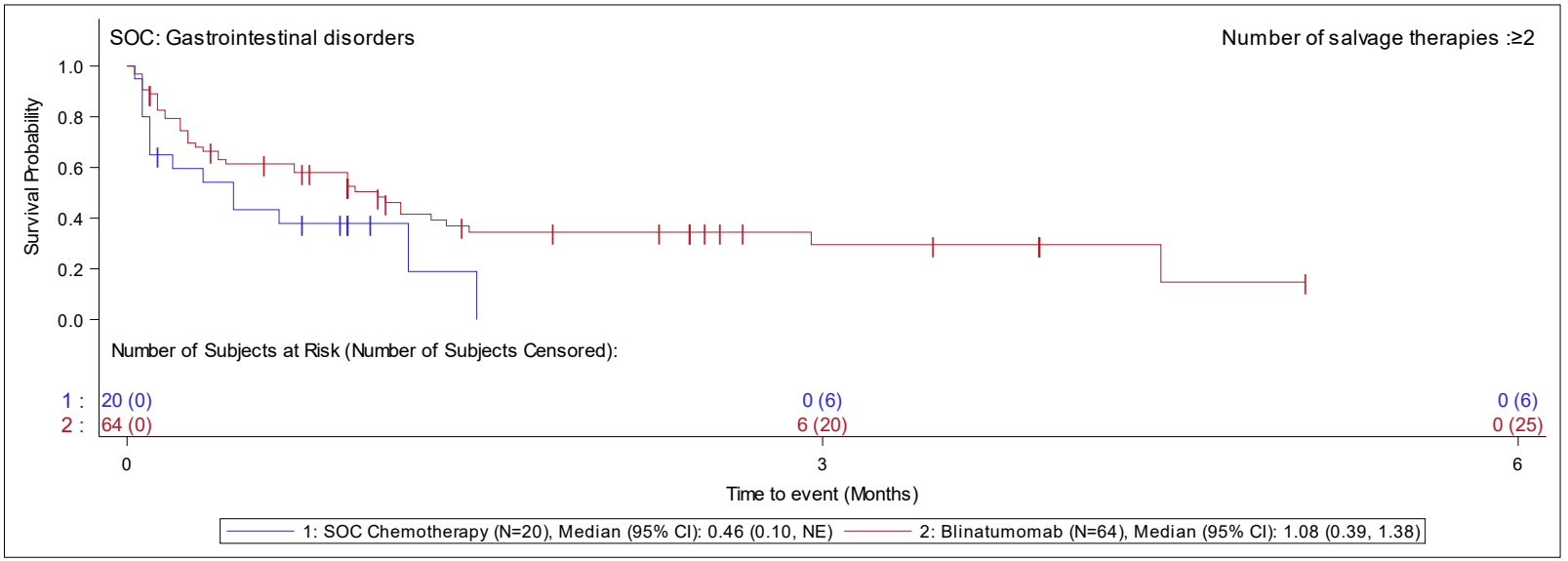
Figure 14-6.2.11. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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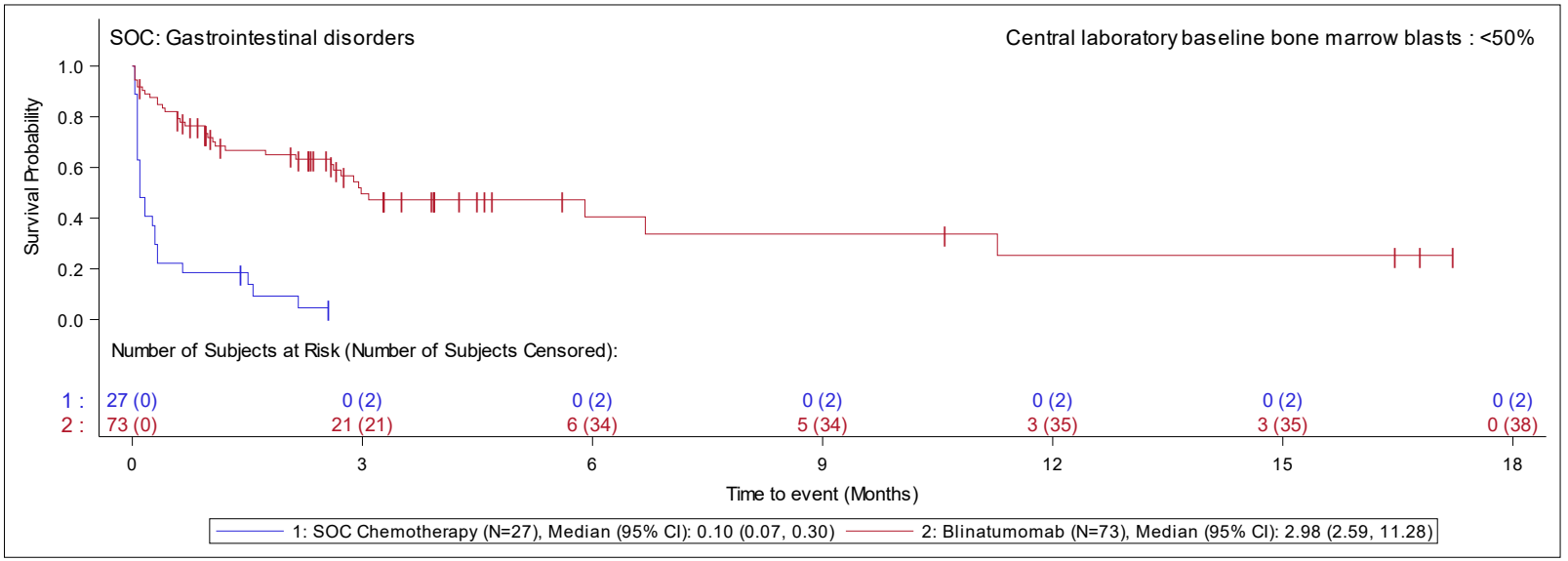

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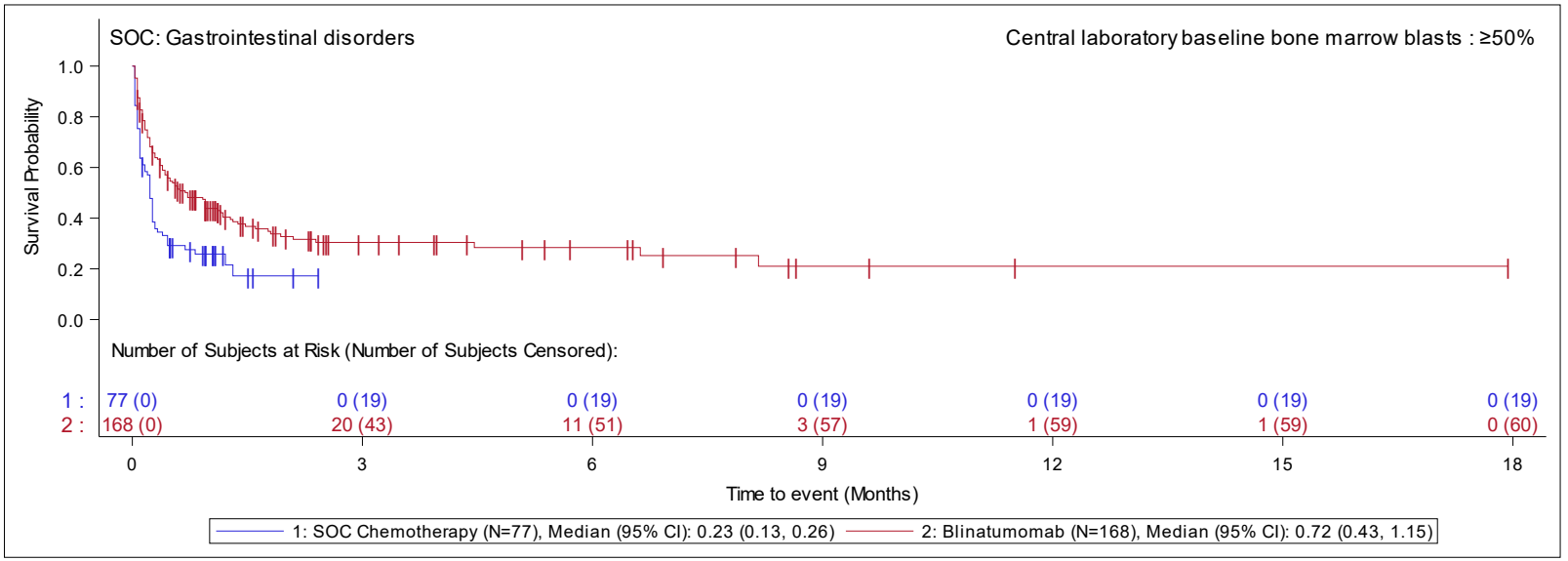

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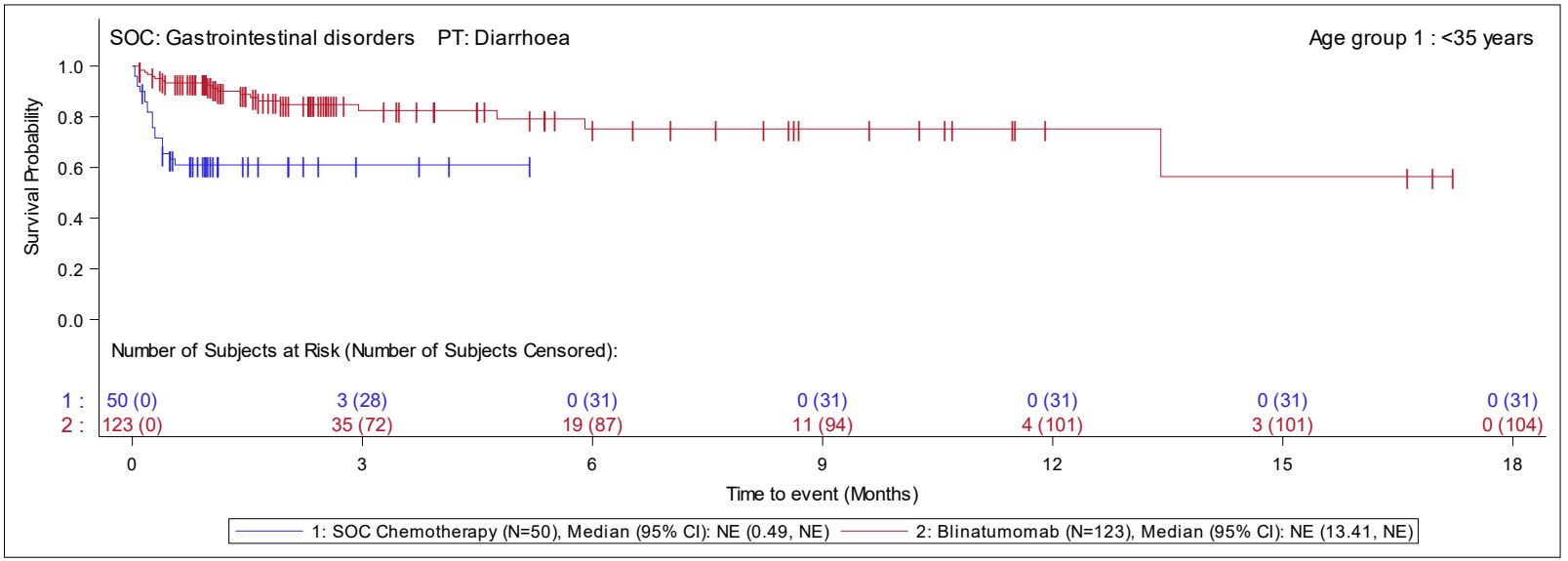

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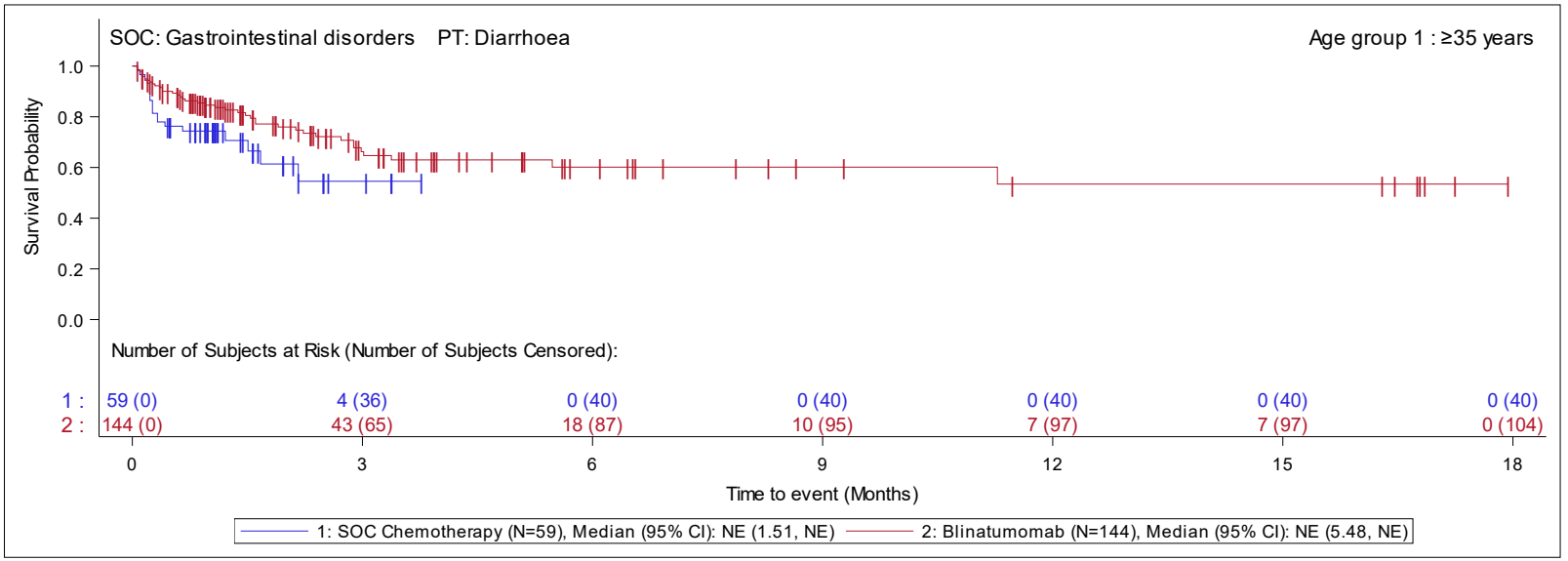

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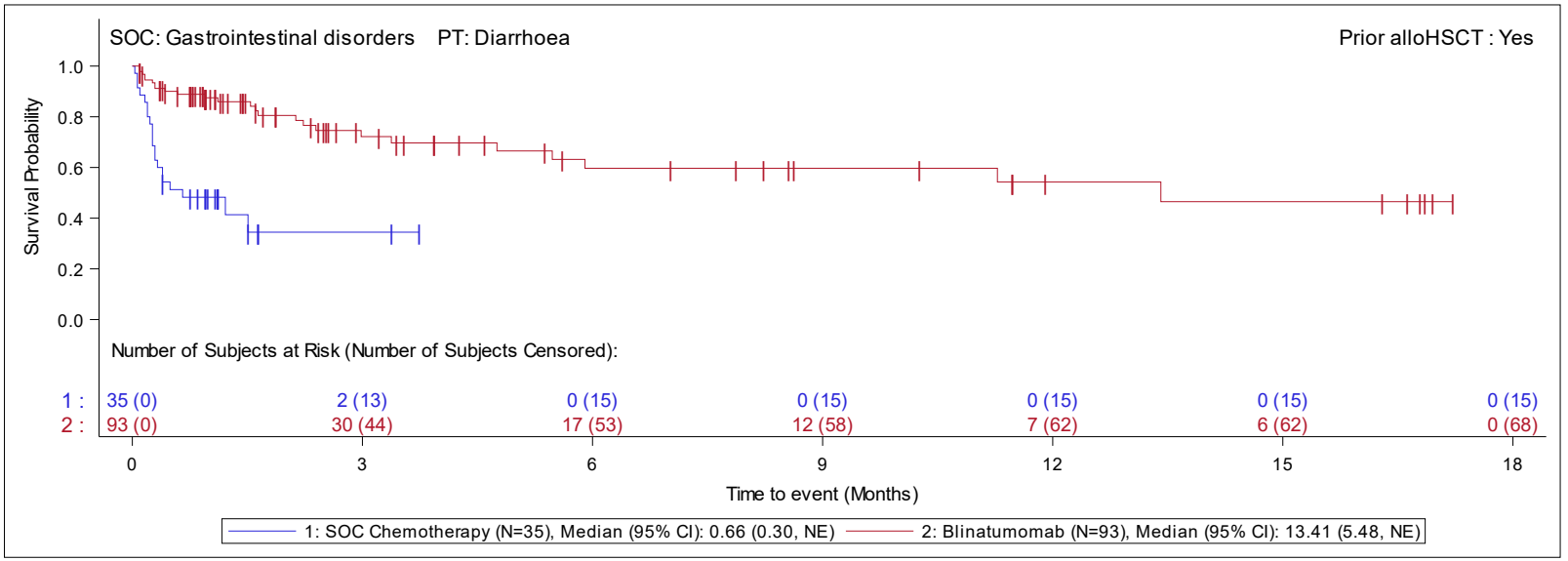

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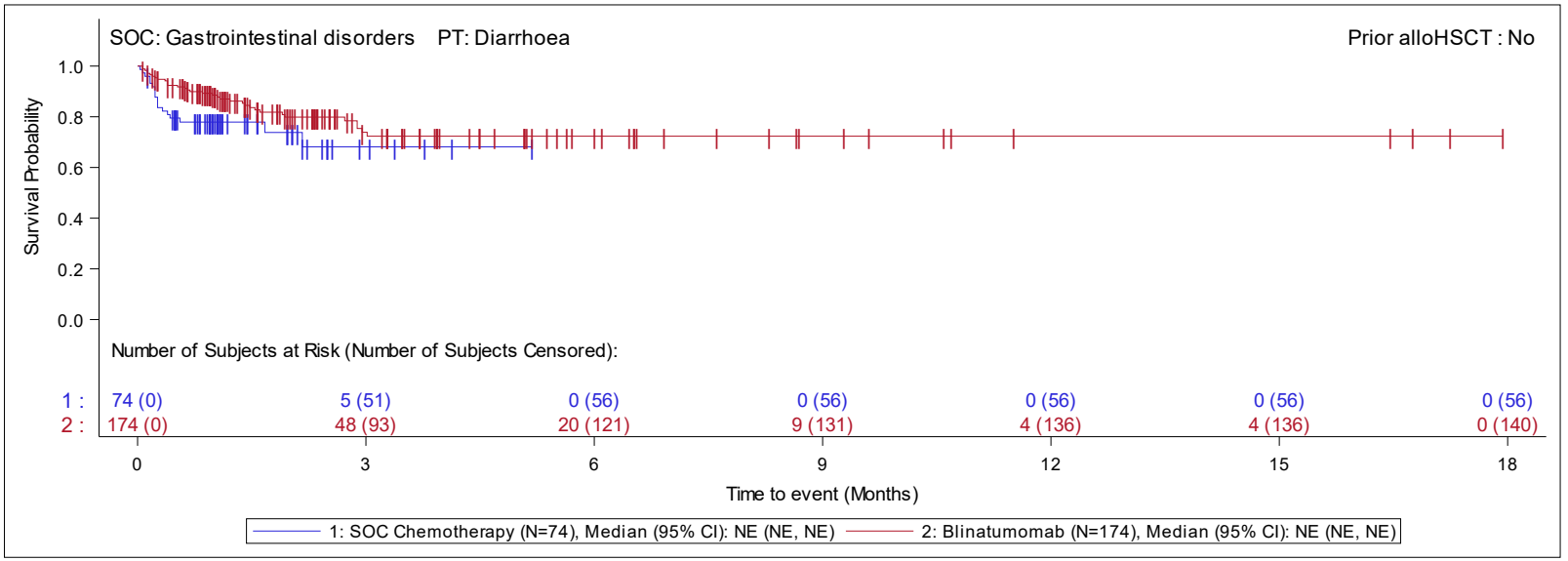

