

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Blinatumomab (BLINCYTO®)

Amgen GmbH

Separater Anhang 4-G: Ergänzende Unterlagen

*Behandlung des Hochrisiko-Erstrezidivs einer
Philadelphia-Chromosom-negativen, CD19-positiven
B-Vorläufer akuten lymphatischen Leukämie im
Rahmen der Konsolidierungstherapie, im Alter von ≥ 1
Monat bis 17 Jahren*

Stand: 26.05.2026

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

Anhang 4-G1.1: Patientendisposition

Product: Blinatumomab
Clinical Study Report: 20120215
Date: 27 April 2020

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Table 14-1.1. Subject Disposition
(Full Analysis set)

	HC3 (N = 54) n (%)	Blinatumomab (N = 54) n (%)	Total (N = 108) n (%)
Subjects randomized	54 (100.0)	54 (100.0)	108 (100.0)
Investigational product accounting			
Subjects who never received investigational product	3 (5.6)	0 (0.0)	3 (2.8)
Subjects who received investigational product	51 (94.4)	54 (100.0)	105 (97.2)
Subjects who completed investigational product	49 (90.7)	50 (92.6)	99 (91.7)
Subjects continuing investigational product	0 (0.0)	2 (3.7)	2 (1.9)
Subjects who discontinued investigational product	2 (3.7)	2 (3.7)	4 (3.7)
Adverse event	1 (1.9)	2 (3.7)	3 (2.8)
Requirement for alternative therapy	1 (1.9)	0 (0.0)	1 (0.9)
Ineligibility determined	0 (0.0)	0 (0.0)	0 (0.0)
Protocol deviation	0 (0.0)	0 (0.0)	0 (0.0)
Noncompliance	0 (0.0)	0 (0.0)	0 (0.0)
Subject request	0 (0.0)	0 (0.0)	0 (0.0)
Disease progression	0 (0.0)	0 (0.0)	0 (0.0)
Decision by sponsor	0 (0.0)	0 (0.0)	0 (0.0)
Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)
Death	0 (0.0)	0 (0.0)	0 (0.0)
Protocol-specified criteria	0 (0.0)	0 (0.0)	0 (0.0)
Pregnancy	0 (0.0)	0 (0.0)	0 (0.0)
Disease flare	0 (0.0)	0 (0.0)	0 (0.0)
Reimbursement	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Study completion accounting			
Subjects who completed study	0 (0.0)	0 (0.0)	0 (0.0)
Subjects continuing study	32 (59.3)	43 (79.6)	75 (69.4)
Subjects who discontinued study	22 (40.7)	11 (20.4)	33 (30.6)
Death	16 (29.6)	8 (14.8)	24 (22.2)
Withdrawal of consent from study	5 (9.3)	2 (3.7)	7 (6.5)
Decision by sponsor	1 (1.9)	1 (1.9)	2 (1.9)
Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
Status of subjects continuing investigational product and study is until the data cut-off date.
First subject enrolled: 10NOV2015. Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/primary_clean/tables/program/t-ds-sum-fas.sas
Output: t14-01-001-ds-sum-fas.rtf (Date Generated: 30JAN20:01:57:32) Source: adam.adsl



Product: Blinatumomab
Clinical Study Report: 20120215
Date: 27 April 2020

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**Table 14-1.3. Summary of Analysis Set Disposition
(Full Analysis Set)**

	HC3 (N = 54) n (%)	Blinatumomab (N = 54) n (%)	Total (N = 108) n (%)
Safety Analysis Set Inclusion	51 (94.4)	54 (100.0)	105 (97.2)
MRD Evaluable Set Inclusion	54 (100.0)	54 (100.0)	108 (100.0)
HSCT Analysis Set Inclusion	38 (70.4)	48 (88.9)	86 (79.6)
Per Protocol Analysis Set Inclusion	26 (48.1)	30 (55.6)	56 (51.9)
Per Protocol Analysis Set Exclusion	28 (51.9)	24 (44.4)	52 (48.1)
Did not receive protocol specified therapy	1 (1.9)	0 (0.0)	1 (0.9)
Missing data (other than TA or TC)	12 (22.2)	15 (27.8)	27 (25.0)
Off-schedule procedures (other than TA or TC)	10 (18.5)	4 (7.4)	14 (13.0)
Other deviations	7 (13.0)	5 (9.3)	12 (11.1)
Entered study even though entry criteria was not satisfied	3 (5.6)	5 (9.3)	8 (7.4)
Received the wrong treatment or incorrect dose	2 (3.7)	3 (5.6)	5 (4.6)
Received an excluded concomitant treatment	3 (5.6)	0 (0.0)	3 (2.8)
Other treatment compliance	0 (0.0)	1 (1.9)	1 (0.9)
Pharmacokinetic Analysis Set Inclusion	0 (0.0)	49 (90.7)	49 (45.4)
Pharmacokinetic Analysis Set Exclusion	54 (100.0)	5 (9.3)	59 (54.6)
Did not have at least one PK sample	54 (100.0)	5 (9.3)	59 (54.6)
Did not receive protocol specified therapy	3 (5.6)	0 (0.0)	3 (2.8)

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N = Number of subjects in the full analysis set. n = Number of subjects with observed data.

Reasons for exclusion from an analysis set are not mutually exclusive.

Pharmacokinetic samples are collected for blinatumomab arm alone for population PK analysis.

Data cut-off date: 17JUL2019

Program:

/userdata/stat/amg103/onc/20120215/analysis/primary_clean/tables/program/t-dm-sum-anaset-fas.sas

Output: t14-01-003-dm-sum-anaset-fas.rtf (Date Generated: 30JAN20:01:58:10) Source: adam.adsl,
adam.addv



Anhang 4-G1.2: Behandlungs- und Beobachtungszeiten

**Table 14-5.1. Summary of Exposure
(Safety Analysis Set)**

	HC3 (N = 52)	Blinatumomab (N = 54)	Total (N = 106)
Duration of exposure (days)			
n	52	54	106
Mean	8.13	26.97	17.73
SD	4.07	5.21	10.55
Median	6.00	27.98	17.00
Q1, Q3	6.00, 7.00	27.83, 28.01	6.00, 28.00
Min, Max	3.0, 17.0	0.5, 29.4	0.5, 29.4
Subjects completing treatment cycle – n (%)		52 (96.3)	
Subjects discontinuing treatment cycle - n (%)		2 (3.7)	
Subjects re-starting treatment cycle – n (%)		0 (0.0)	
Relative treatment duration ^a (%)			
n		54	
Mean		96.31	
SD		18.62	
Median		99.94	
Q1, Q3		99.40, 100.04	
Min, Max		1.9, 105.1	
Cumulative dose (µg/m ²)			
n		54	
Mean		385.05	
SD		101.74	
Median		419.38	
Q1, Q3		415.78, 420.04	
Min, Max		8.0, 441.3	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.