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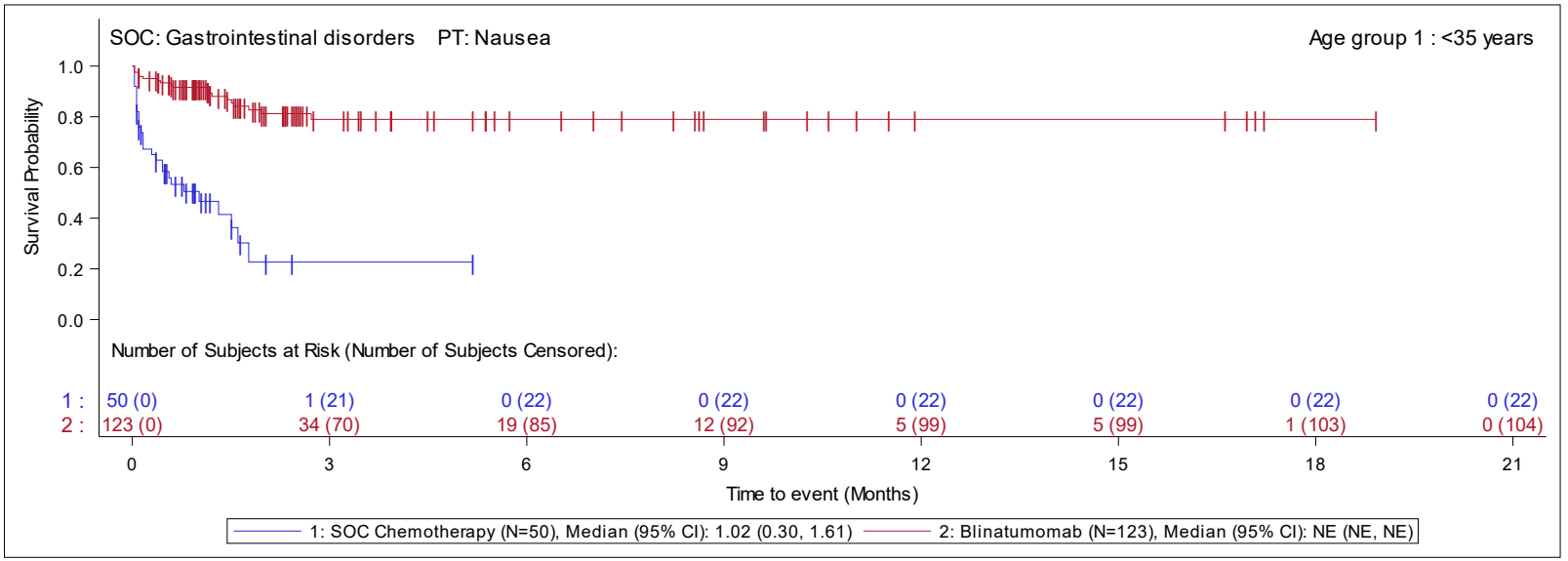

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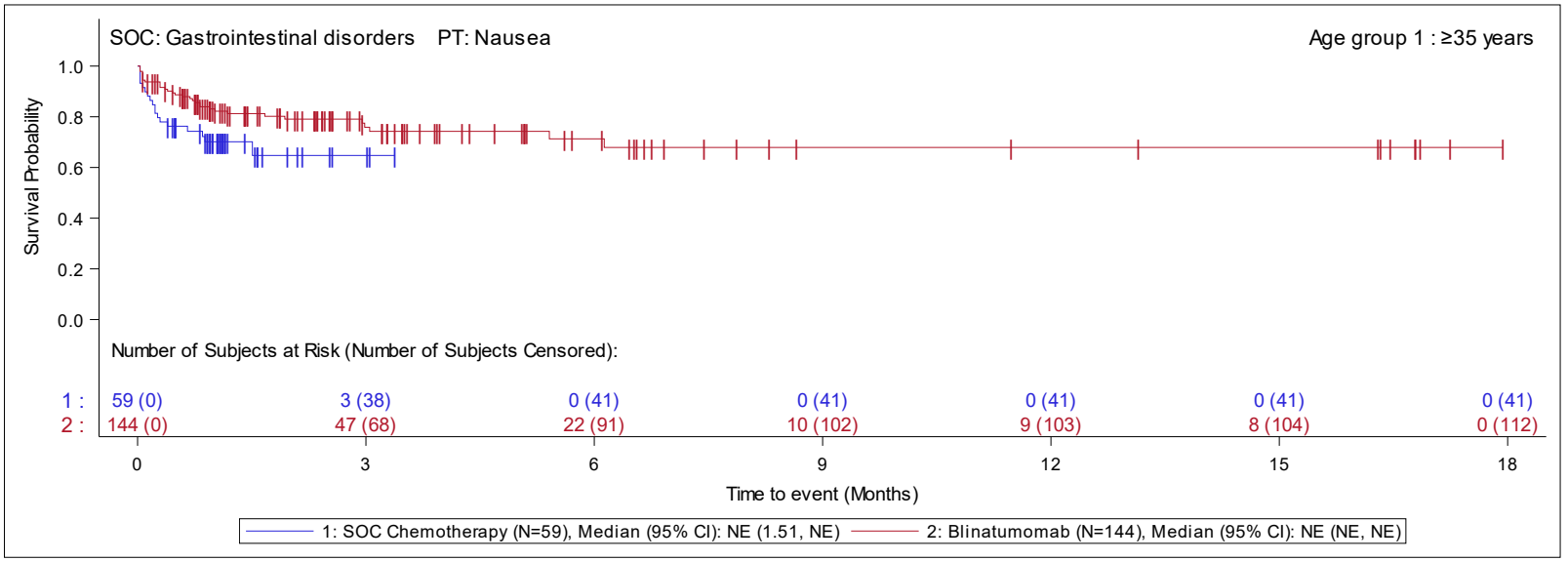

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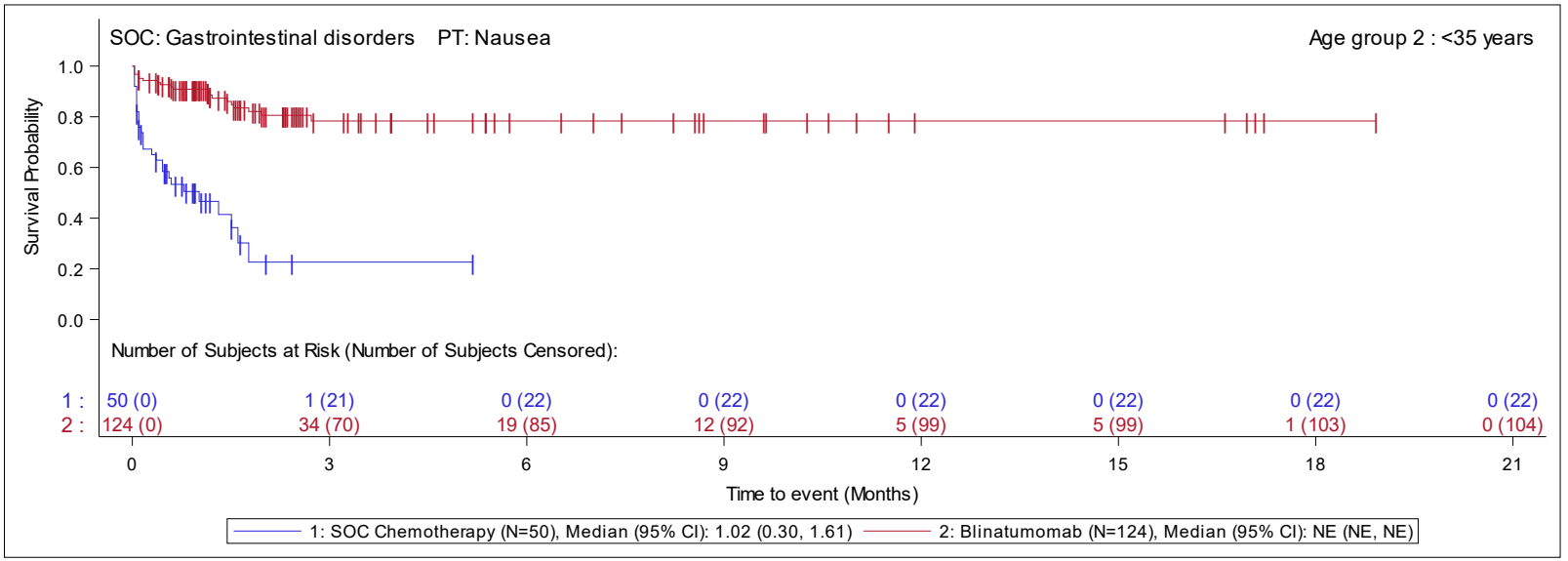

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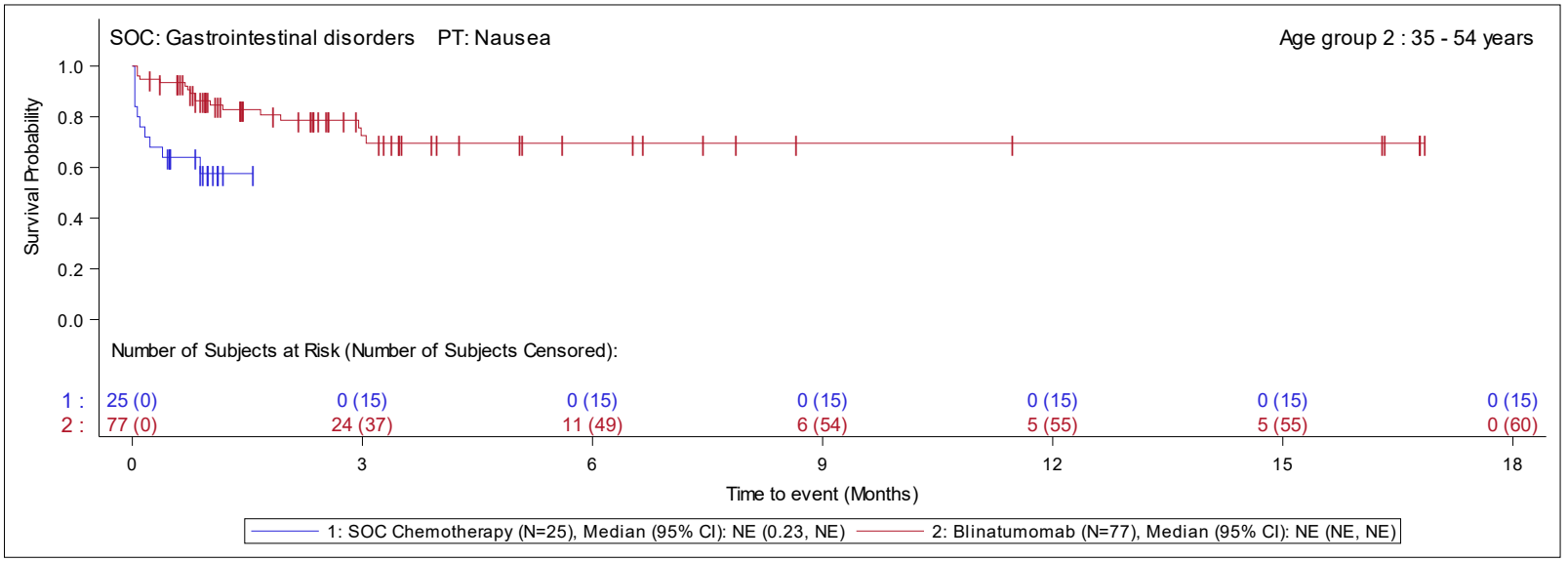

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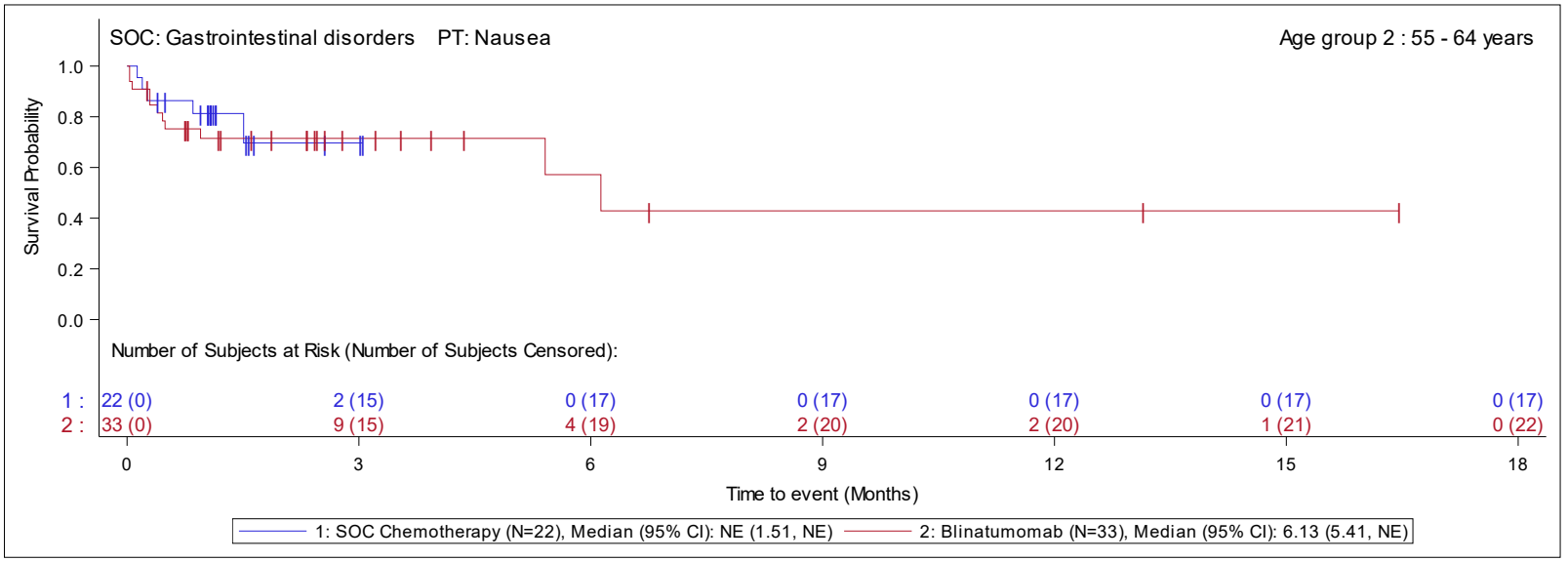

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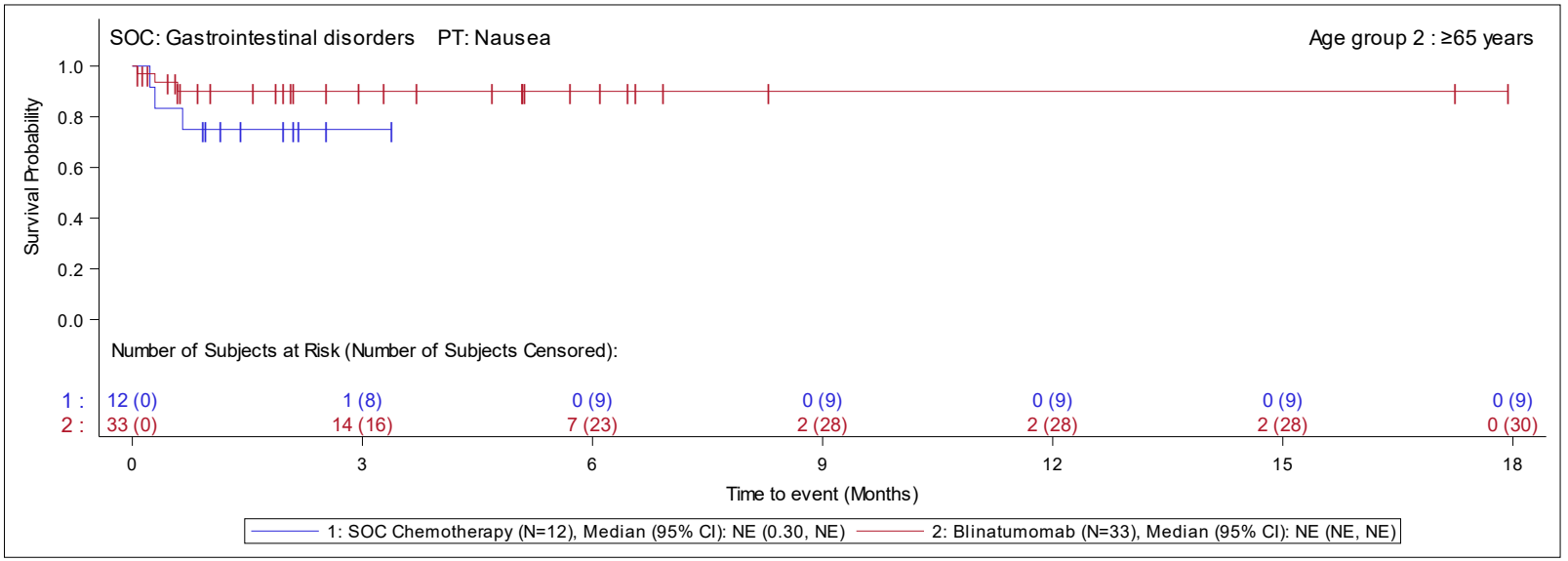

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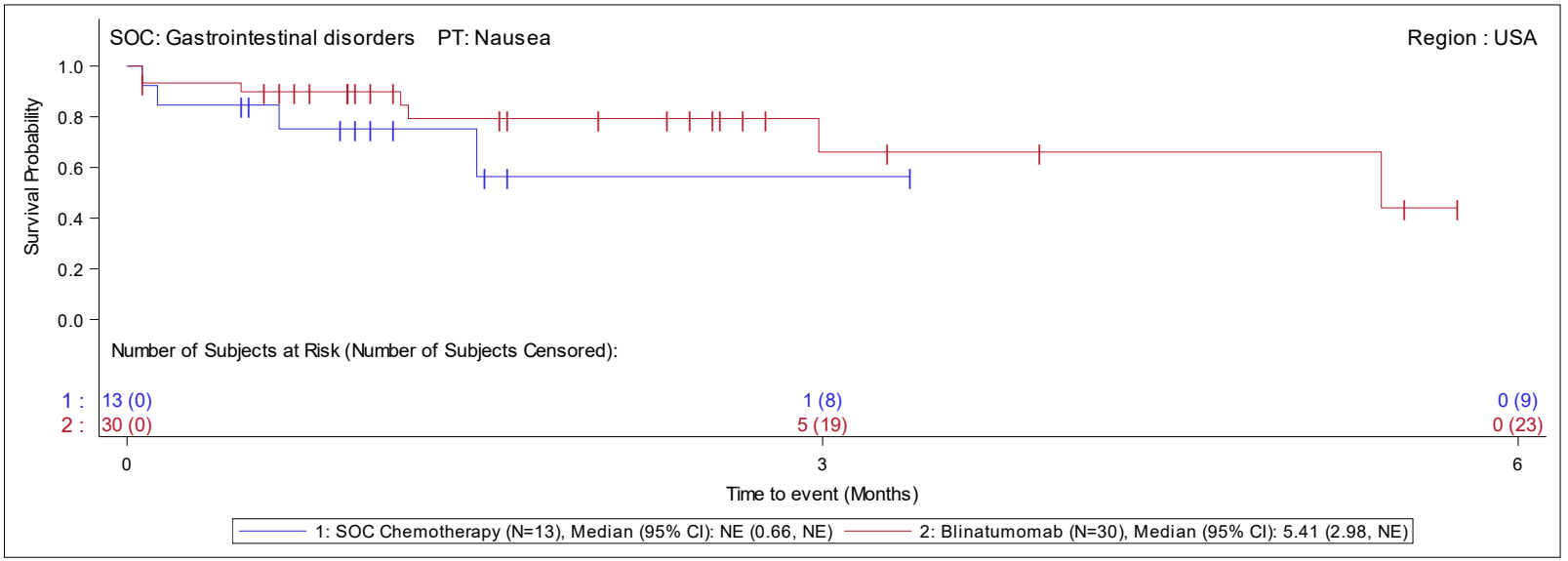