^a Relative treatment duration is the actual duration of a cycle divided by 28 days.^b Percent of intended dose is the cumulative dose in a given cycle divided by the planned intended cumulative dose for that cycle.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ex-sum-saf.sas

Output: t14-05-001-ex-sum-saf.rtf (Date generated: 05SEP2025:00:49) Source data: a215up.adsl, a215.adexcyc, a215.adex

**Table 14-5.1. Summary of Exposure
(Safety Analysis Set)**

	HC3 (N = 52)	Blinatumomab (N = 54)	Total (N = 106)
Percent of intended dose ^b			
n		54	
Mean		91.68	
SD		24.22	
Median		99.85	
Q1, Q3		99.00, 100.01	
Min, Max		1.9, 105.1	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.

^a Relative treatment duration is the actual duration of a cycle divided by 28 days.^b Percent of intended dose is the cumulative dose in a given cycle divided by the planned intended cumulative dose for that cycle.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ex-sum-saf.sas

Output: t14-05-001-ex-sum-saf.rtf (Date generated: 05SEP2025:00:49) Source data: a215up.adsl, a215.adexcyc, a215.adex

**Table 14-8.1.1. Summary of Duration of Observation of EFS Events
(Full Analysis Set)**

	HC3 (N = 57)	Blinatumomab (N = 54)	Total (N = 111)
Duration of observation of EFS (months) ^a			
n	57	54	111
Mean	18.17	37.31	27.48
SD	23.63	27.14	27.05
Median	6.39	45.87	11.97
Min, Max	0.0, 80.9	1.0, 82.0	0.0, 82.0

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^a Months are calculated as days from randomization to documented progression (relapse or M2 marrow after having achieved a CR, failure to achieve a CR at the end of treatment, second malignancy, or death due to any cause, whichever occurs first) or last disease assessment, 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.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-obs-dur-mes-fas.sas

Output: t14-08-001-sum-dur-obs-efs-fas.rtf (Date generated: 12AUG2025:03:24) Source data: a215up.adsl, a215up.adtteff

**Table 14-8.1.2. Summary of Duration of Observation of Overall Survival
(Full Analysis Set)**

	HC3 (N = 57)	Blinatumomab (N = 54)	Total (N = 111)
Duration of observation of Overall Survival (months) ^a			
n	57	54	111
Mean	29.99	46.32	37.93
SD	24.54	25.47	26.20
Median	20.13	49.62	42.30
Min, Max	0.1, 80.9	1.0, 82.0	0.1, 82.0

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^a Months are calculated as days from randomization to death or last observation on study in absence of death, divided by 30.5.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-obs-dur-hsct-fas.sas

Output: t14-08-001-002-sum-dur-obs-os-fas.rtf (Date generated: 12AUG2025:03:25) Source data: a215up.adsl, a215up.adtteff

Table 14-8.1.3. Summary of Duration of Observation of MRD response (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Total (N = 111)
Duration of observation of MRD response (months) ^a			
n	52	54	106
Mean	0.34	0.99	0.67
SD	0.14	0.19	0.37
Median	0.26	1.00	0.66
Min, Max	0.2, 0.7	0.1, 1.4	0.1, 1.4

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MRD = minimal residual disease.

^a Months are calculated as days from randomization to end of treatment date, divided by 30.5.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-obs-dur-mes-fas.sas

Output: t14-08-001-003-sum-dur-obs-mrd-mes.rtf (Date generated: 12AUG2025:03:24) Source data: a215up.adsl, a215up.adtteff

Table 14-8.1.4. Summary of Duration of Observation of Allogeneic HSCT (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Total (N = 111)
Duration of observation of Allogeneic HSCT (months) ^a			
n	57	54	111
Mean	2.73	2.65	2.69
SD	3.05	5.53	4.41
Median	1.80	1.87	1.84
Min, Max	0.1, 18.8	1.0, 42.3	0.1, 42.3

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Allogeneic HSCT = allogeneic hematopoietic stem cell transplantation.

^a Months are calculated as days from randomization to first alloHSCT or last observation on study, whichever occurs first, divided by 30.5.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-obs-dur-hsct-fas.sas

Output: t14-08-001-004-sum-dur-obs-allohsct-fas.rtf (Date generated: 12AUG2025:03:25) Source data: a215up.adsl

Table 14-8.1.5. Summary of Duration of Observation of Survival Status After Allogeneic HSCT (HSCT Analysis Set)

	HC3 (N = 39)	Blinatumomab (N = 51)	Total (N = 90)
Duration of observation of survival status after Allogeneic HSCT (days) ^a			
n	39	51	90
Mean	989.90	1411.37	1228.73
SD	722.09	753.59	765.36
Median	1042.00	1505.00	1380.50
Min, Max	22.0, 2387.0	63.0, 2459.0	22.0, 2459.0

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Allogeneic HSCT = allogeneic hematopoietic stem cell transplantation.

^a Days are calculated as days from first alloHSCT to death or last observation on study in absence of death.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-obs-dur-hsct-fas.sas

Output: t14-08-001-005-sum-dur-obs-ss-allo-hsct.rtf (Date generated: 12AUG2025:03:25) Source data: a215up.adsl

Table 14-8.1.6. Summary of Duration of Observation for Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 50)	Blinatumomab (N = 54)	Total (N = 104)
Treatment-emergent adverse event (months) ^a			
n	50	54	104
Mean	1.25	1.90	1.59
SD	0.14	0.23	0.38
Median	1.18	1.93	1.54
Min, Max	1.1, 1.5	1.0, 2.2	1.0, 2.2

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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.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-dur-teae-saf.sas

Output: t14-08-001-006-sum-dur-teae-saf.rtf (Date generated: 12AUG2025:03:42) Source data: a215up.adsl, a215.adae

**Table 14-8.1.7. Summary of Observation on Study
(Full Analysis Set)**

	HC3 (N = 57)	Blinatumomab (N = 54)	Total (N = 111)
Observation on study (months) ^a			
n	57	54	111
Mean	29.97	46.31	37.92
SD	24.55	25.48	26.21
Median	20.10	49.62	42.30
Min, Max	0.1, 80.9	1.0, 82.0	0.1, 82.0

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^a Months are calculated as days from randomization to last observation on study, divided by 30.5.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-obs-dur-mes-fas.sas

Output: t14-08-001-007-sum-obs-stdy-fas.rtf (Date generated: 12AUG2025:03:24) Source data: a215up.adsl

Anhang 4-G1.3: Erste Folgetherapien

Table 14-8.4.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Regimen/ Agent	HC3 (N = 57) n (%)	Blinatumomab (N = 54) n (%)	Total (N = 111) n (%)
Number of subjects reporting first subsequent anti-cancer therapies	28 (49.1)	14 (25.9)	42 (37.8)
METHOTREXATE	4 (7.0)	4 (7.4)	8 (7.2)
BLINATUMOMAB	6 (10.5)	1 (1.9)	7 (6.3)
CYTARABINE	2 (3.5)	2 (3.7)	4 (3.6)
VINCISTINE	4 (7.0)	0 (0.0)	4 (3.6)
HYDROCORTISONE	1 (1.8)	2 (3.7)	3 (2.7)
PREDNISONE	2 (3.5)	1 (1.9)	3 (2.7)
CICLOFOSFAMIDE	1 (1.8)	1 (1.9)	2 (1.8)
CITARABINE	1 (1.8)	1 (1.9)	2 (1.8)
DONOR LYMPHOCYTE INFUSION	1 (1.8)	1 (1.9)	2 (1.8)
ETOPOSIDE	0 (0.0)	2 (3.7)	2 (1.8)
INOTUZUMAB	2 (3.5)	0 (0.0)	2 (1.8)
INOTUZUMAB OZOGAMICIN	1 (1.8)	1 (1.9)	2 (1.8)
MERCAPTOPYRINE	0 (0.0)	2 (3.7)	2 (1.8)
30 MG ARAC, 12MG MTX, 10 MG PRED	1 (1.8)	0 (0.0)	1 (0.9)
6-MERCAPTOPYRINE	0 (0.0)	1 (1.9)	1 (0.9)
ARACYTINE	1 (1.8)	0 (0.0)	1 (0.9)
BLINATUMOMAB COMMERCIALY PURCHASED	1 (1.8)	0 (0.0)	1 (0.9)
BLINATUMUMAB	1 (1.8)	0 (0.0)	1 (0.9)
BORTEZOMIB	1 (1.8)	0 (0.0)	1 (0.9)
CHT BEFORE CAR-T-CELLTHERAPY	1 (1.8)	0 (0.0)	1 (0.9)
CITARABIN	0 (0.0)	1 (1.9)	1 (0.9)
CLOFARABINA	1 (1.8)	0 (0.0)	1 (0.9)
CYCLOPHOSPHAMIDE	0 (0.0)	1 (1.9)	1 (0.9)
DEXAMETHASON	1 (1.8)	0 (0.0)	1 (0.9)
DEXAMETHASONA	1 (1.8)	0 (0.0)	1 (0.9)
DEXAMETHASONE	1 (1.8)	0 (0.0)	1 (0.9)
ETOPOSID	1 (1.8)	0 (0.0)	1 (0.9)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-anti-can-ltfu-fas.sas

Output: t14-08-004-001-anti-can-ltfu-fas.rtf (Date generated: 29OCT2025:23:08) Source data: a215up.adsl, a215.adcm

Table 14-8.4.1. Summary of First Subsequent Anti-cancer Therapies During Long-term Follow-up (Full Analysis Set)

Regimen/ Agent	HC3 (N = 57) n (%)	Blinatumomab (N = 54) n (%)	Total (N = 111) n (%)
F2 BLOCK	0 (0.0)	1 (1.9)	1 (0.9)
FLUDARABINE	1 (1.8)	0 (0.0)	1 (0.9)
IT METHOTREXATE	0 (0.0)	1 (1.9)	1 (0.9)
MAINTENANCE LAL REC 2003	1 (1.8)	0 (0.0)	1 (0.9)
METHATREXATE	0 (0.0)	1 (1.9)	1 (0.9)
METHROTREXAT	1 (1.8)	0 (0.0)	1 (0.9)
METHYLPREDNISOLON	0 (0.0)	1 (1.9)	1 (0.9)
METHYLPREDNISOLONE	1 (1.8)	0 (0.0)	1 (0.9)
MORPHINE	1 (1.8)	0 (0.0)	1 (0.9)
POLICYMOTHERAPY	0 (0.0)	1 (1.9)	1 (0.9)
PREDNISOLNE	0 (0.0)	1 (1.9)	1 (0.9)
VINCRISTIN	1 (1.8)	0 (0.0)	1 (0.9)
VP16	1 (1.8)	0 (0.0)	1 (0.9)

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-anti-can-ltfu-fas.sas

Output: t14-08-004-001-anti-can-ltfu-fas.rtf (Date generated: 29OCT2025:23:08) Source data: a215up.adsl, a215.adcm

Anhang 4-G1.4: Zusammenfassung der Allo HSZT

**Table 14-4.4.1. Summary of Allogenic HSCT
(Full Analysis Set)**

	HC3 (N=57) n (%)	Blinatumomab (N=54) n (%)
Subjects receiving transplant - n (%) ^a		
No	10 (17.5)	3 (5.6)
Yes	47 (82.5)	51 (94.4)
Subjects receiving transplant prior to relapse - n (%) ^a	39 (68.4)	51 (94.4)
Time to transplant (months) ^b		
Mean (SD)	2.0 (0.6)	1.9 (0.3)
Median	1.7	1.9
Q1, Q3	1, 2	2, 2
Min, Max	1, 4	1, 3
Stem cell source - n (%) ^c		
Peripheral blood	9 (23.1)	21 (41.2)
Bone marrow	25 (64.1)	25 (49.0)
Cord blood	5 (12.8)	5 (9.8)
Donor type - n (%) ^c		
Matched sibling	10 (25.6)	12 (23.5)
Mismatched sibling	1 (2.6)	0 (0.0)
Haploidentical (mother)	3 (7.7)	6 (11.8)
Haploidentical (father)	7 (17.9)	8 (15.7)
Matched unrelated	12 (30.8)	18 (35.3)
Mismatched unrelated	6 (15.4)	7 (13.7)
Subjects receiving conditioning total body irradiation - n (%) ^c	19 (48.7)	30 (58.8)
Subjects receiving conditioning chemotherapy - n (%) ^c	19 (48.7)	20 (39.2)

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allogenic HSCT = allogeneic hematopoietic stem cell transplantation. N = Number of subjects in the analysis set. n = Number of subjects with observed data.