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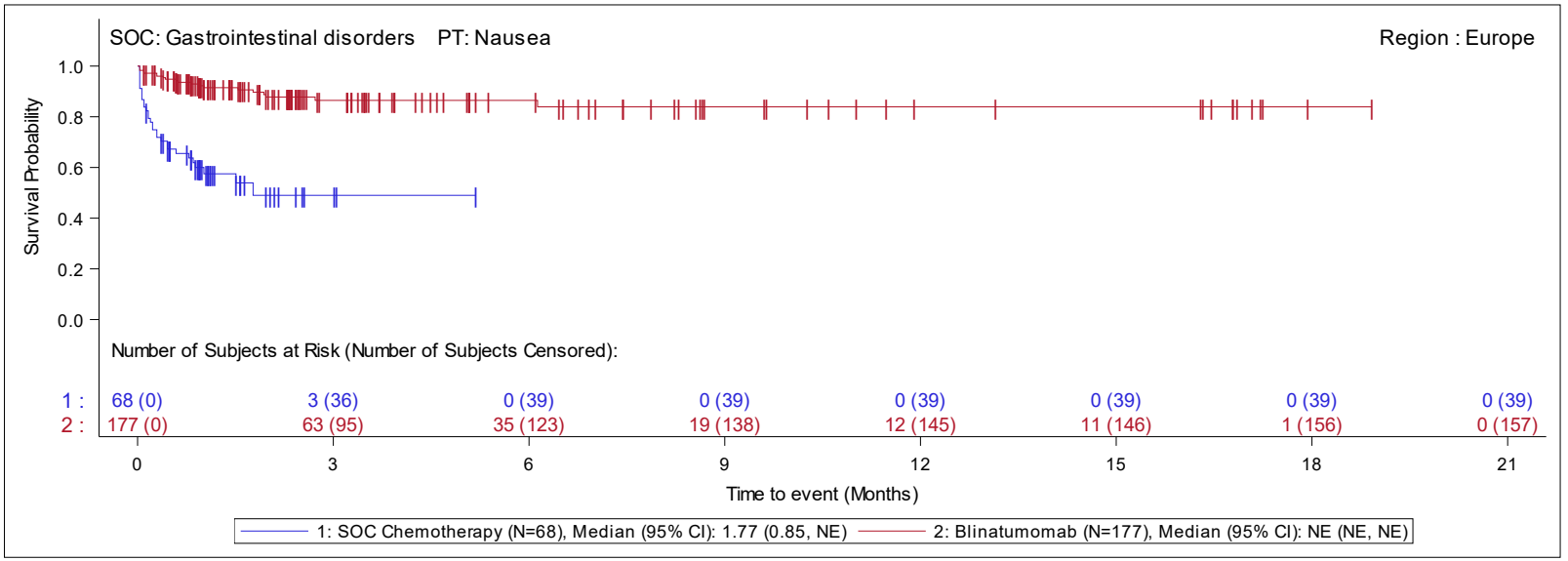

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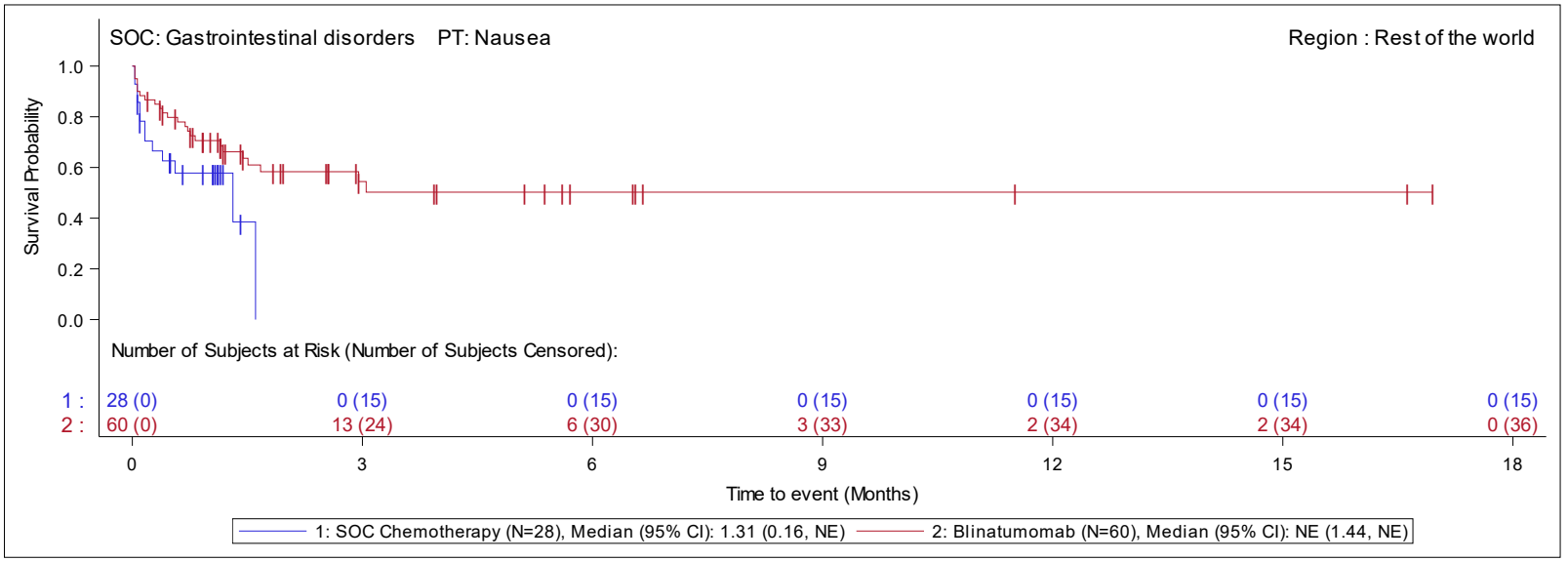

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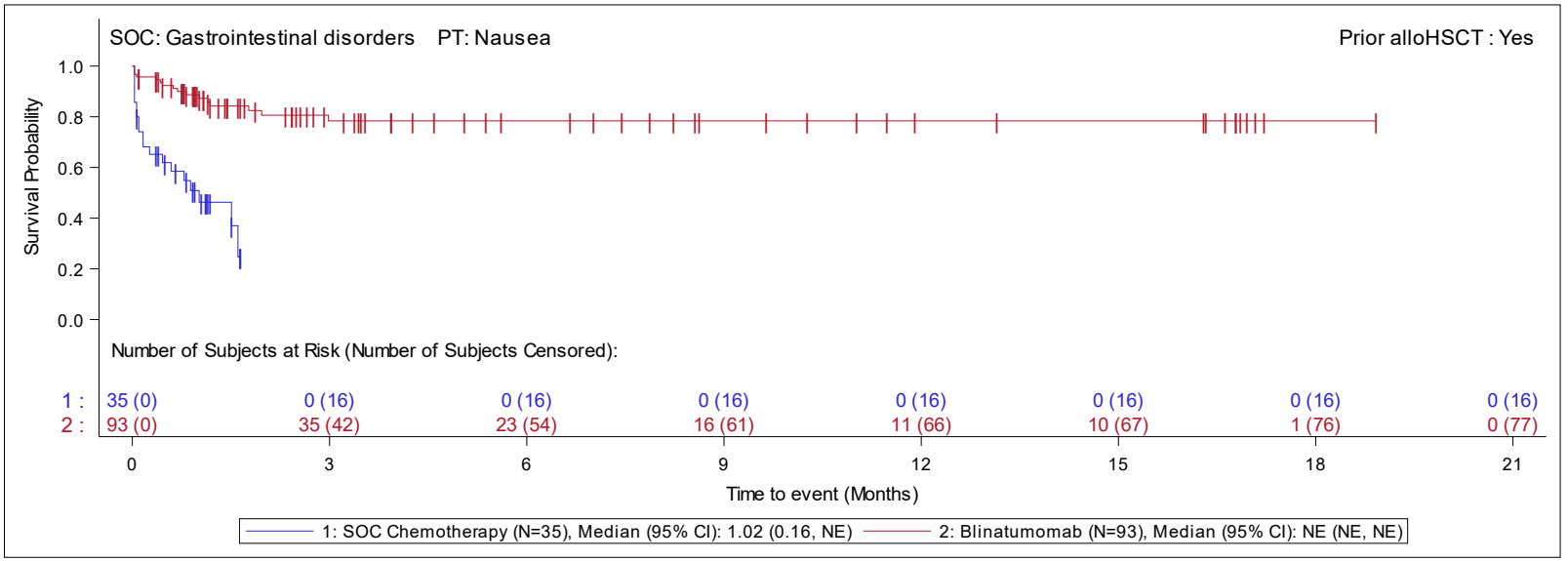

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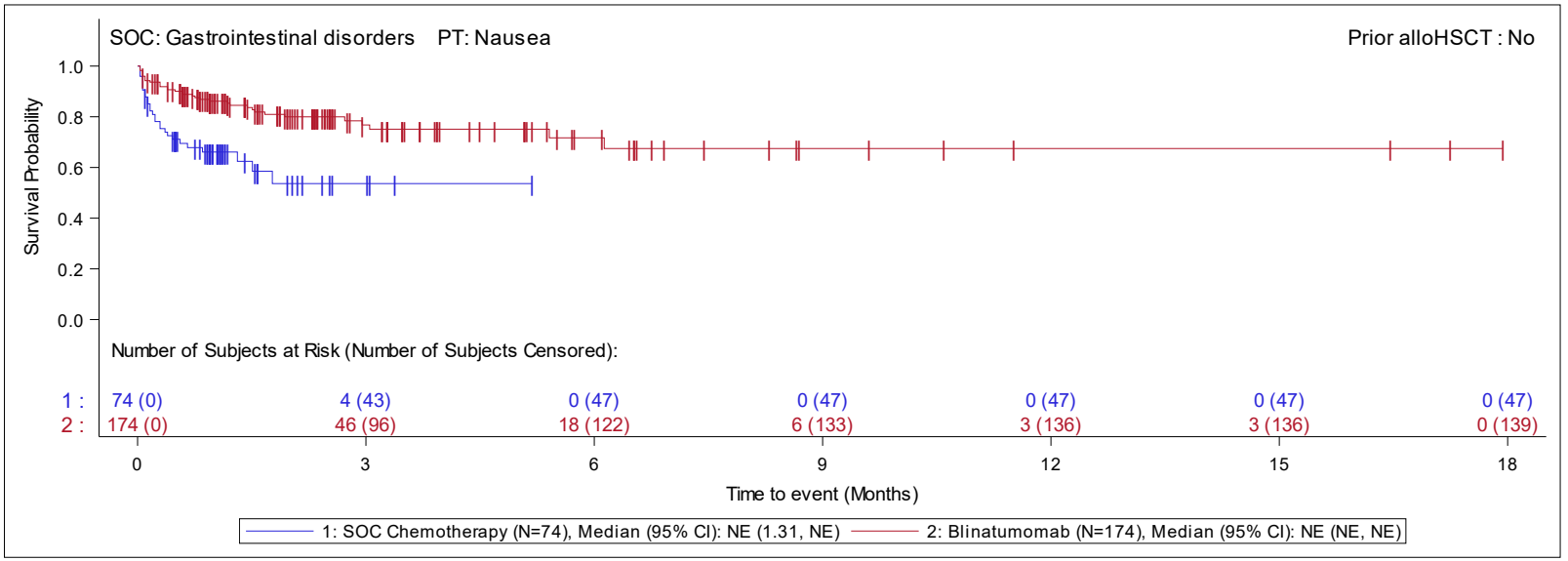

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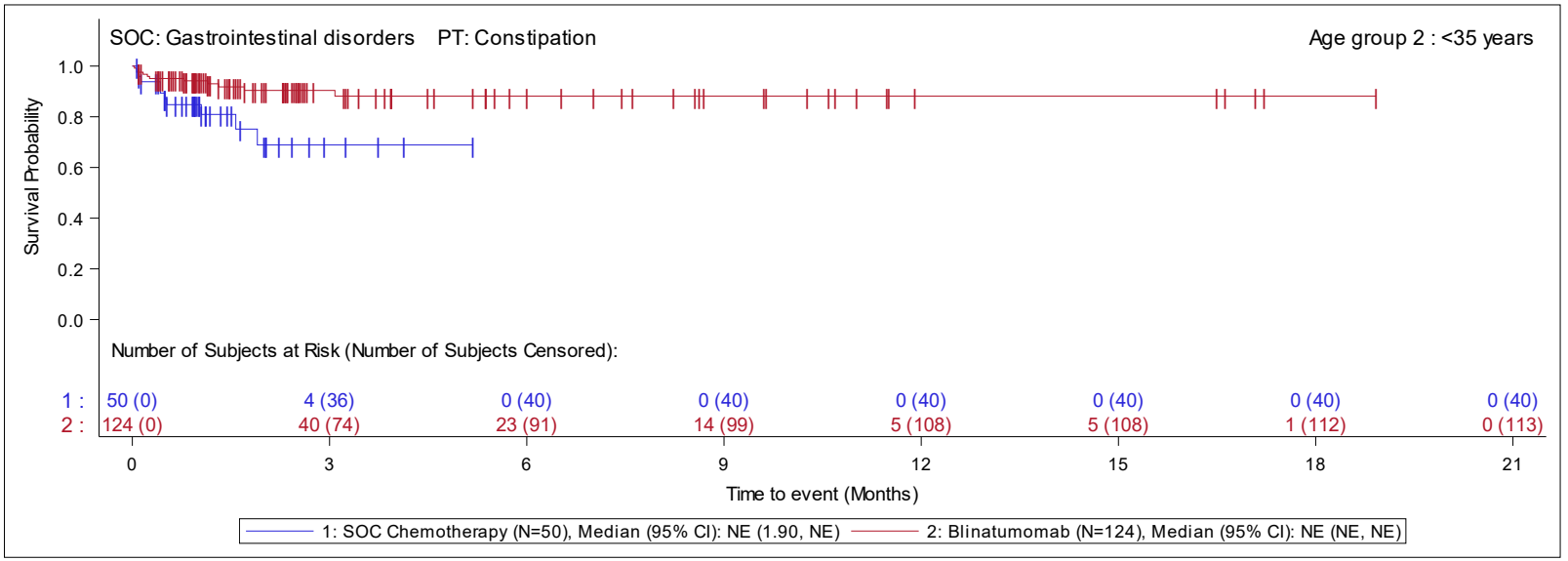

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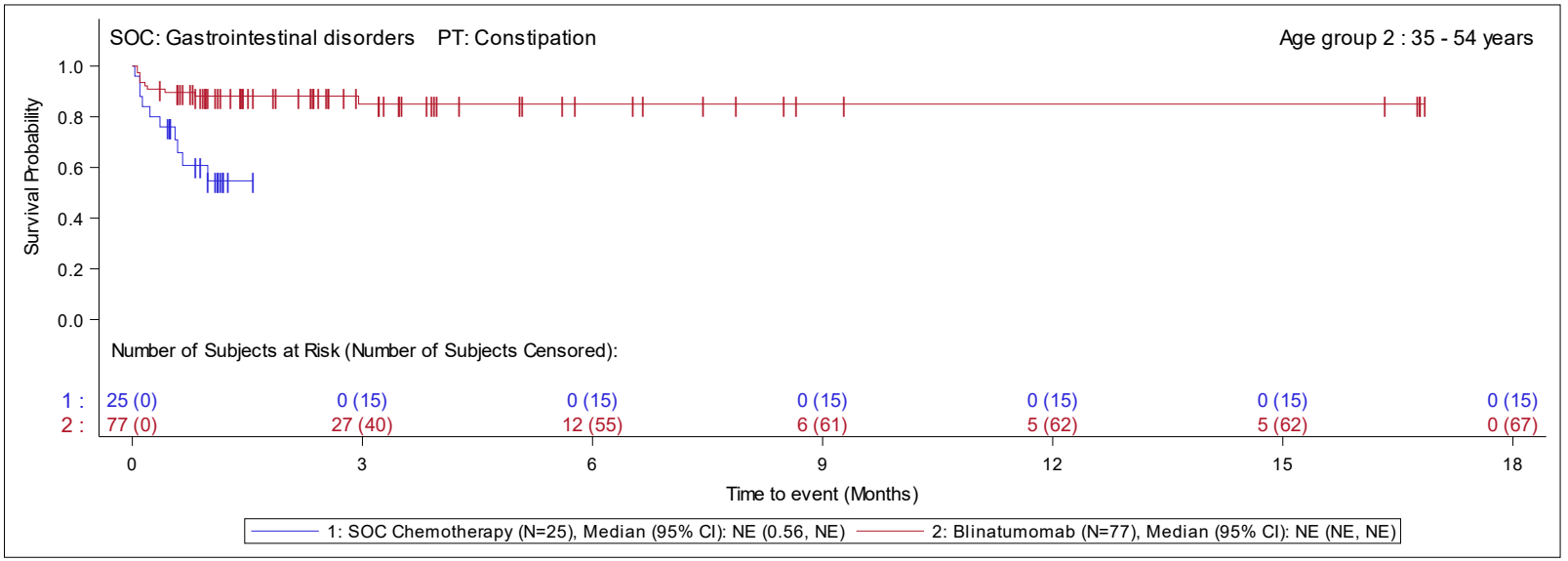

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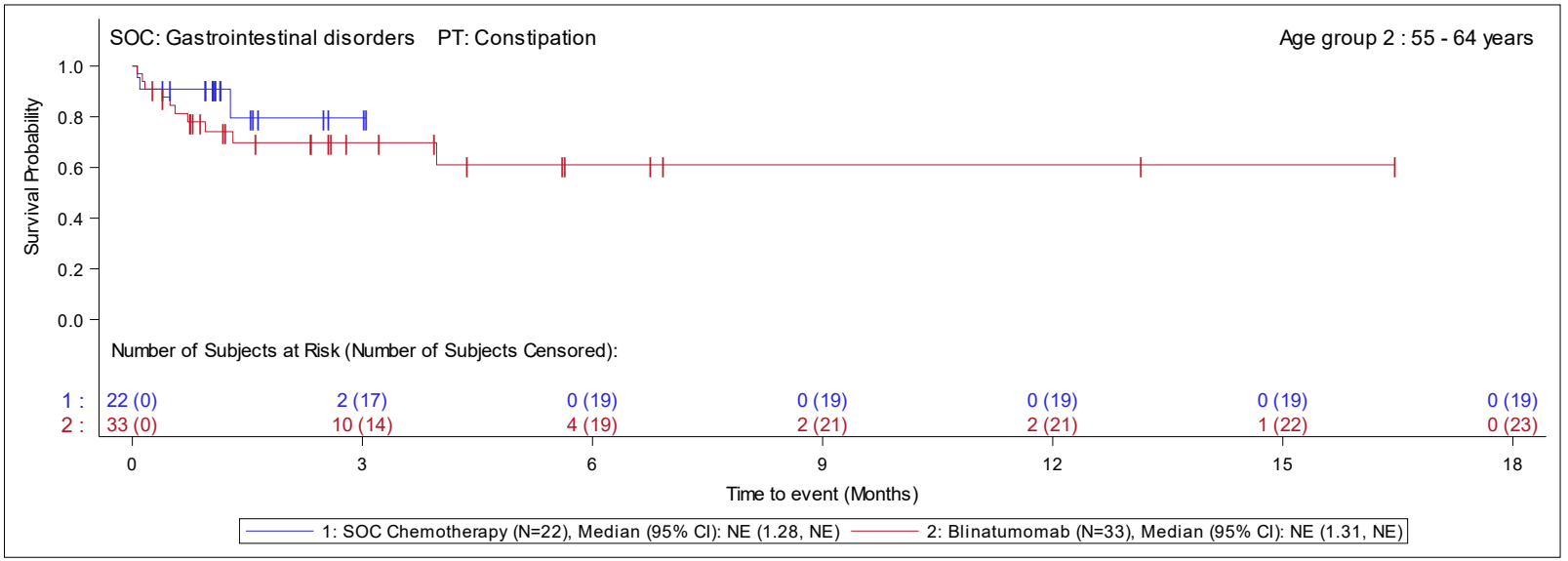