^aPercentages are based on subjects in full analysis set.

^bMonths are calculated as days from randomization date to transplant date, divided by 30.5.

^cPercentages are based on subjects in full analysis set receiving transplant prior to relapse.

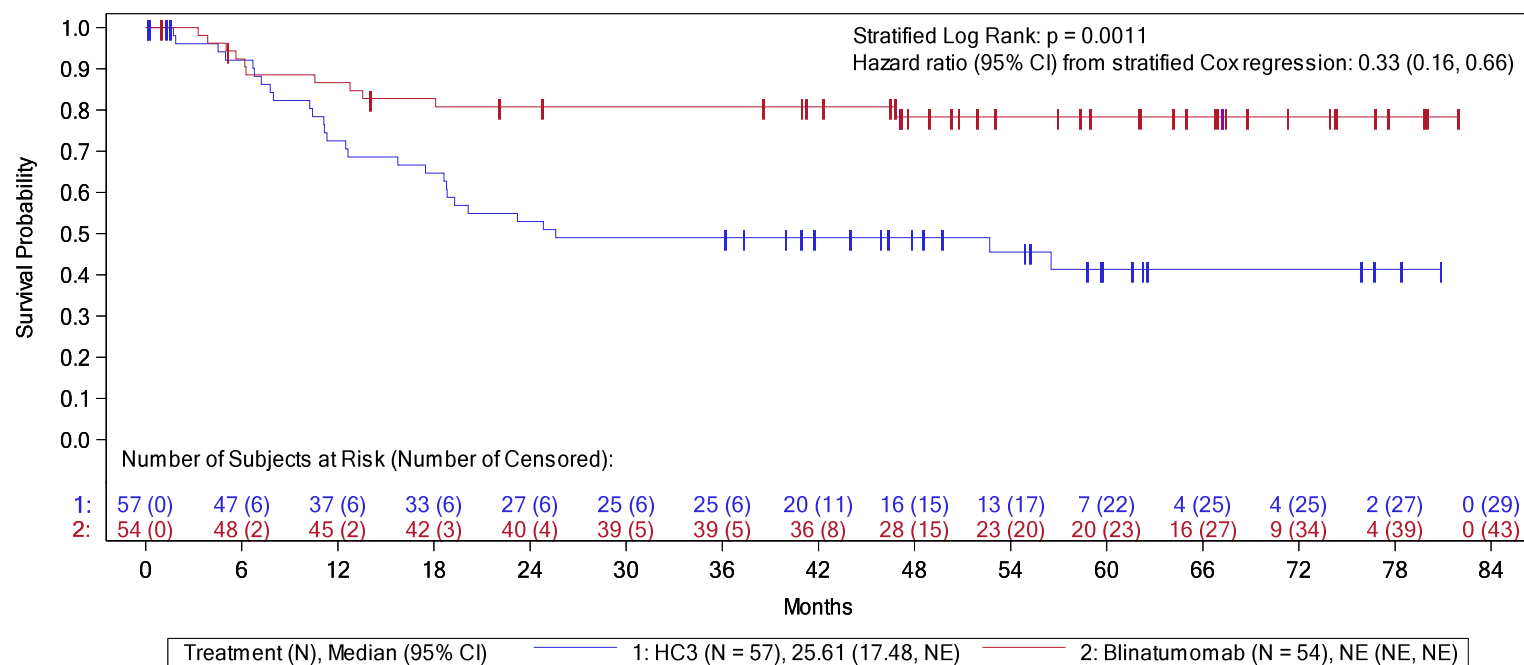
Program: /userdata/stat/amg103/onc/20120215/analysis/final_update/tables/t-allo-hsct-fas.sas

Output: t14-04-004-001-allo-hsct-fas.rtf (Date generated: 05APR2023:08:04) Source data: adam.adsl, adam.adsl, adam.adtteff, adam.adcm

Anhang 4-G2: Ergänzende Ergebnisdarstellung

Anhang 4-G2.1: Gesamtüberleben

**Figure 14-4.2.1. Kaplan-Meier plot for Overall Survival
(Full Analysis Set)**



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Death events which occurred after the end of study are also included as the overall survival event.

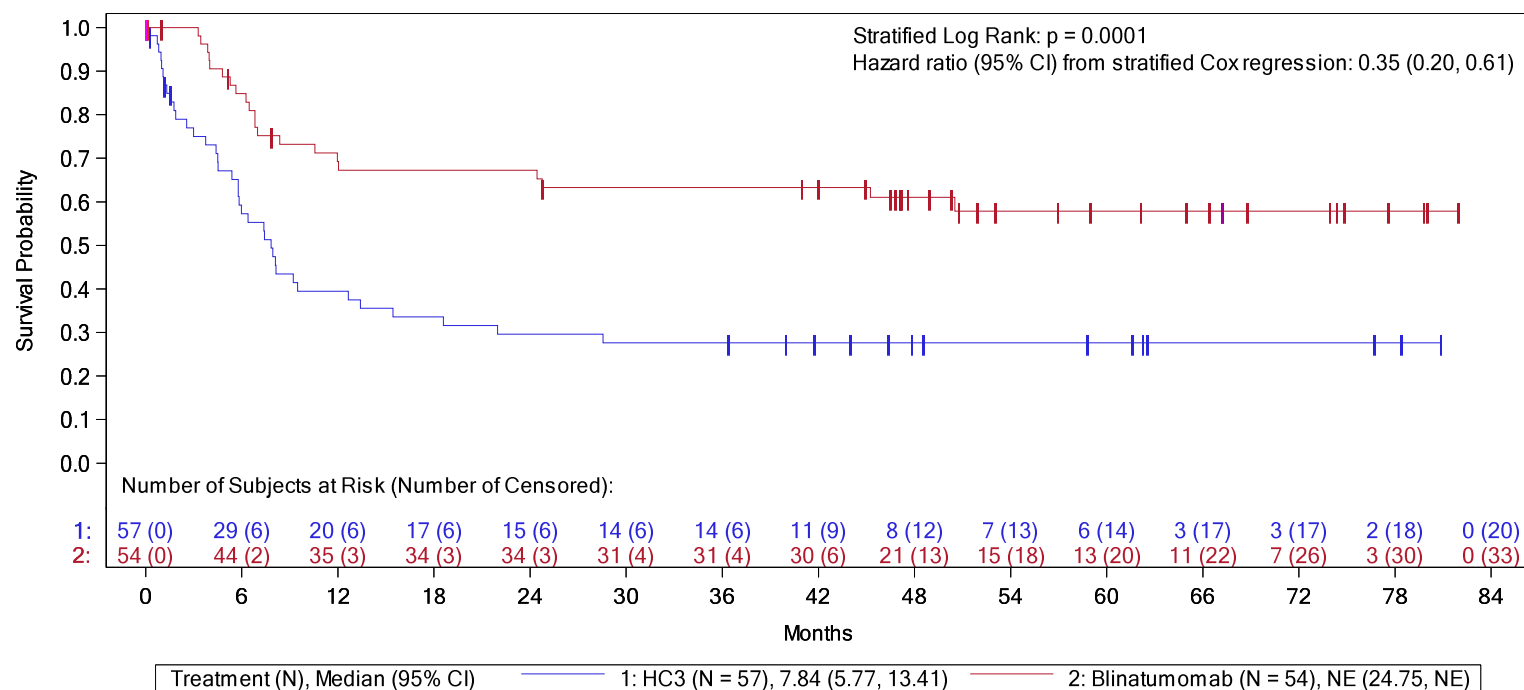
Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-os-fas.sas