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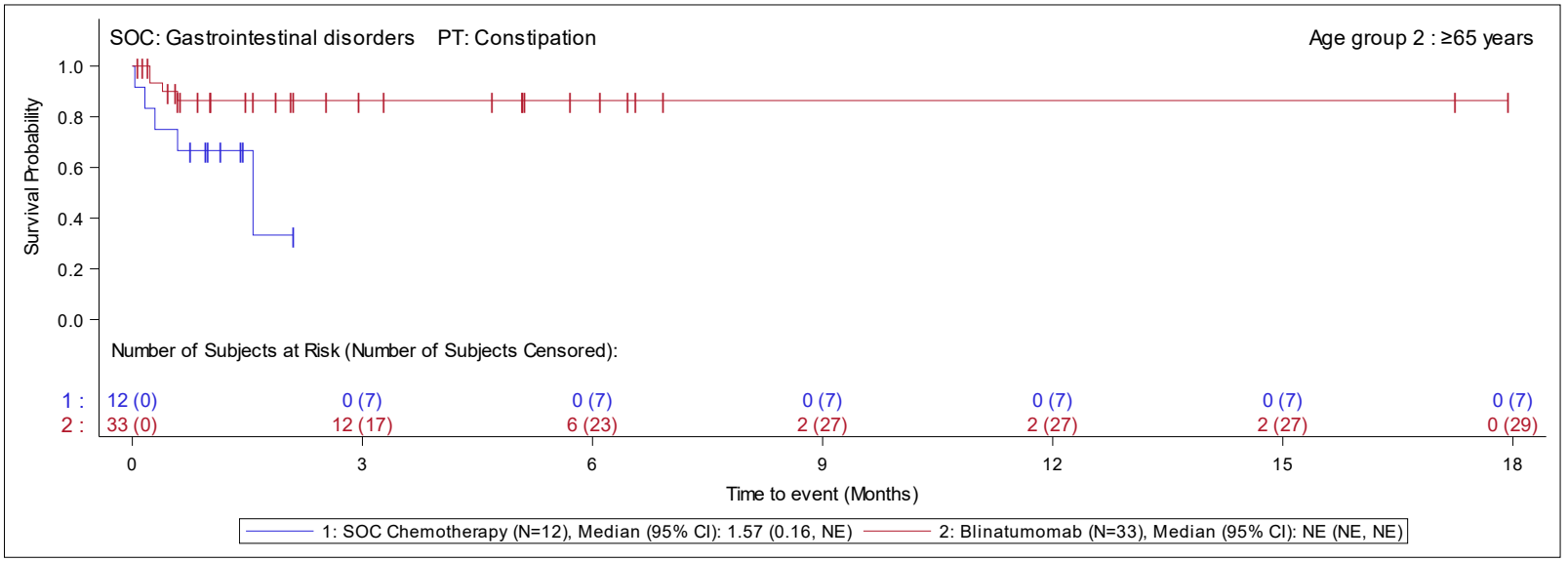

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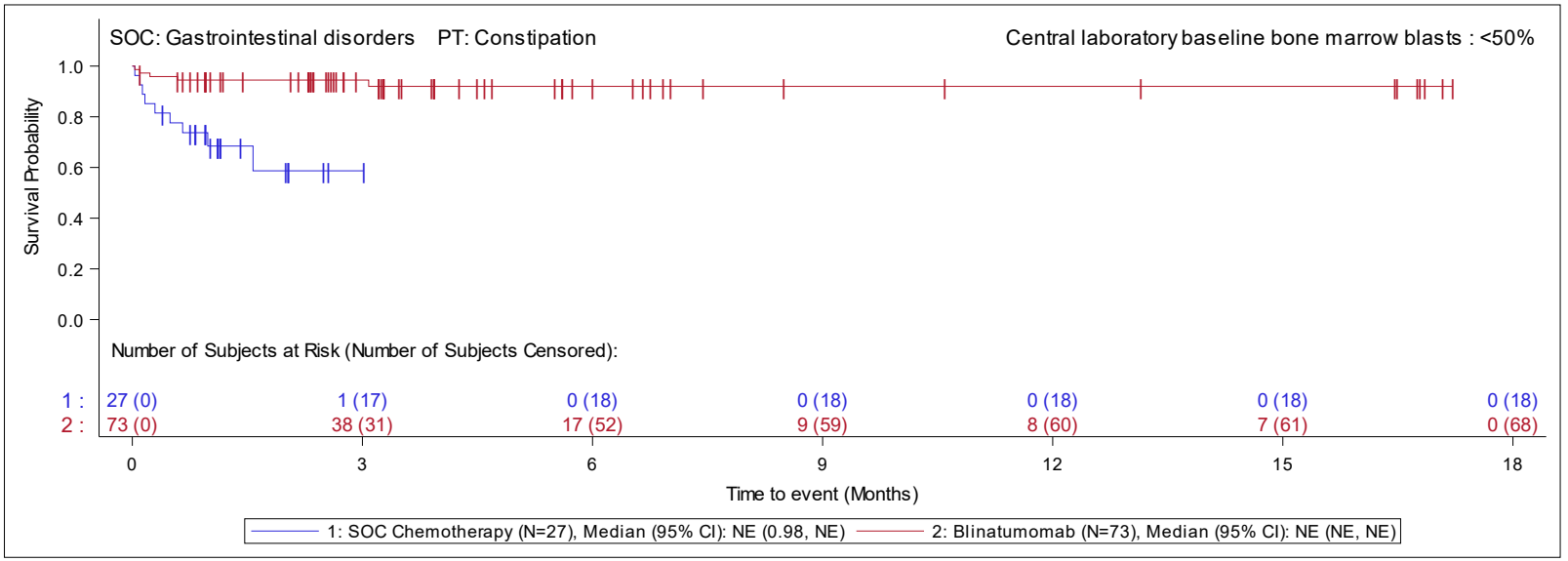

Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0.
Data cut-off date: 14MAR2017

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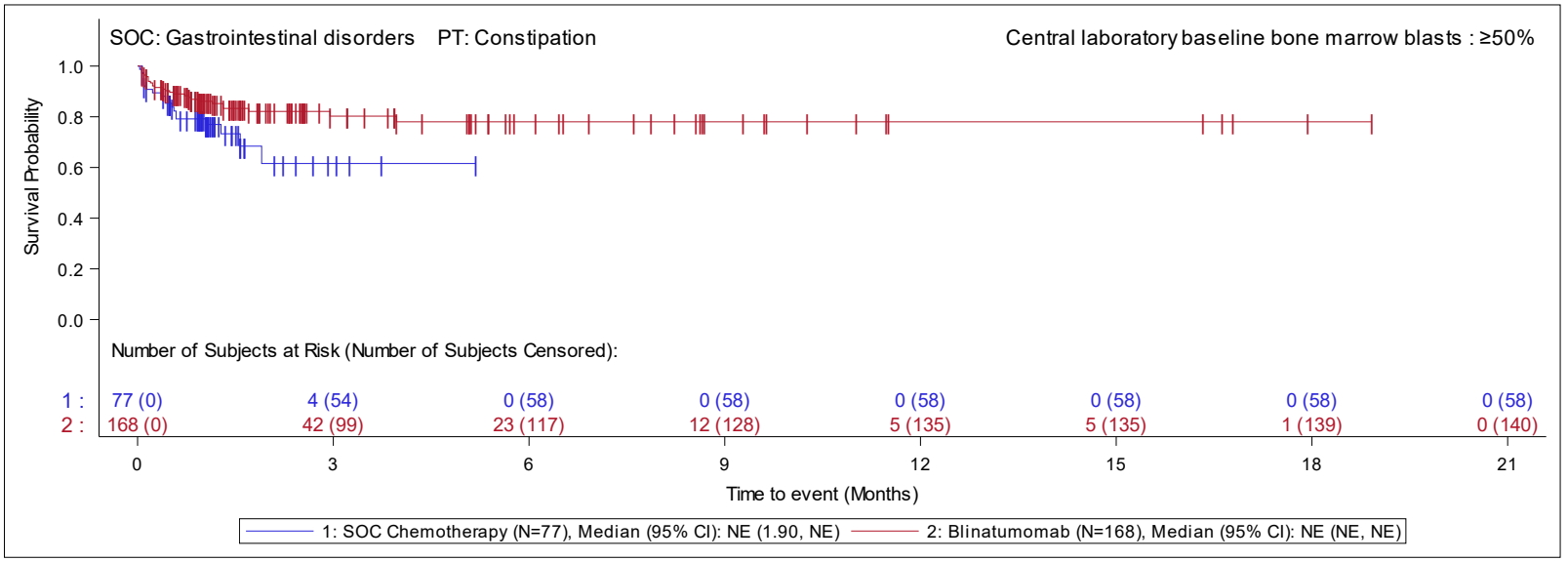

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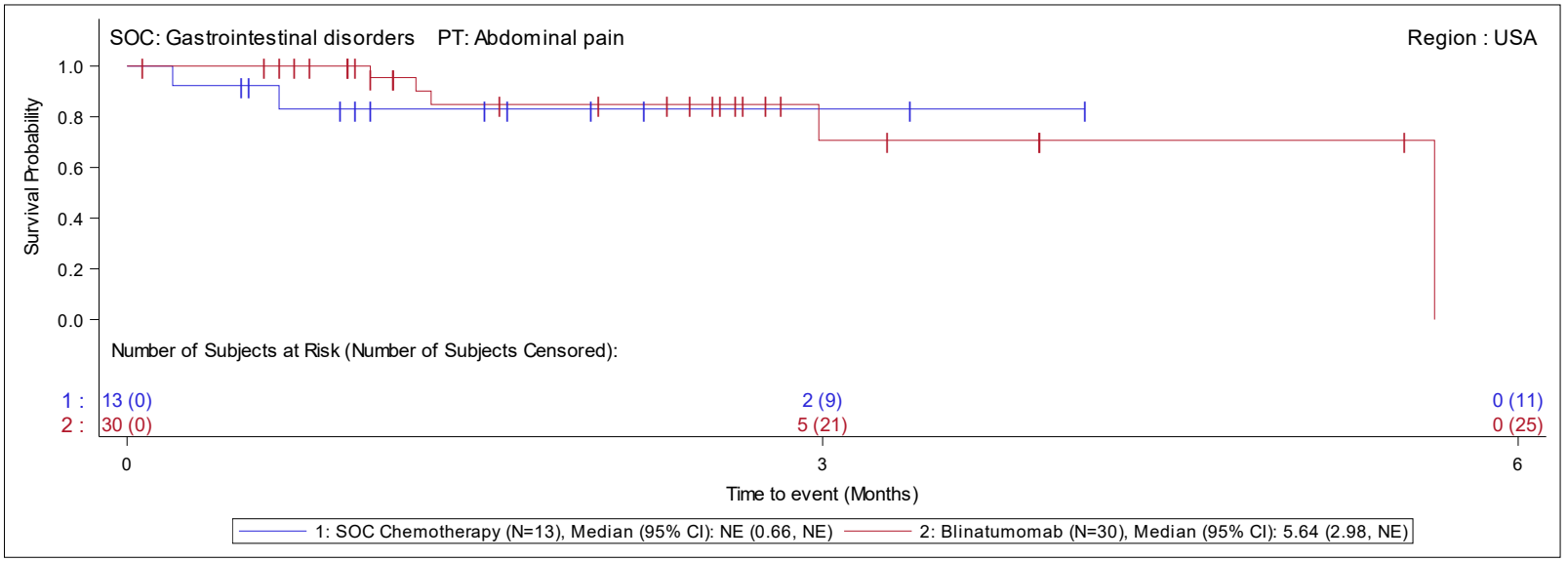

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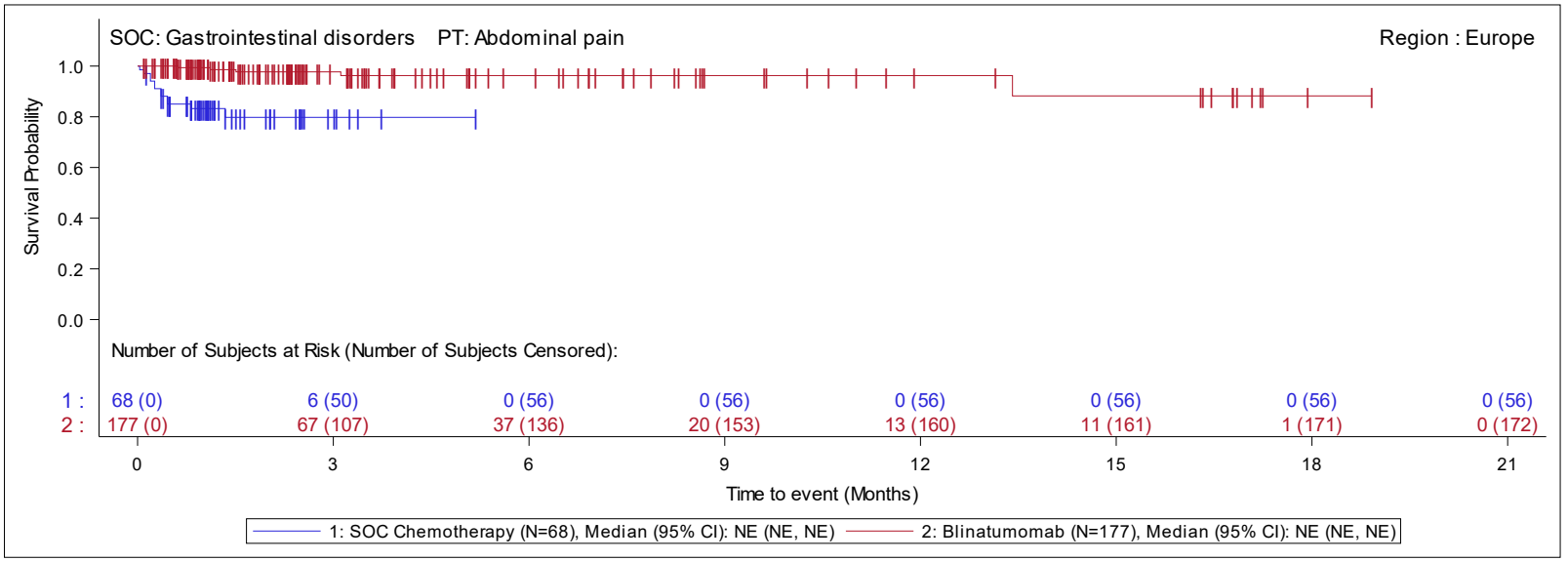

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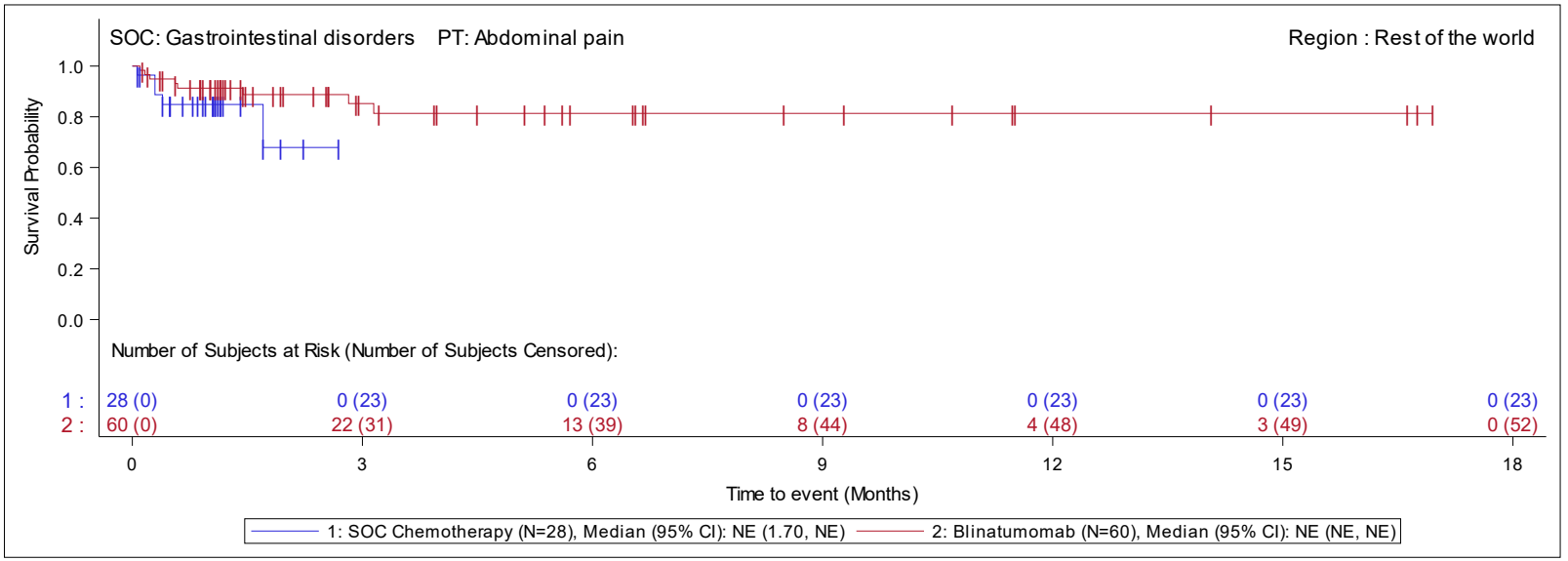

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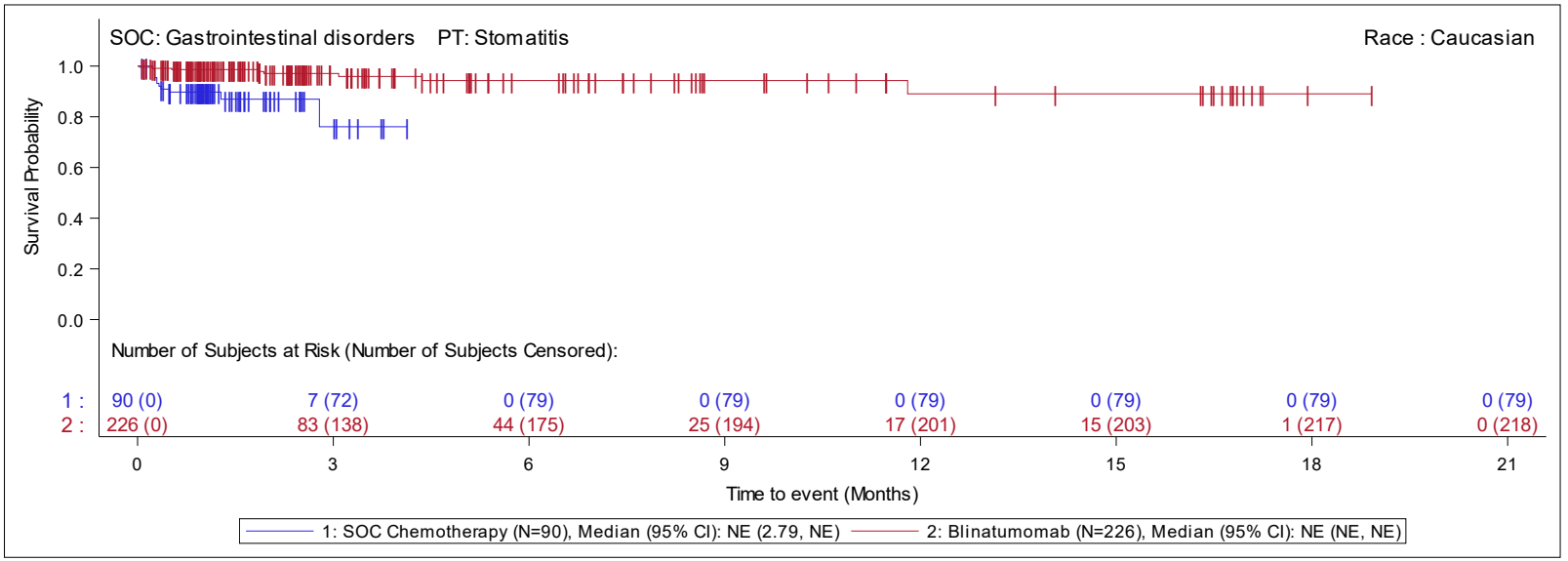

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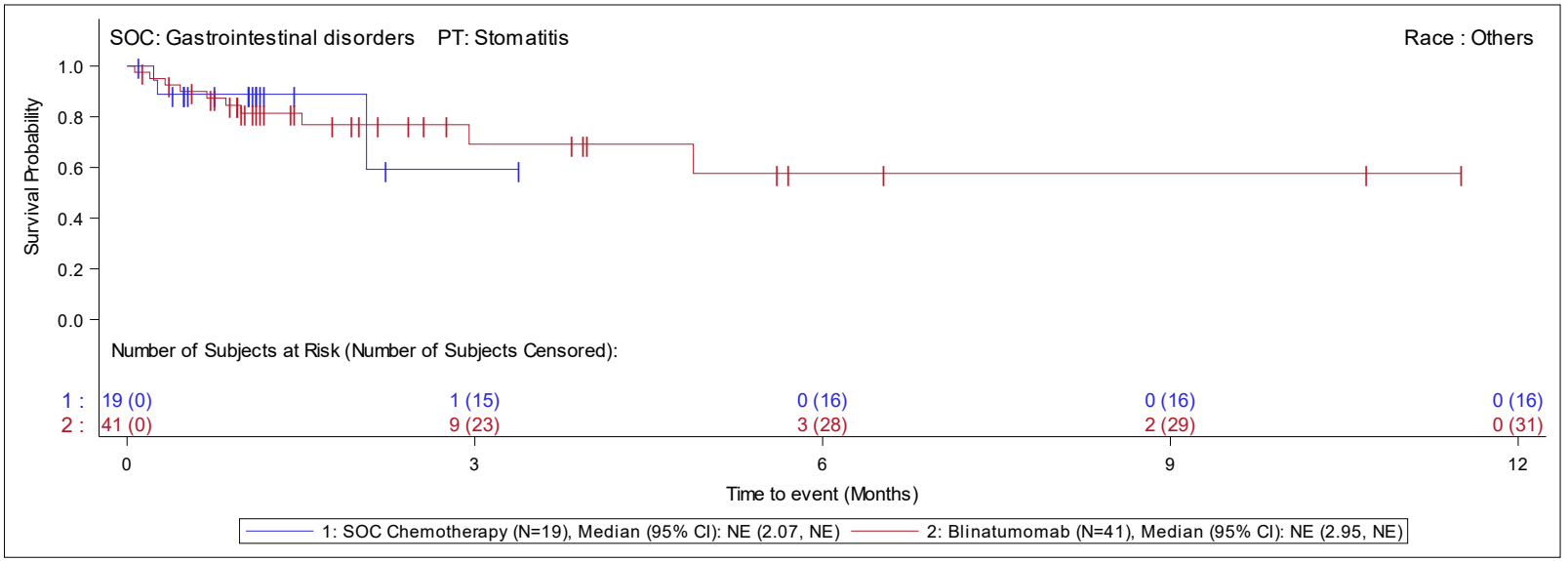