Output: f14-04-002-001-km-os-fas.rtf (Date Generated: 06NOV2025:01:07) Source Data: a215up.adsl, a215up.adtteff

Anhang 4-G2.2: Ereignisfreies Überleben

Anhang 4-G2.2.1: EFS

**Figure 14-4.1.1. Kaplan-Meier plot for Event Free Survival
(Full Analysis Set)**

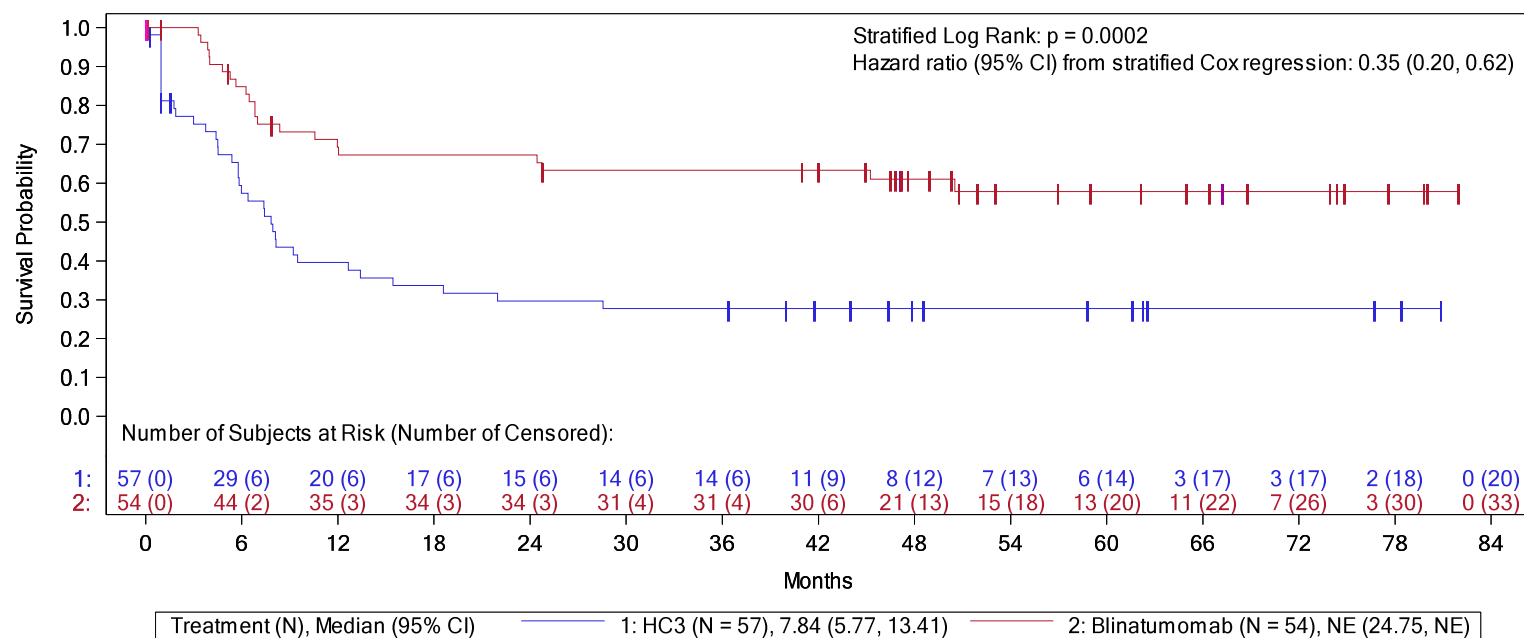


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-efs-fas.sas
Output: f14-04-001-001-km-efs-fas.rtf (Date Generated: 06NOV2025 : 01:07) Source Data: a215up.adsl, a215up.adtteff

Anhang 4-G2.2.2: EFS (Sensitivitätsanalyse)

Figure 14-4.1.2. Kaplan-Meier for Sensitivity Analysis - Event Free Survival (Full Analysis Set)



CI = Confidence Interval. NE = Not estimable.

Censor indicated by vertical bar |.

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.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sen-efs-fas.sas

Output: f14-04-001-002-km-sen-efs-fas.rtf (Date Generated: 19JAN2026:22:24) Source Data: a215up.adsl, a215up.adtteff

Anhang 4-G2.3: MRD-Remission

Table 14-4.1.1. Summary of MRD level $<10^{-4}$ Reduction (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
Number of subjects assessed	56	54	
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	27 (48.2)	51 (94.4)	46.2
Unstratified odds ratio ^a			18.26
(95% CI)			(5.09, 65.46)
p-value			<0.0001
Stratified odds ratio ^{a, b}			15.93
(95% CI)			(4.56, 55.64)
p-value			<0.0001
Unstratified risk ratio ^a			1.96
(95% CI)			(1.48, 2.59)
p-value			<0.0001
Stratified risk ratio ^{a, b, c}			1.80
(95% CI)			(1.30, 2.49)
p-value			0.0004
Absolute risk reduction			0.46
(95% CI)			(0.32, 0.61)
p-value			<0.0001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. CI = Confidence interval.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

PCR is used as the main method to determine MRD response, but the flow cytometry information is also analysed and flow response considered if PCR data is missing.