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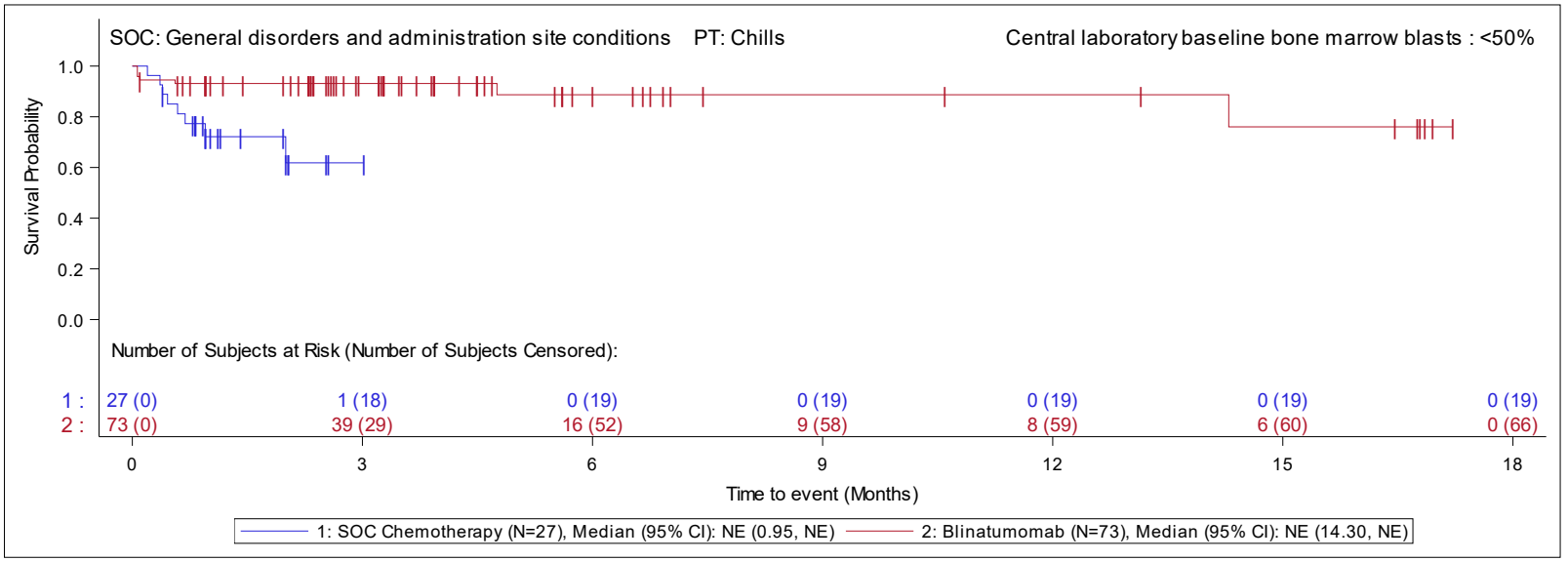

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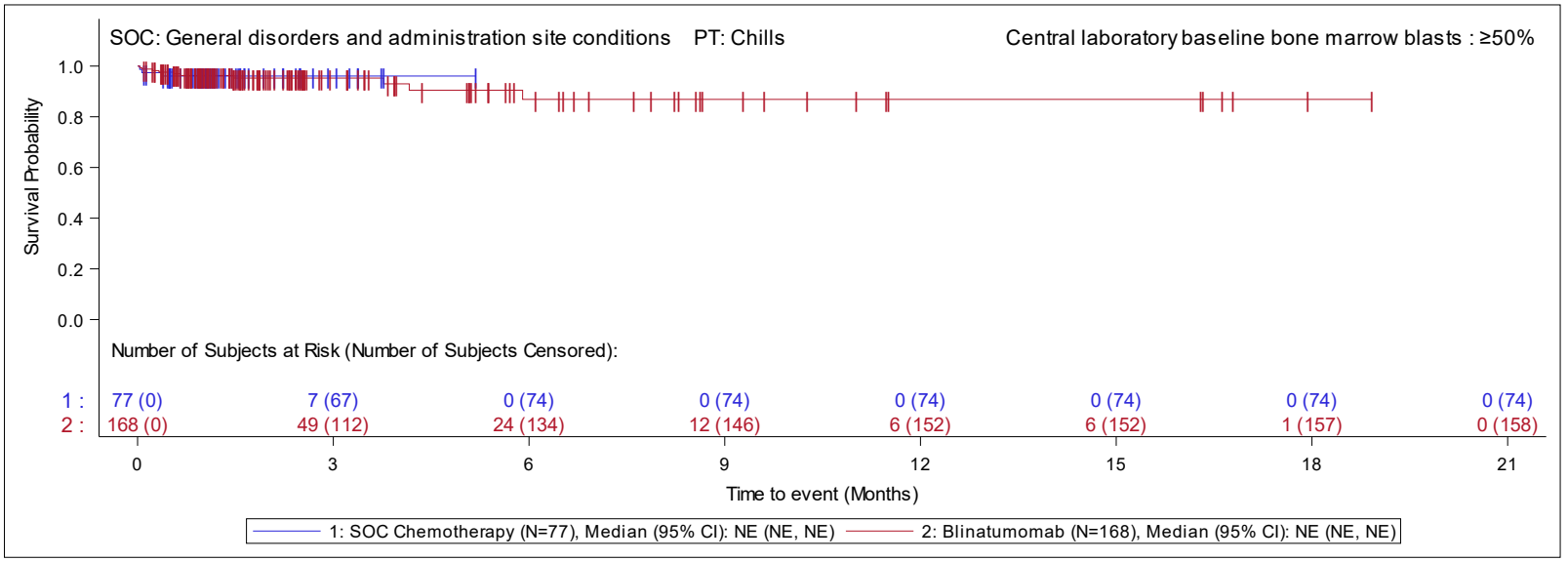

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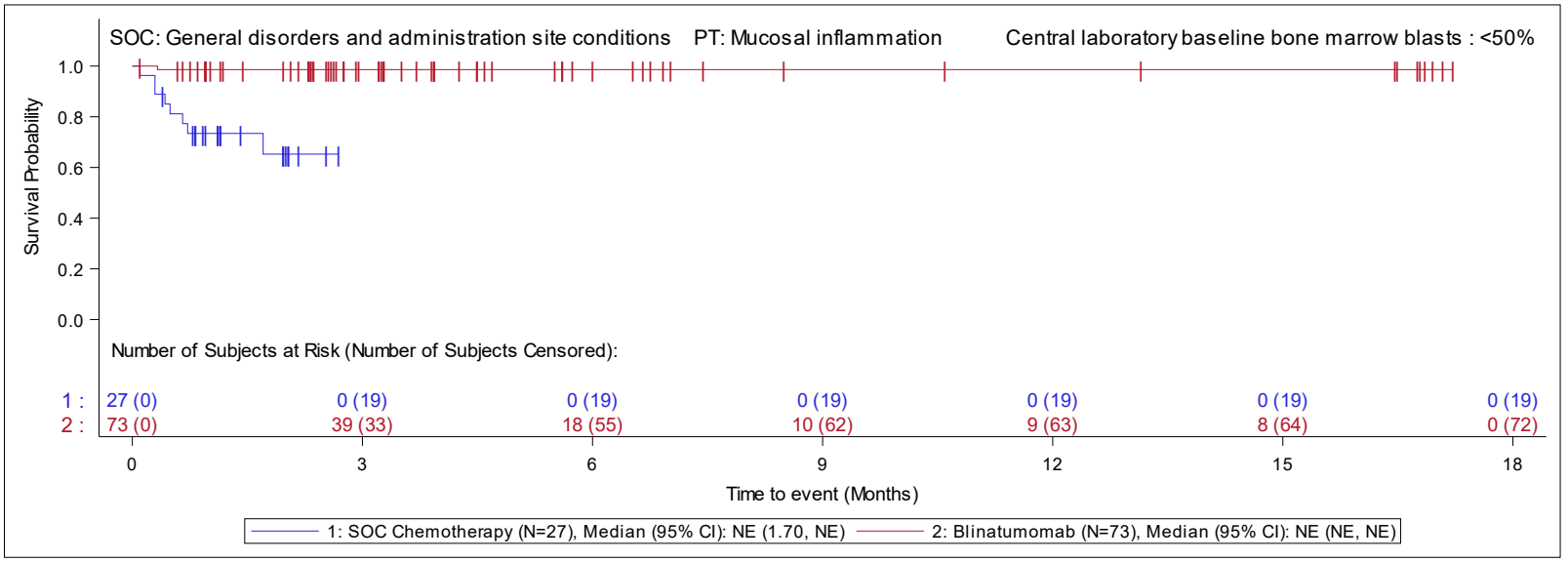

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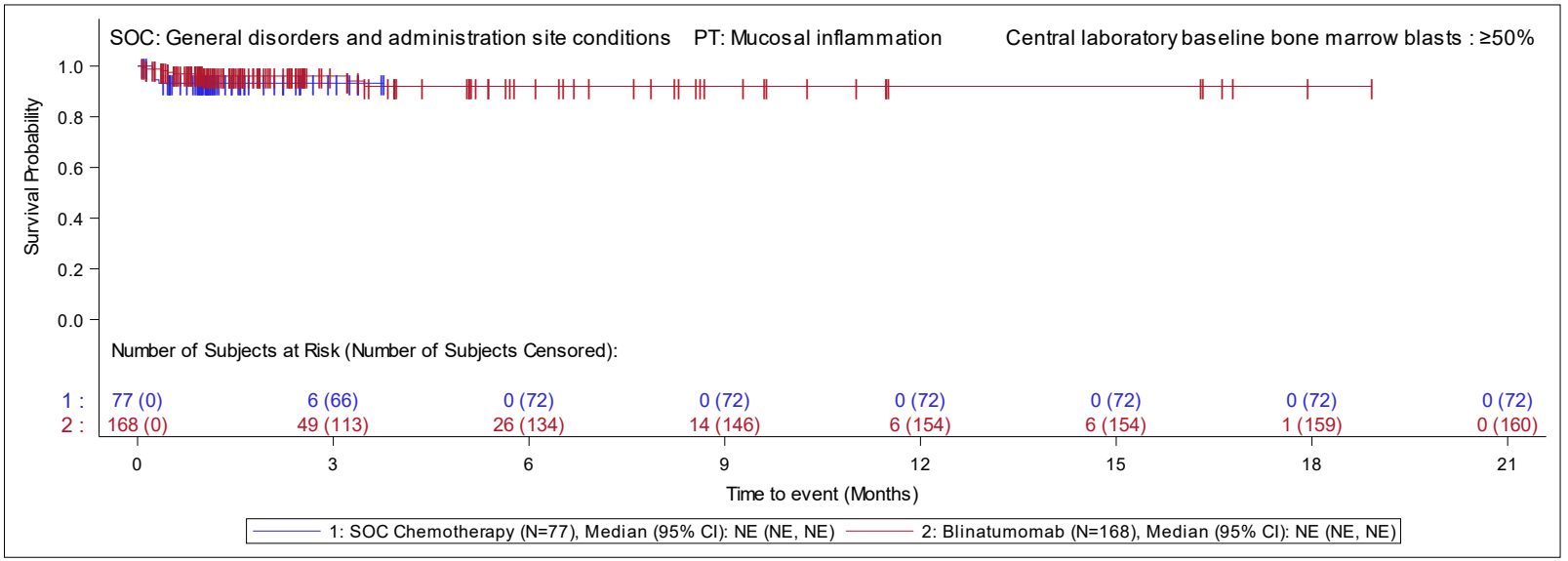

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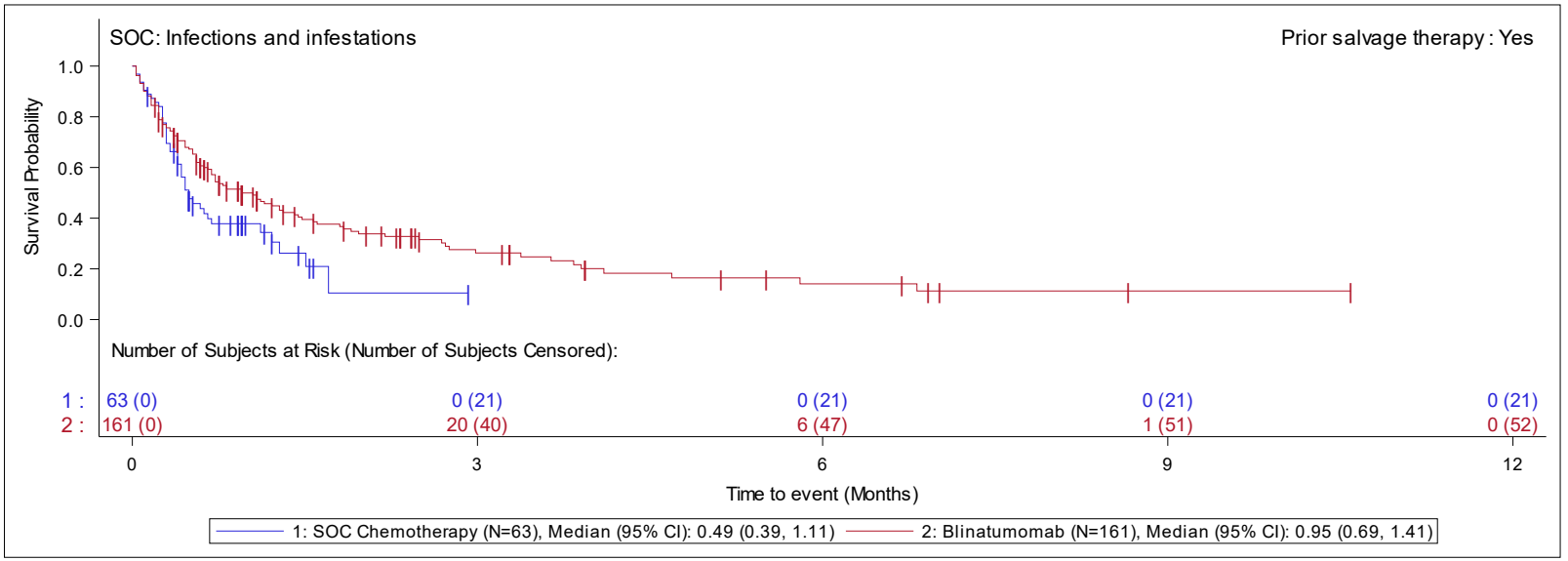

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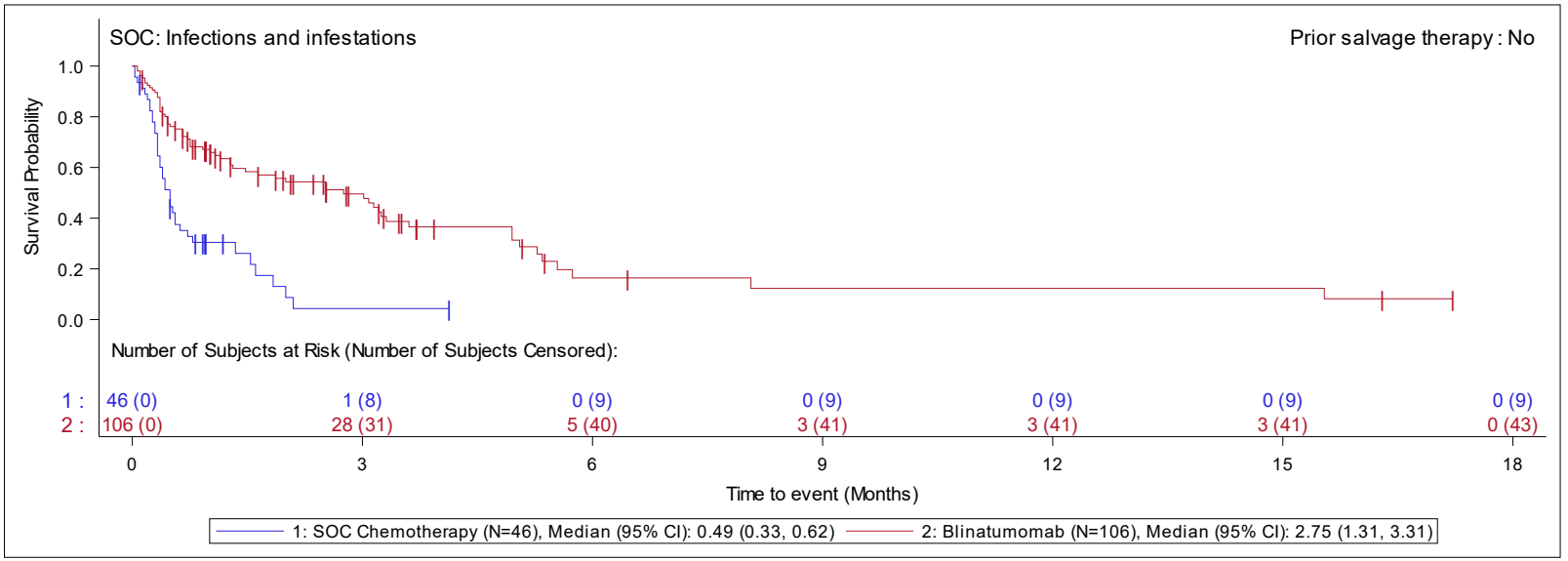

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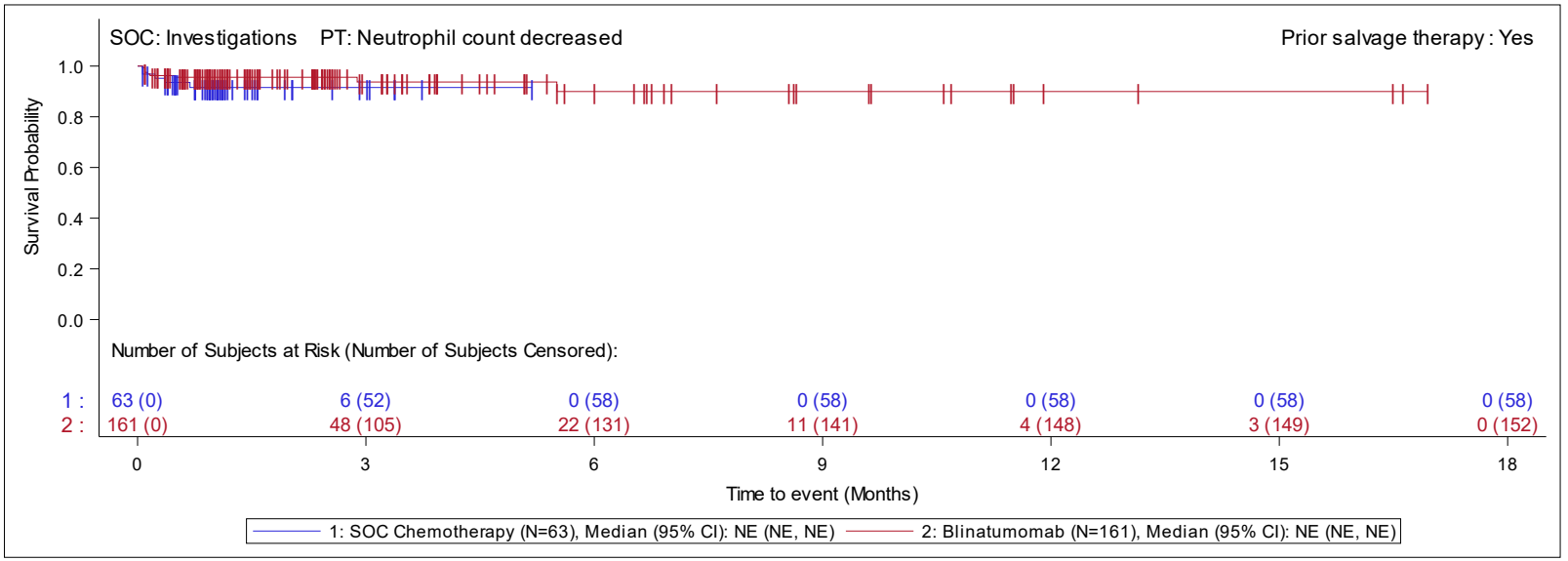

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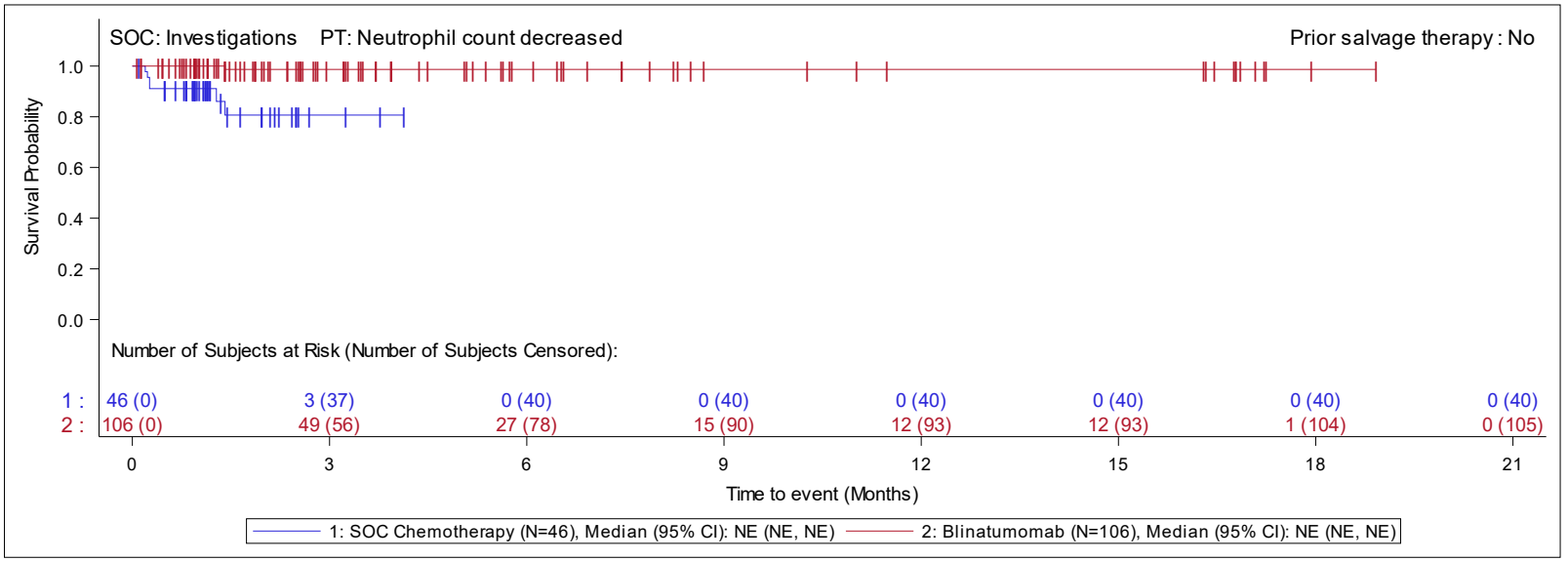

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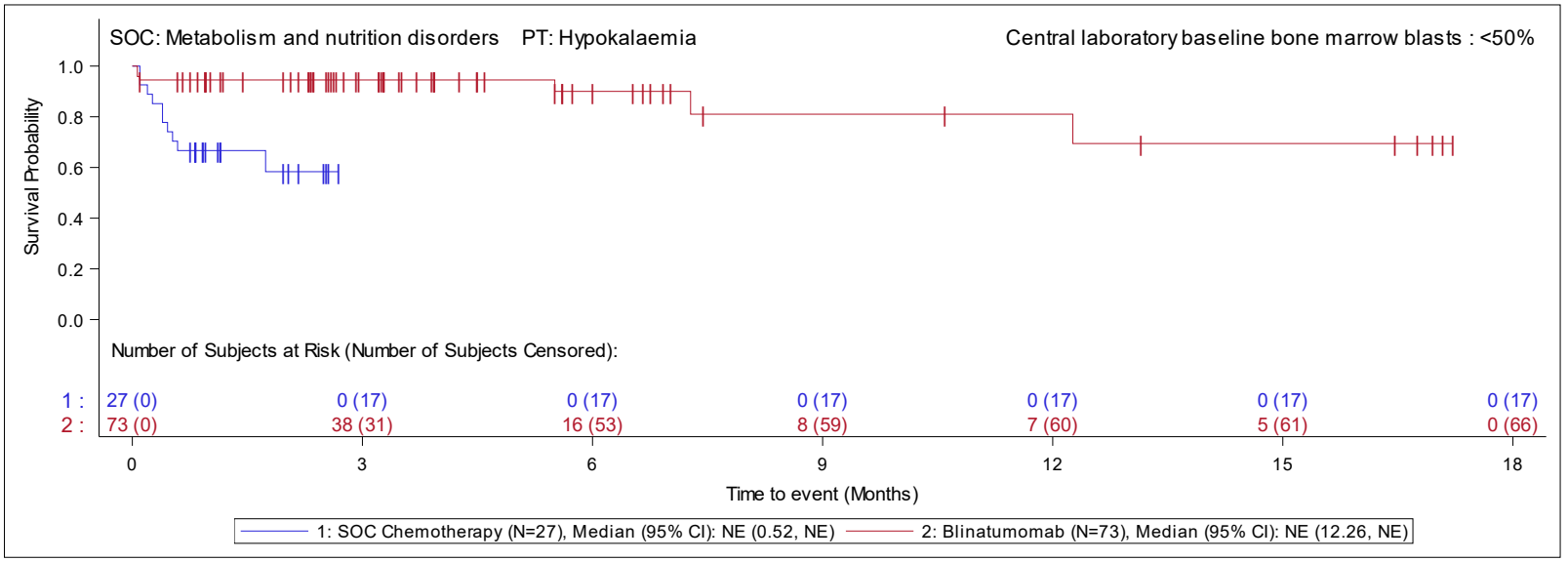

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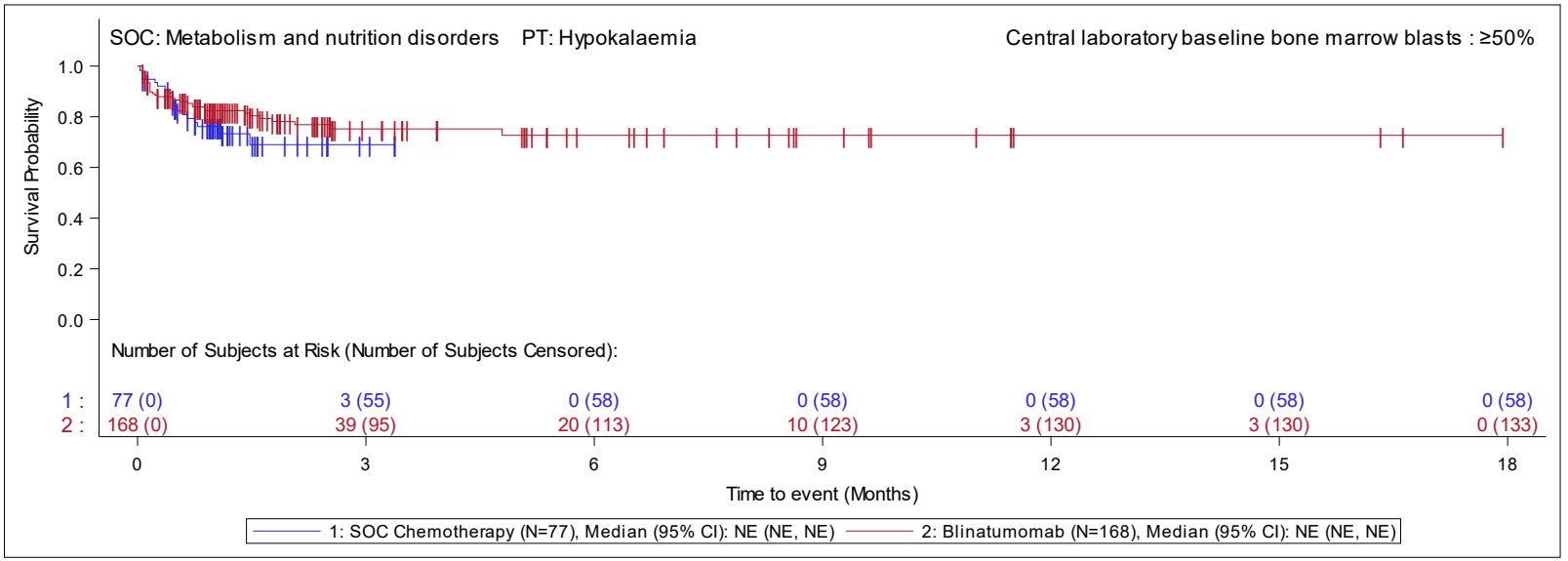

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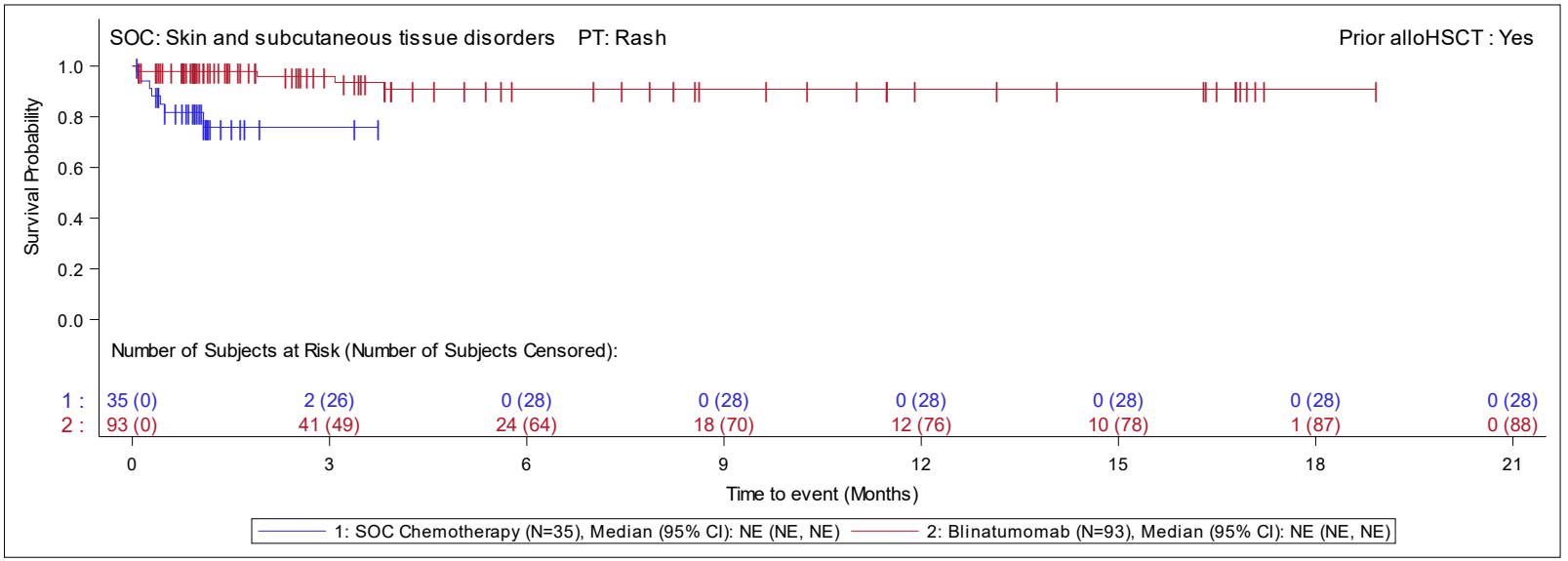

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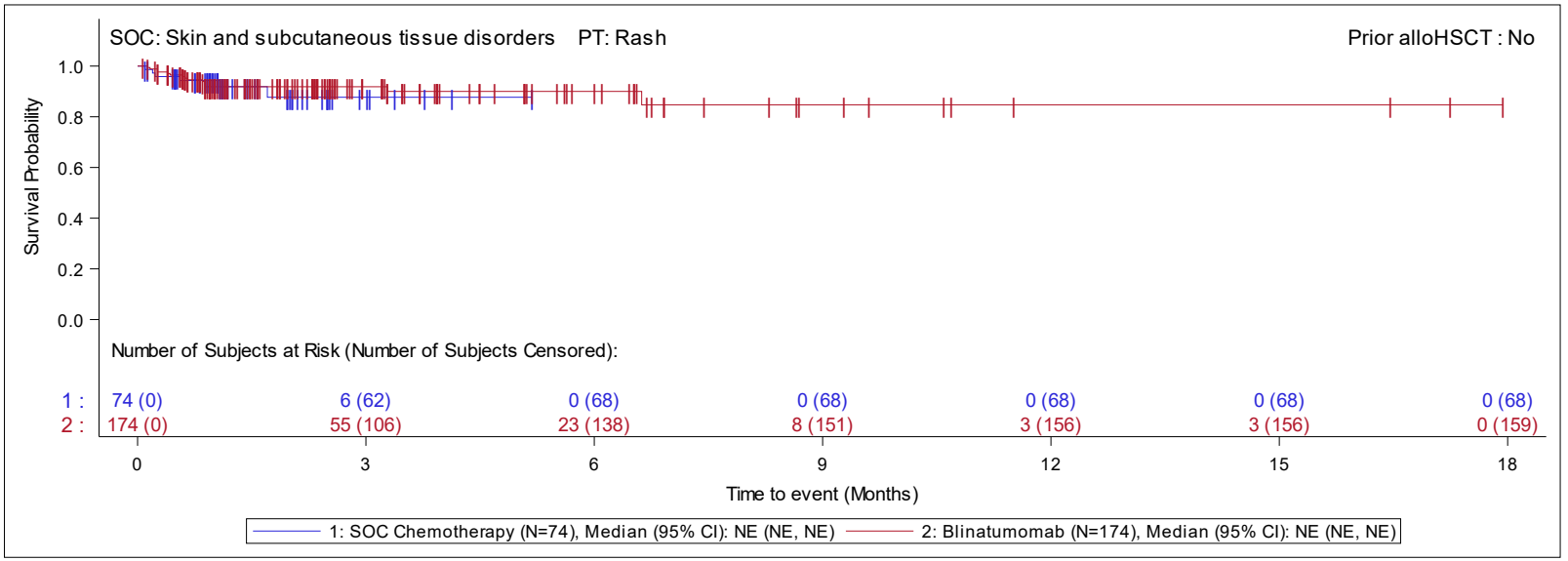

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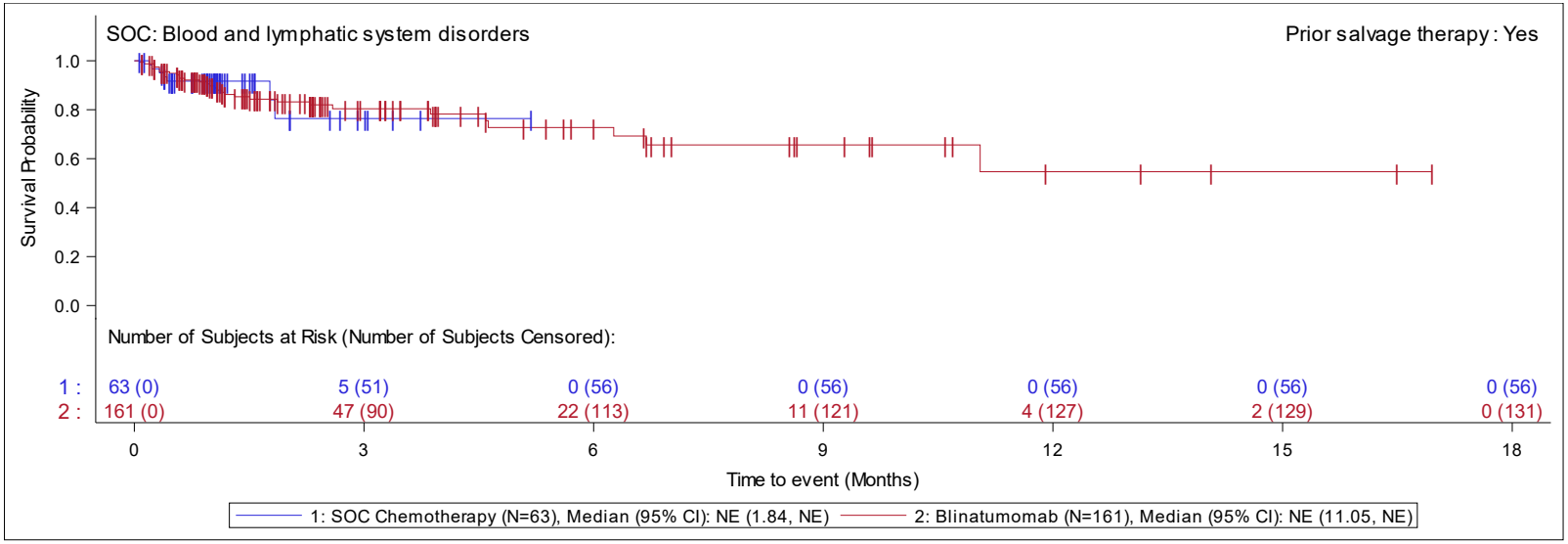
Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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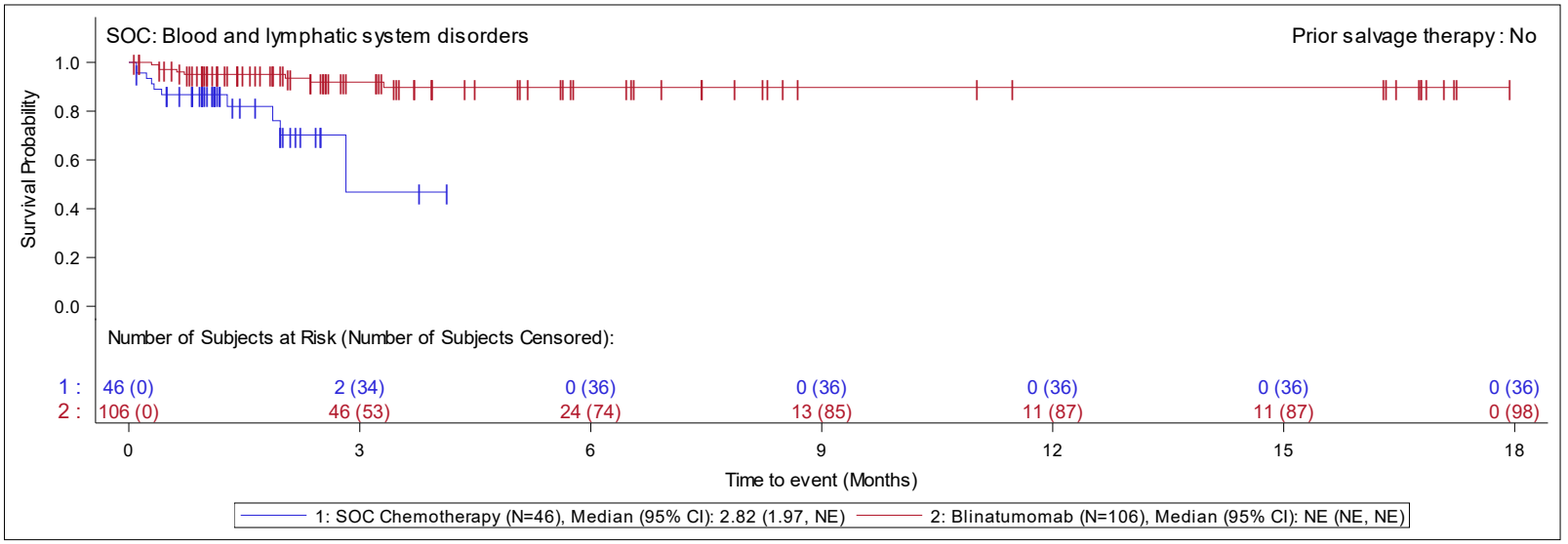