Percentages calculated by using number of subjects assessed as denominator.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level $<10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-mrd-fas.sas
Output: t14-04-001-001-mrd-fas.rtf (Date generated: 29MAY2025:01:06) Source data: a215up.adsl, a215up.adrs

Table 14-4.1.2. Summary of MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
Number of subjects assessed	48	47	
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	26 (54.2)	46 (97.9)	43.7
Unstratified odds ratio ^a			38.92
(95% CI)			(4.96, 305.62)
p-value			0.0005
Stratified odds ratio ^{a, b}			35.08
(95% CI)			(4.52, 272.06)
p-value			0.0007
Unstratified risk ratio ^a			1.81
(95% CI)			(1.39, 2.35)
p-value			<0.0001
Stratified risk ratio ^{a, b, c}			1.28
(95% CI)			(1.03, 1.59)
p-value			0.0291
Absolute risk reduction			0.44
(95% CI)			(0.29, 0.58)
p-value			<0.0001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages calculated by using number of subjects assessed as denominator.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level $<10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-mrd-pcr-fas.sas

Output: t14-04-001-002-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:07) Source data: a215up.adsl, a215up.adrs

Table 14-4.1.3. Summary of MRD level $<10^{-4}$ Reduction by Flow Cytometry (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
Number of subjects assessed	55	54	
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	33 (60.0)	50 (92.6)	32.6
Unstratified odds ratio ^a			8.33
(95% CI)			(2.63, 26.38)
p-value			0.0003
Stratified odds ratio ^{a, b}			7.97
(95% CI)			(2.56, 24.87)
p-value			0.0003
Unstratified risk ratio ^a			1.54
(95% CI)			(1.23, 1.94)
p-value			0.0002
Stratified risk ratio ^{a, b}			1.50
(95% CI)			(1.19, 1.90)
p-value			0.0007
Absolute risk reduction			0.33
(95% CI)			(0.18, 0.47)
p-value			<0.0001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. CI = Confidence interval.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages calculated by using number of subjects assessed as denominator.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level $<10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-mrd-fcy-fas.sas

Output: t14-04-001-003-mrd-fcy-fas.rtf (Date generated: 29MAY2025:01:08) Source data: a215up.adsl, a215up.adrs

Table 14-4.1.4. Summary of Cytomorphology by Central Bone Marrow Assessment (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
Number of subjects with Cytomorphology response as M1 - n (%)	54 (94.7)	54 (100.0)	5.3
Unstratified odds ratio ^{a, d} (95% CI) p-value			7.00 (0.35, 138.75) 0.2016
Stratified odds ratio ^{a, b} (95% CI) p-value			NE (NE, NE) NE
Unstratified risk ratio ^{a, d} (95% CI) p-value			1.05 (0.98, 1.13) 0.1368
Stratified risk ratio ^{a, b, c} (95% CI) p-value			1.05 (0.99, 1.12) 0.0764
Absolute risk reduction ^d (95% CI) p-value			0.05 (-0.01, 0.12) 0.1293

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. CI = Confidence interval. NE = Not estimable.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c Stratified risk ratio obtained from generalized poisson model with log link.

^d Results estimated by using zero cell continuity correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-cyto-cbm-fas.sas

Output: t14-04-001-004-cyto-cbm-fas.rtf (Date generated: 29MAY2025:01:08) Source data: a215up.adsl, a215up.adbase

Table 14-4.3.1. Summary of Baseline MRD Response with $<10^{-4}$ (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
MRD response by PCR			
Number of subjects assessed	45	46	
Number of subjects with baseline MRD level $<10^{-4}$ - n (%)	23 (51.1)	20 (43.5)	-7.6
Unstratified odds ratio ^a			0.74
(95% CI)			(0.32, 1.68)
p-value			0.4663
Stratified odds ratio ^{a, b}			0.72
(95% CI)			(0.30, 1.76)
p-value			0.4764
Unstratified risk ratio ^a			0.85
(95% CI)			(0.55, 1.32)
p-value			0.4673
Stratified risk ratio ^{a, b}			0.90
(95% CI)			(0.64, 1.28)
p-value			0.5623
Absolute risk reduction			-0.08
(95% CI)			(-0.28, 0.13)
p-value			0.4646

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level $<10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-bas-mrd-rem-fas.sas

Output: t14-04-003-001-sum-bas-mrd-rem-fas.rtf (Date generated: 11AUG2025:00:30) Source data: a215up.adsl, a215up.adrs

Table 14-4.3.1. Summary of Baseline MRD Response with $<10^{-4}$ (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
MRD response by flow cytometry			
Number of subjects assessed	54	51	
Number of subjects with baseline MRD level $<10^{-4}$ - n (%)	36 (66.7)	38 (74.5)	7.8
Unstratified odds ratio ^a			1.46
(95% CI)			(0.63, 3.41)
p-value			0.3796
Stratified odds ratio ^{a, b}			1.58
(95% CI)			(0.59, 4.22)
p-value			0.3657
Unstratified risk ratio ^a			1.12
(95% CI)			(0.87, 1.43)
p-value			0.3787
Stratified risk ratio ^{a, b}			1.04
(95% CI)			(0.89, 1.23)
p-value			0.6190
Absolute risk reduction			0.08
(95% CI)			(-0.10, 0.25)
p-value			0.3757

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level $< 10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-bas-mrd-rem-fas.sas

Output: t14-04-003-001-sum-bas-mrd-rem-fas.rtf (Date generated: 11AUG2025:00:30) Source data: a215up.adsl, a215up.adrs

Table 14-4.3.2. Summary of Baseline MRD Response with $\geq 10^{-4}$ (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
MRD response by PCR			
Number of subjects assessed	45	46	
Number of subjects with baseline MRD level $\geq 10^{-4}$ - n (%)	22 (48.9)	26 (56.5)	7.6
Unstratified odds ratio ^a			1.36
(95% CI)			(0.60, 3.10)
p-value			0.4663
Stratified odds ratio ^{a, b}			1.38
(95% CI)			(0.57, 3.37)
p-value			0.4764
Unstratified risk ratio ^a			1.16
(95% CI)			(0.78, 1.71)
p-value			0.4680
Stratified risk ratio ^{a, b, c}			1.04
(95% CI)			(0.79, 1.38)
p-value			0.7647
Absolute risk reduction			0.08
(95% CI)			(-0.13, 0.28)
p-value			0.4646

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (< 1 year and > 9 years)), and marrow/MRD status (M1 with MRD level $< 10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-bas-mrd-nrem-fas.sas

Output: t14-04-003-002-sum-bas-mrd-nrem-fas.rtf (Date generated: 11AUG2025:00:19) Source data: a215up.adsl, a215up.adrs