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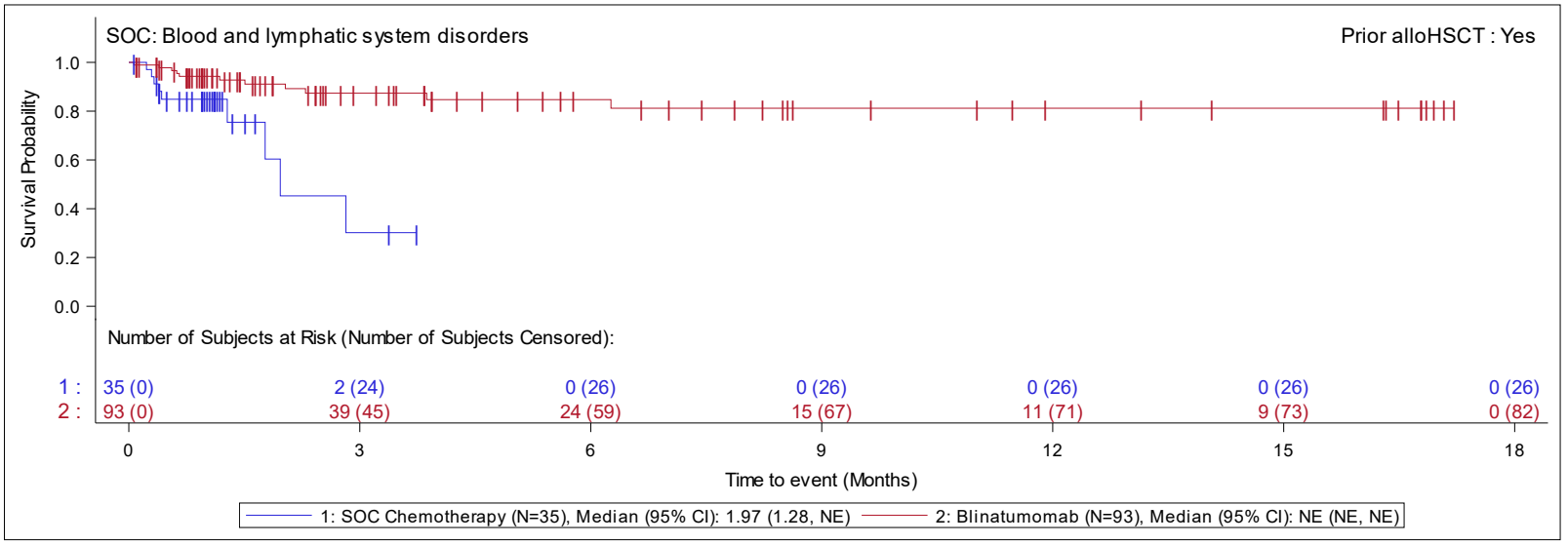

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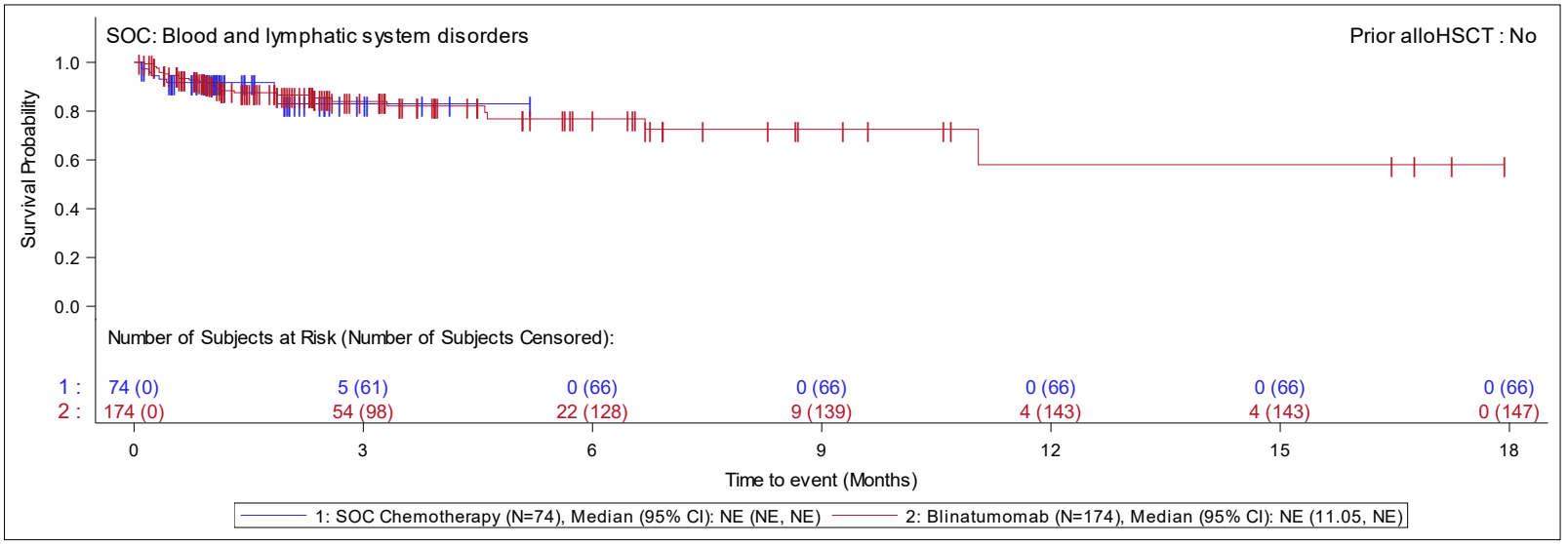

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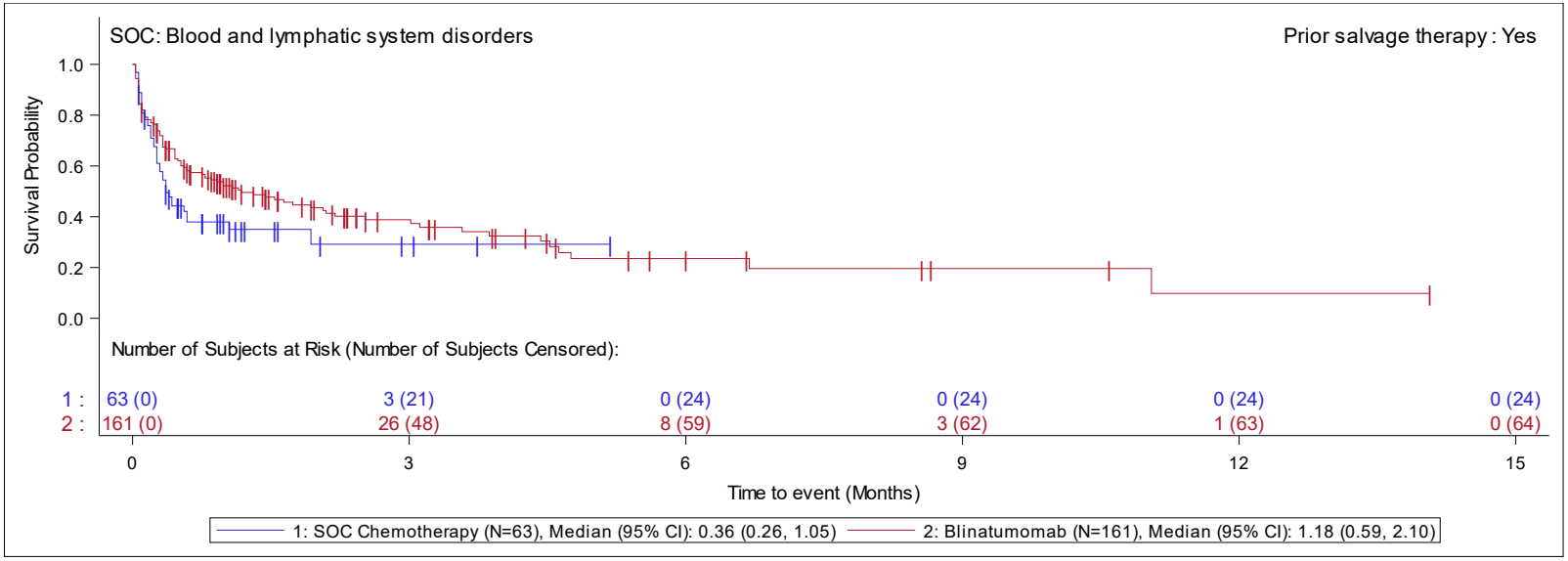
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
Data cut-off date: 14MAR2017

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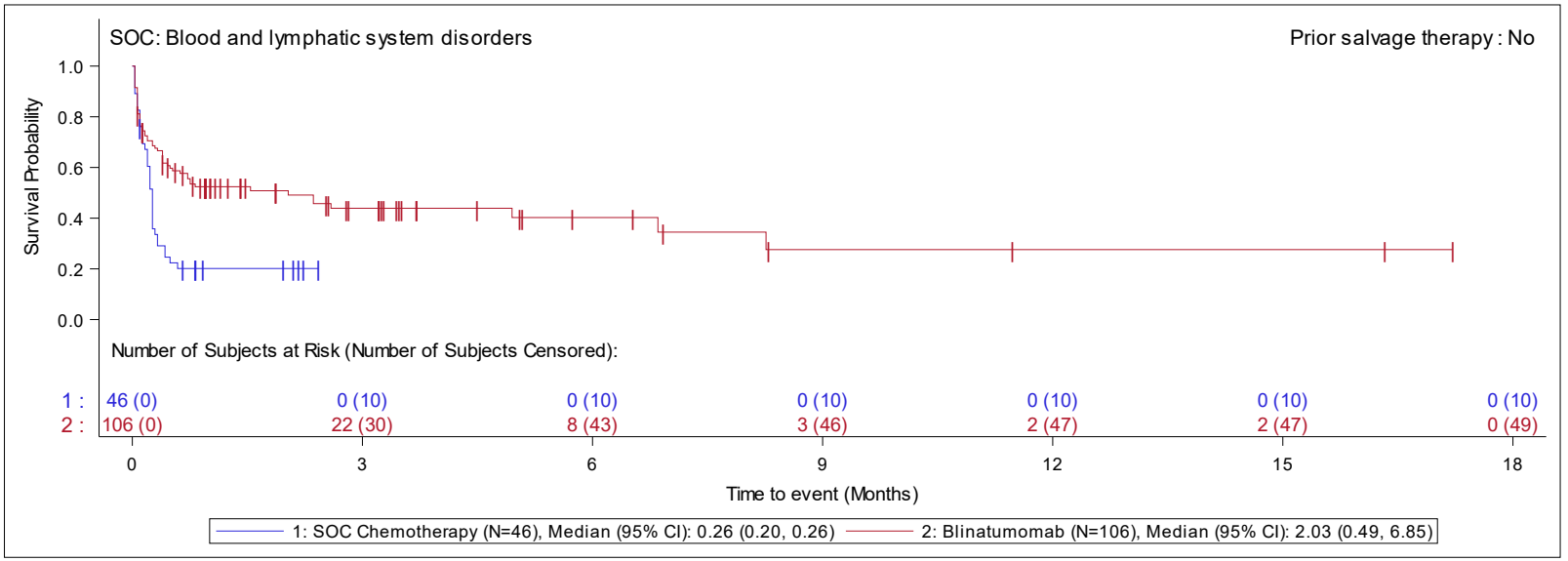
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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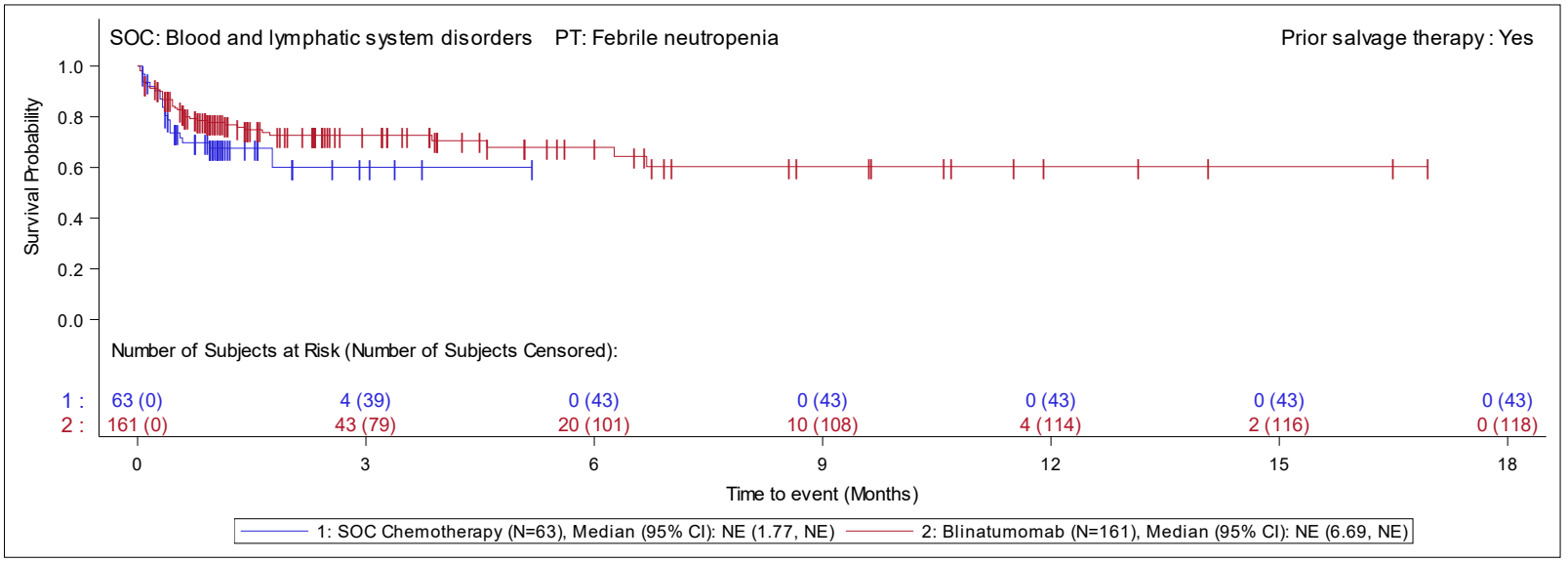

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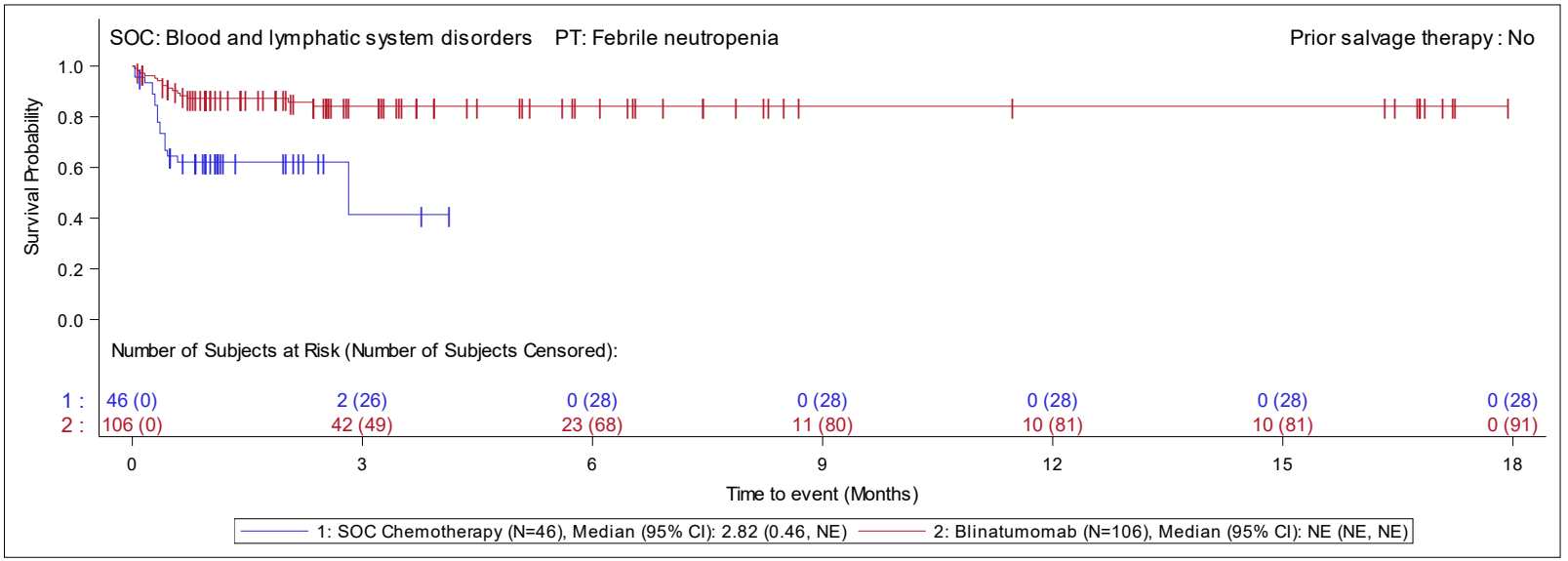

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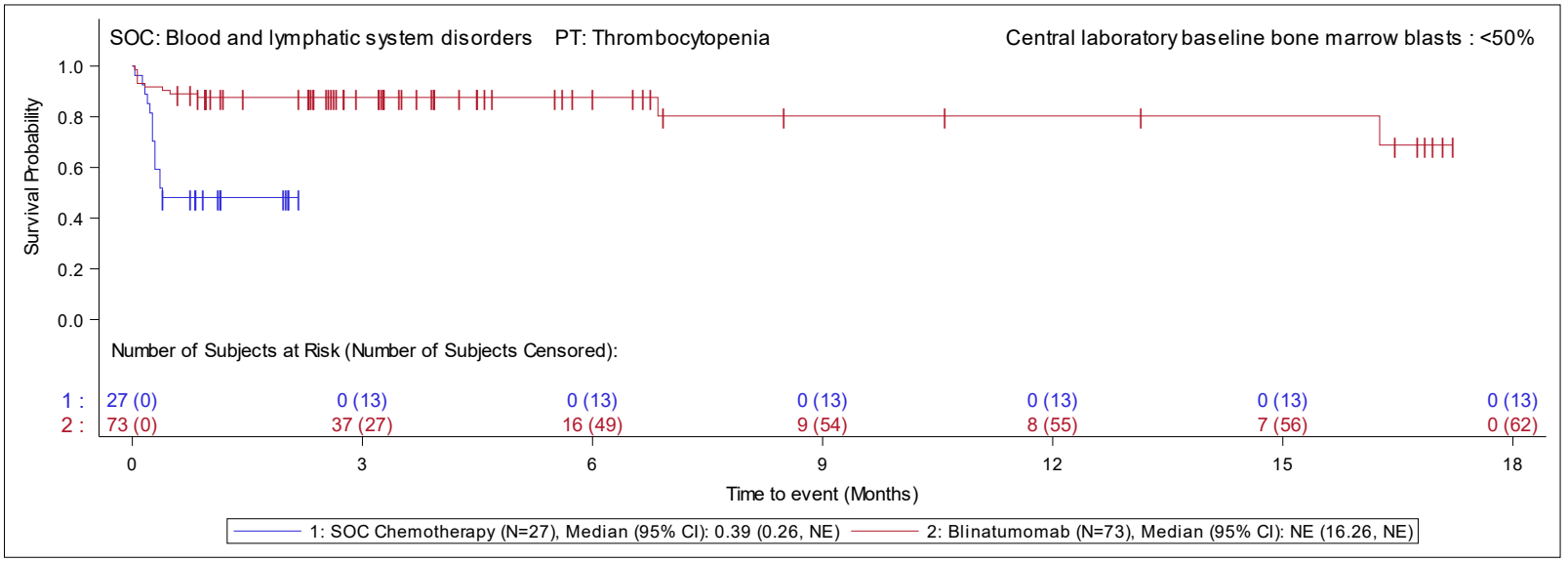

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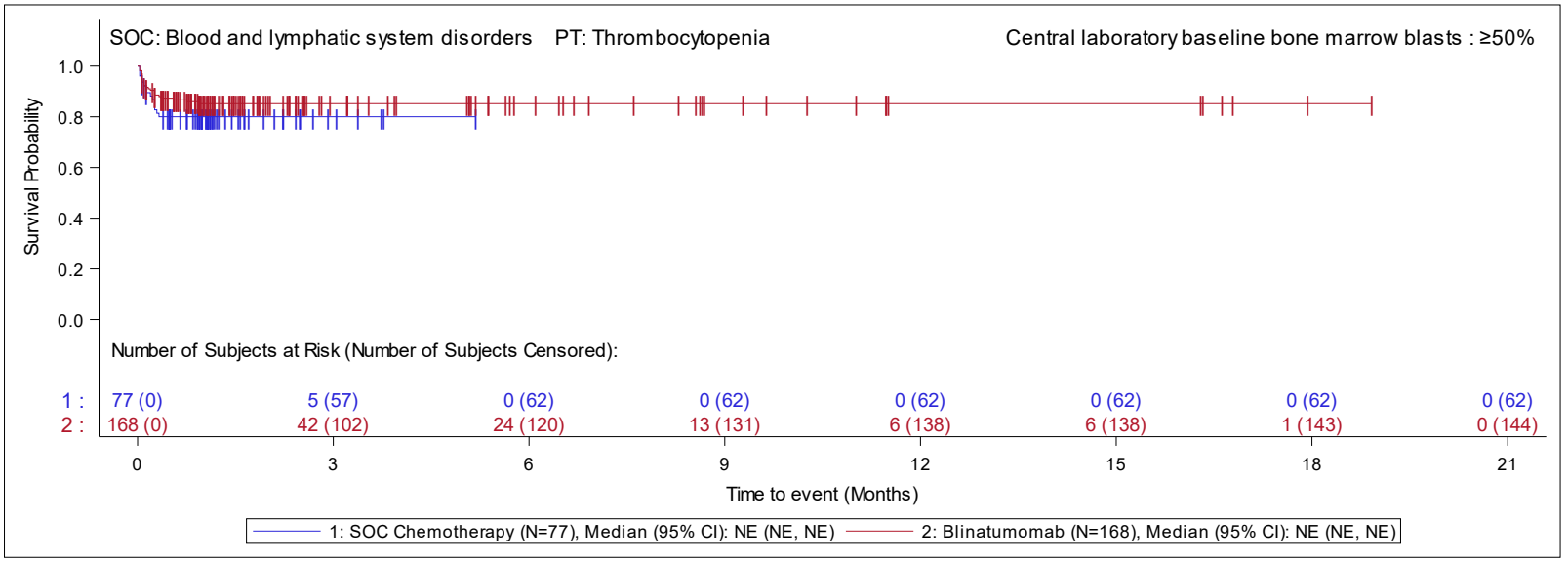

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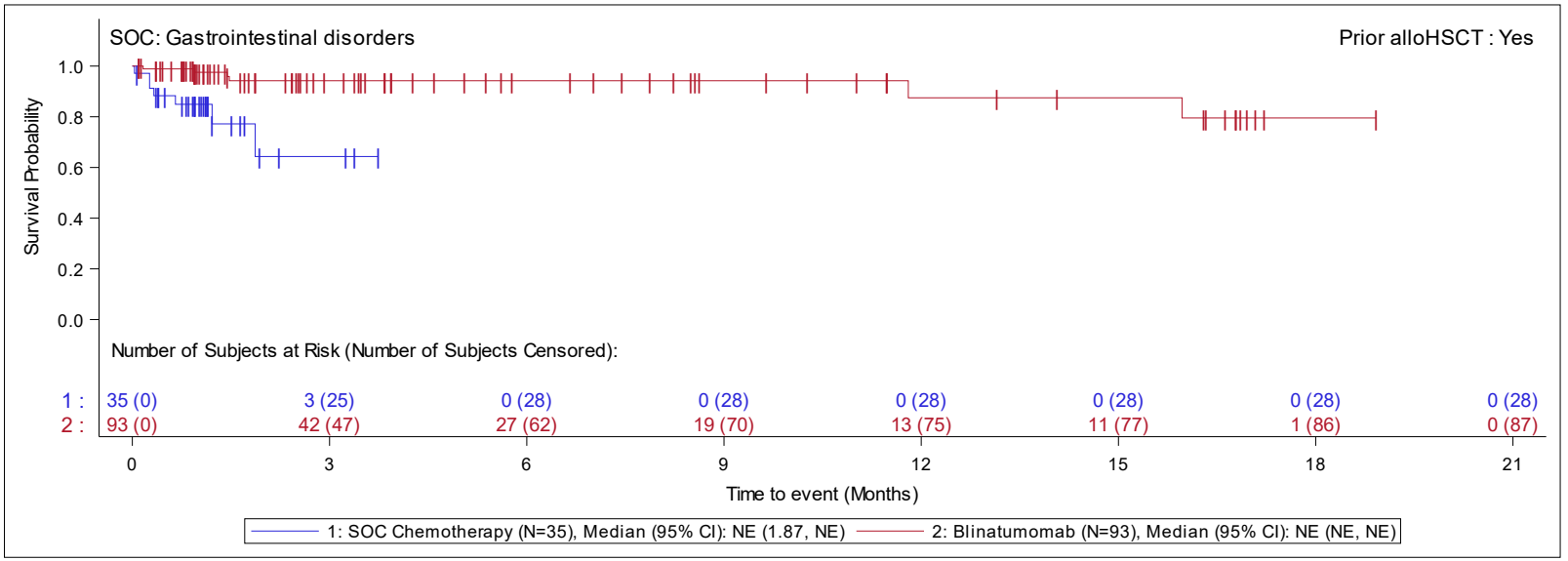
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Adverse events coded using MedDRA version 20.0. Grading categories determined using CTCAE version 4.03.
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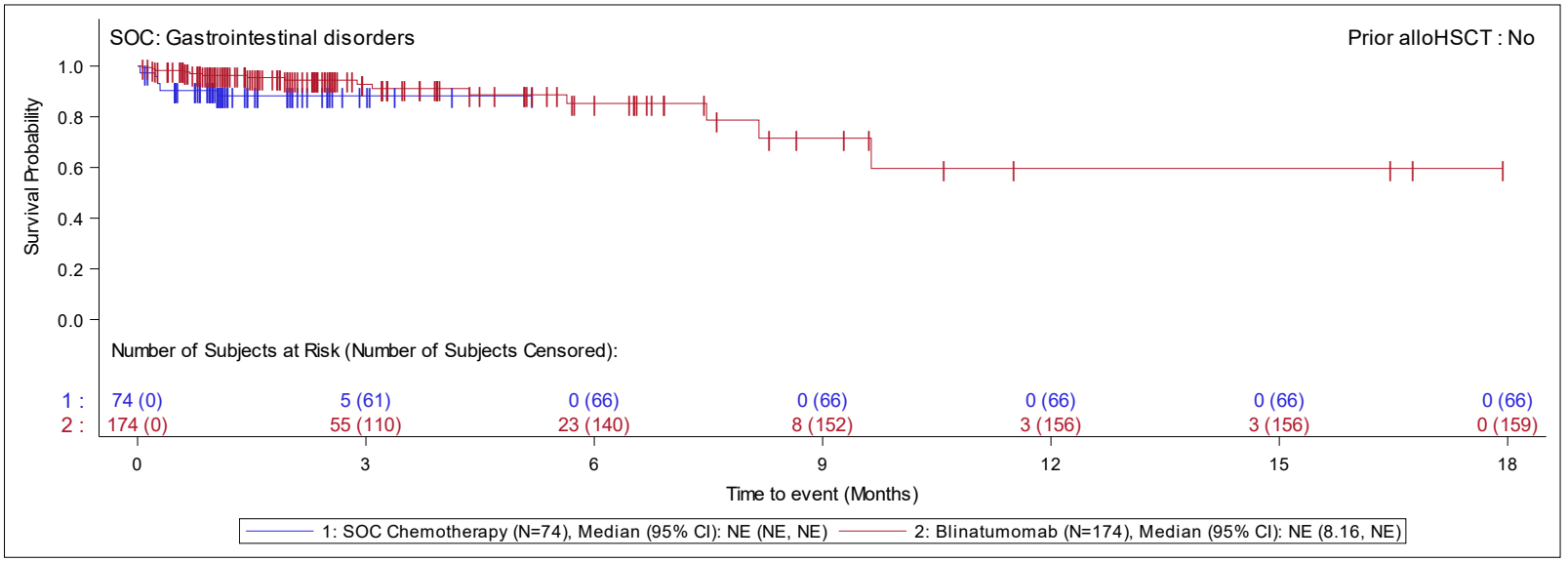
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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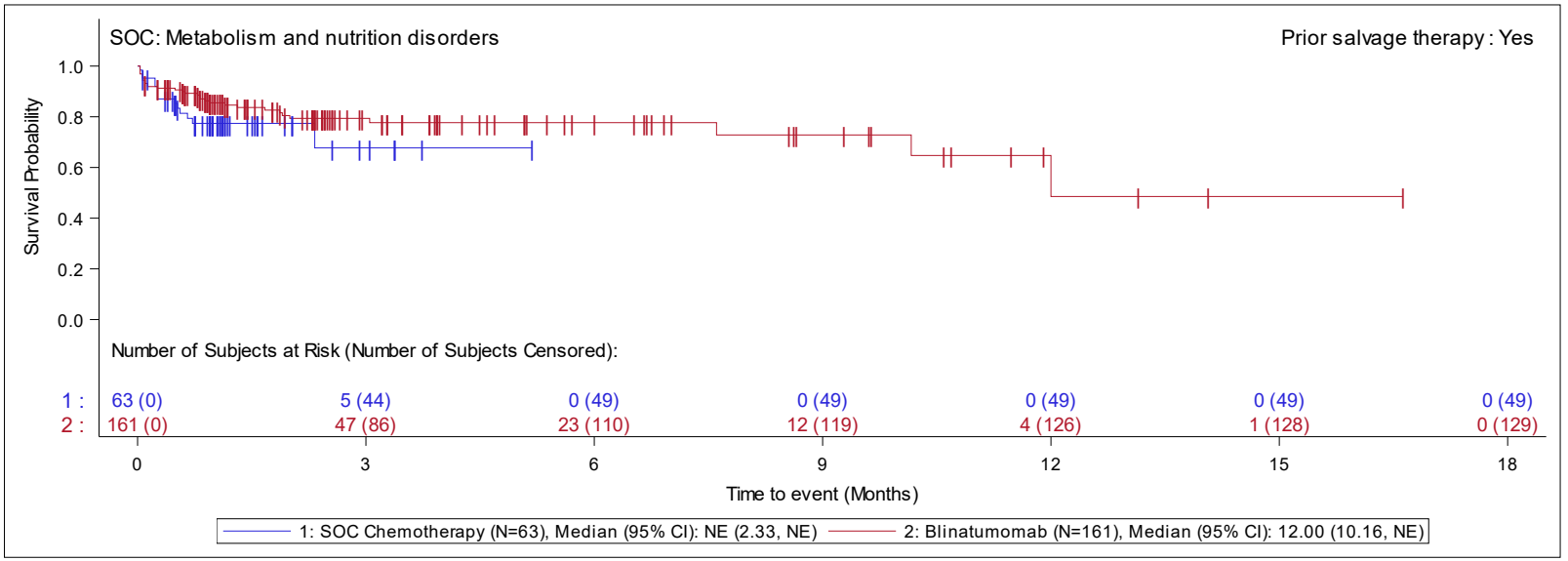
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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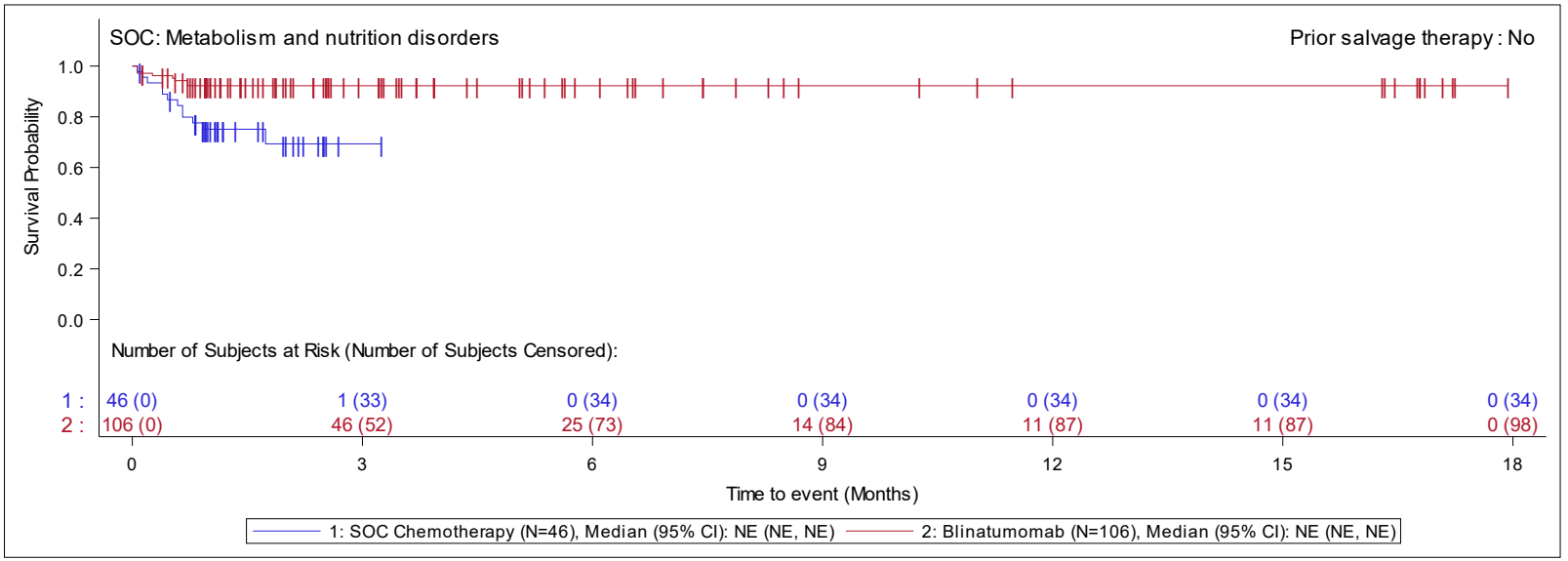
Figure 14-6.2.13. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Severe (Grade ≥ 3) Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
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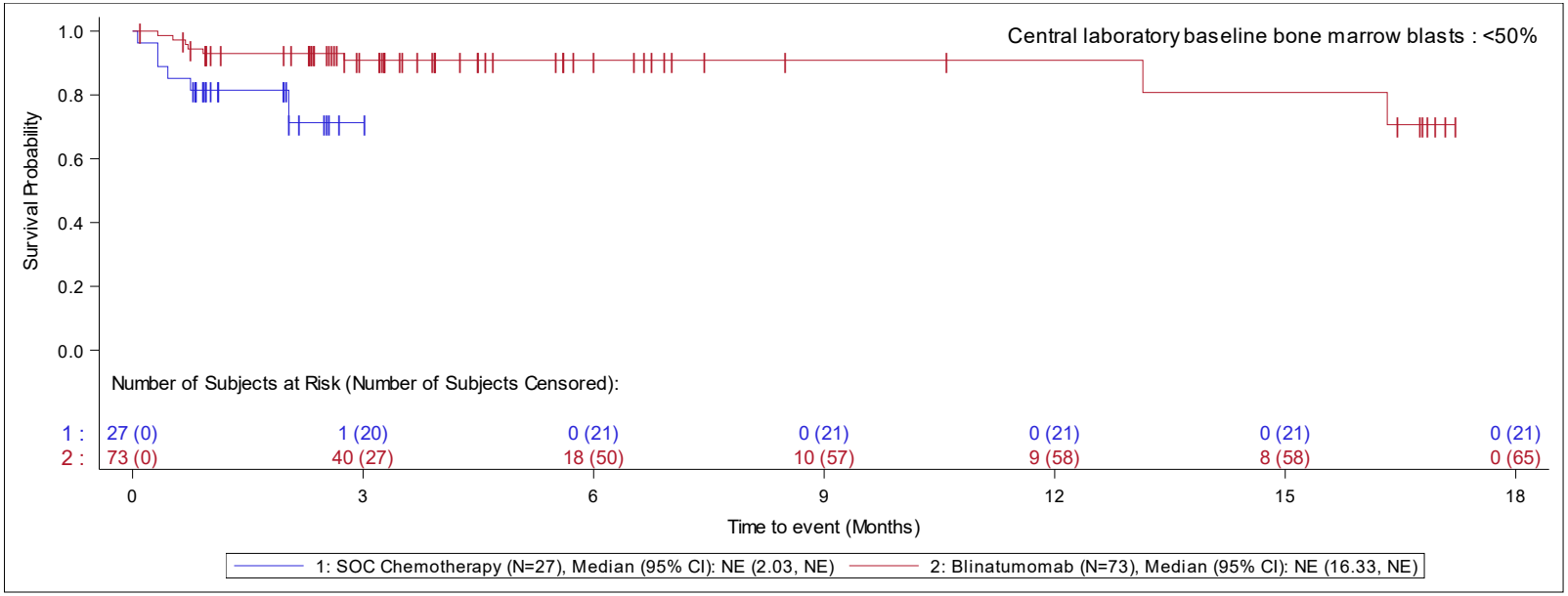
Figure 14-6.2.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

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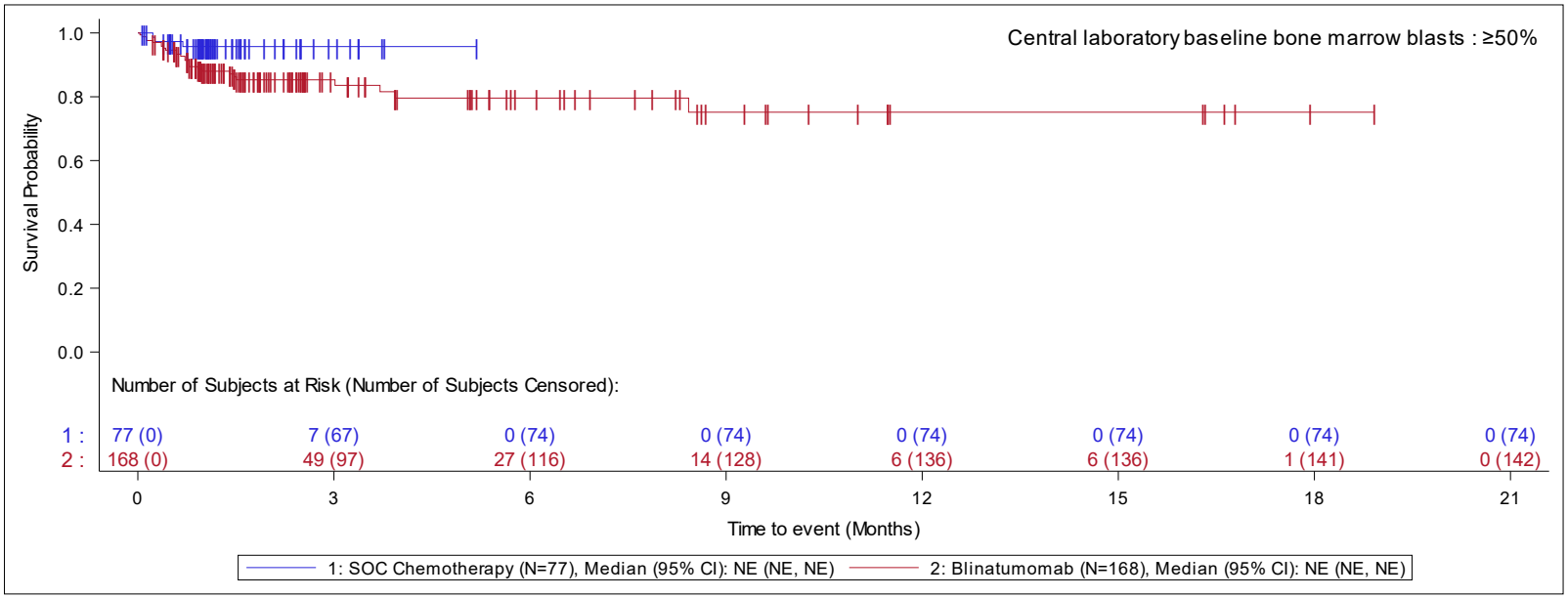
Figure 14-6.2.14. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event Leading to Discontinuation of Study Treatment Excluding Disease-related Events (Safety Analysis Set)



Censor indicated by vertical bar |. CI = Confidence interval. NE = Not estimable.
Data cut-off date: 14MAR2017

Program: /userdata/stat/amg103/onc/mt103_311/analysis/final_german_payer_202504/figures/f-km-sub-teae-trt-disc-edp-saf.sas
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