Table 14-4.3.2. Summary of Baseline MRD Response with $\geq 10^{-4}$ (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
MRD response by flow cytometry			
Number of subjects assessed	54	51	
Number of subjects with baseline MRD level $\geq 10^{-4}$ - n (%)	18 (33.3)	13 (25.5)	-7.8
Unstratified odds ratio ^a			0.68
(95% CI)			(0.29, 1.60)
p-value			0.3796
Stratified odds ratio ^{a, b}			0.63
(95% CI)			(0.24, 1.70)
p-value			0.3657
Unstratified risk ratio ^a			0.76
(95% CI)			(0.42, 1.40)
p-value			0.3825
Stratified risk ratio ^{a, b, c}			0.72
(95% CI)			(0.40, 1.28)
p-value			0.2577
Absolute risk reduction			-0.08
(95% CI)			(-0.25, 0.10)
p-value			0.3757

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (< 1 year and > 9 years)), and marrow/MRD status (M1 with MRD level $< 10^{-3}$ vs. M1 with MRD level $\geq 10^{-3}$ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sum-bas-mrd-nrem-fas.sas

Output: t14-04-003-002-sum-bas-mrd-nrem-fas.rtf (Date generated: 11AUG2025:00:19) Source data: a215up.adsl, a215up.adrs

Anhang 4-G2.4: MRD-Remission (Sensitivitätsanalysen)

Table 14-4.3.3. Sensitivity Analysis - MRD Response
(Subjects in Full Analysis Set Who Received Investigational Product)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
MRD response by PCR			
Number of subjects assessed	48	47	
Number of subjects with MRD response - n (%)	26 (54.2)	46 (97.9)	43.7
Unstratified odds ratio ^a			38.92
(95% CI)			(4.96, 305.62)
p-value			0.0005
Stratified odds ratio ^{a, b}			35.08
(95% CI)			(4.52, 272.06)
p-value			0.0007
Unstratified risk ratio ^a			1.81
(95% CI)			(1.39, 2.35)
p-value			<0.0001
Stratified risk ratio ^{a, b, c}			1.28
(95% CI)			(1.03, 1.59)
p-value			0.0291
Absolute risk reduction			0.44
(95% CI)			(0.29, 0.58)
p-value			<0.0001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd.sas
Output: t14-04-003-sen-mrd.rtf (Date generated: 07AUG2025:00:05) Source data: a215up.adsl,
a215up.adrs

Table 14-4.3.3. Sensitivity Analysis - MRD Response
(Subjects in Full Analysis Set Who Received Investigational Product)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
MRD response by flow cytometry			
Number of subjects assessed	51	54	
Number of subjects with MRD response - n (%)	33 (64.7)	50 (92.6)	27.9
Unstratified odds ratio ^a			6.82
(95% CI)			(2.12, 21.95)
p-value			0.0013
Stratified odds ratio ^{a, b}			6.52
(95% CI)			(2.06, 20.64)
p-value			0.0014
Unstratified risk ratio ^a			1.43
(95% CI)			(1.15, 1.78)
p-value			0.0012
Stratified risk ratio ^{a, b}			1.41
(95% CI)			(1.12, 1.76)
p-value			0.0029
Absolute risk reduction			0.28
(95% CI)			(0.13, 0.43)
p-value			0.0002

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd.sas
Output: t14-04-003-sen-mrd.rtf (Date generated: 07AUG2025:00:05) Source data: a215up.adsl, a215up.adrs

Table 14-4.3.4. Sensitivity Analysis - MRD Response
(Subjects in Full Analysis Set Who Had at Least One Post-baseline MRD Assessment)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
MRD response by PCR			
Number of subjects assessed	47	47	
Number of subjects with MRD response - n (%)	26 (55.3)	46 (97.9)	42.6
Unstratified odds ratio ^a			37.15
(95% CI)			(4.72, 292.33)
p-value			0.0006
Stratified odds ratio ^{a, b}			33.87
(95% CI)			(4.35, 263.95)
p-value			0.0008
Unstratified risk ratio ^a			1.77
(95% CI)			(1.36, 2.30)
p-value			<0.0001
Stratified risk ratio ^{a, b, c}			1.25
(95% CI)			(1.00, 1.56)
p-value			0.0506

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd-post.sas

Output: t14-04-003-004-sen-mrd-post.rtf (Date generated: 07AUG2025:00:56) Source data: a215up.adsl, a215up.adrs

Table 14-4.3.4. Sensitivity Analysis - MRD Response
(Subjects in Full Analysis Set Who Had at Least One Post-baseline MRD Assessment)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Absolute risk reduction (95% CI) p-value			0.43 (0.28, 0.57) <0.0001
MRD response by flow cytometry			
Number of subjects assessed	48	52	
Number of subjects with MRD response - n (%)	33 (68.8)	50 (96.2)	27.4
Unstratified odds ratio ^a (95% CI) p-value			11.36 (2.44, 52.97) 0.0020
Stratified odds ratio ^{a, b} (95% CI) p-value			10.91 (2.37, 50.22) 0.0022
Unstratified risk ratio ^a (95% CI) p-value			1.40 (1.15, 1.71) 0.0009

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd-post.sas

Output: t14-04-003-004-sen-mrd-post.rtf (Date generated: 07AUG2025:00:56) Source data: a215up.adsl, a215up.adrs

Table 14-4.3.4. Sensitivity Analysis - MRD Response
(Subjects in Full Analysis Set Who Had at Least One Post-baseline MRD Assessment)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Stratified risk ratio ^{a, b, c}			1.25
(95% CI)			(1.02, 1.52)
p-value			0.0291
Absolute risk reduction			0.27
(95% CI)			(0.13, 0.42)
p-value			0.0001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd-post.sas

Output: t14-04-003-004-sen-mrd-post.rtf (Date generated: 07AUG2025:00:56) Source data: a215up.adsl, a215up.adrs

**Table 14-4.3.5. Sensitivity Analysis - MRD Response
(Per Protocol Analysis Set)**

	HC3 (N = 27)	Blinatumomab (N = 28)	Treatment Difference
MRD response by PCR			
Number of subjects assessed	22	24	
Number of subjects with MRD response - n (%)	11 (50.0)	24 (100.0)	50.0
Unstratified odds ratio ^{a, d} (95% CI) p-value			48.99 (2.65, 905.35) 0.0089
Stratified odds ratio ^{a, b} (95% CI) p-value			NE (NE, NE) NE
Unstratified risk ratio ^{a, d} (95% CI) p-value			1.96 (1.30, 2.96) 0.0014
Stratified risk ratio ^{a, b, c} (95% CI) p-value			2.06 (1.39, 3.05) 0.0003

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. NE = Not estimable.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Per protocol set includes all subjects in the full analysis set who did not have any important protocol deviations which could have an impact on the efficacy evaluation of the subject.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c Stratified risk ratio obtained from generalized poisson model with log link.

^d Results estimated by using zero cell continuity correction.

^e The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd-pp.sas

Output: t14-04-003-005-sen-mrd-pp.rtf (Date generated: 07AUG2025:05:12) Source data: a215up.adsl, a215up.adrs

**Table 14-4.3.5. Sensitivity Analysis - MRD Response
(Per Protocol Analysis Set)**

	HC3 (N = 27)	Blinatumomab (N = 28)	Treatment Difference
Absolute risk reduction ^d			0.48
(95% CI)			(0.27, 0.69)
p-value			<0.0001
MRD response by flow cytometry			
Number of subjects assessed	27	28	
Number of subjects with MRD response - n (%)	13 (48.1)	27 (96.4)	48.3
Unstratified odds ratio ^a			29.08
(95% CI)			(3.44, 245.64)
p-value			0.0020
Stratified odds ratio ^{a, b}			35.85
(95% CI)			(3.83, 335.28)
p-value			0.0017
Unstratified risk ratio ^a			2.00
(95% CI)			(1.35, 2.98)
p-value			0.0006

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. NE = Not estimable.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Per protocol set includes all subjects in the full analysis set who did not have any important protocol deviations which could have an impact on the efficacy evaluation of the subject.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c Stratified risk ratio obtained from generalized poisson model with log link.

^d Results estimated by using zero cell continuity correction.

^e The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd-pp.sas

Output: t14-04-003-005-sen-mrd-pp.rtf (Date generated: 07AUG2025:05:12) Source data: a215up.adsl, a215up.adrs

**Table 14-4.3.5. Sensitivity Analysis - MRD Response
(Per Protocol Analysis Set)**

	HC3 (N = 27)	Blinatumomab (N = 28)	Treatment Difference
Stratified risk ratio ^{a, b, e}			1.58
(95% CI)			(0.69, 3.60)
p-value			0.2793
Absolute risk reduction			0.48
(95% CI)			(0.28, 0.68)
p-value			<0.0001

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. NE = Not estimable.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Per protocol set includes all subjects in the full analysis set who did not have any important protocol deviations which could have an impact on the efficacy evaluation of the subject.

Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c Stratified risk ratio obtained from generalized poisson model with log link.

^d Results estimated by using zero cell continuity correction.

^e The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-sen-mrd-pp.sas

Output: t14-04-003-005-sen-mrd-pp.rtf (Date generated: 07AUG2025:05:12) Source data: a215up.adsl, a215up.adrs

Anhang 4-G2.5: Kumulative Rezidivinzidenz

Table 14-4.5.1. Cumulative Incidence of Relapse with Death due to other causes as a Competing Event (Full Analysis Set)

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference
Cumulative incidence of relapse			
Subject status			
Number of subjects	57	54	
Events - n (%)	36 (63.2)	16 (29.6)	
Relapse	35 (61.4)	16 (29.6)	
Death due to disease progression	1 (1.8)	0 (0.0)	
Competing event - n (%)			
Death due to other cause	1 (1.8)	4 (7.4)	
Censored - n (%)			
Alive w/o relapse	20 (35.1)	34 (63.0)	
Unstratified Gray's test			
p-value			<0.0001
Stratified Gray's test ^c			
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. CIF =

Cumulative Incidence Function. CI = Confidence interval. NE = Not estimable.

^a Months are calculated as days from randomization date to event/censor date, divided by 30.5.^b The subdistribution hazard ratio estimates are obtained from the subdistribution Cox model. A hazard ratio < 1.0 indicates a lower average event rate and a longer relapse free time for Blinatumomab relative to HC3.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-cif-dth-fas.sas

Output: t14-04-005-001-cif-dth-fas.rtf (Date generated: 04SEP2025:16:55) Source data: a215up.adsl, a215up.adtteff

Table 14-4.5.1. Cumulative Incidence of Relapse with Death due to other causes as a Competing Event (Full Analysis Set)

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference
Time to event (CIF) (months) ^a			
Median	7.93	NE	
95% CI (median)	5.84, 18.59	NE, NE	
Q1, Q3	4.39, NE	12.03, NE	
Min, Max	0.3, 28.6	3.4, 45.2	
CIF estimate - %			
At time 3 months ^a	23.0	0.0	
(95% CI)	(12.63, 35.22)	(NE, NE)	
At time 6 months ^a	40.8	11.4	
(95% CI)	(27.18, 53.91)	(4.58, 21.67)	
At time 12 months ^a	58.5	23.1	
(95% CI)	(43.57, 70.81)	(12.67, 35.31)	
At time 18 months ^a	64.5	25.0	
(95% CI)	(49.40, 76.08)	(14.17, 37.50)	
At time 24 months ^a	68.4	25.0	
(95% CI)	(53.39, 79.48)	(14.17, 37.50)	
At time 36 months ^a	70.4	29.0	
(95% CI)	(55.42, 81.15)	(17.28, 41.79)	
At time 48 months ^a	70.4	31.3	
(95% CI)	(55.42, 81.15)	(19.03, 44.28)	
At time 60 months ^a	70.4	31.3	
(95% CI)	(55.42, 81.15)	(19.03, 44.28)	
At time 72 months ^a	70.4	31.3	
(95% CI)	(55.42, 81.15)	(19.03, 44.28)	
At time 84 months ^a	70.4	31.3	
(95% CI)	(55.42, 81.15)	(19.03, 44.28)	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. CIF = Cumulative Incidence Function. CI = Confidence interval. NE = Not estimable.

^a Months are calculated as days from randomization date to event/censor date, divided by 30.5.

^b The subdistribution hazard ratio estimates are obtained from the subdistribution Cox model. A hazard ratio < 1.0 indicates a lower average event rate and a longer relapse free time for Blinatumomab relative to HC3.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-cif-dth-fas.sas
Output: t14-04-005-001-cif-dth-fas.rtf (Date generated: 04SEP2025:16:55) Source data: a215up.adsl, a215up.adtteff

Table 14-4.5.1. Cumulative Incidence of Relapse with Death due to other causes as a Competing Event (Full Analysis Set)

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference
Hazard ratio ^b			0.29
(95% CI)			(0.16, 0.52)
p-value			<0.0001
Stratified hazard ratio ^{b, c}			0.27
(95% CI)			(0.15, 0.48)
p-value			<0.0001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. CIF = Cumulative Incidence Function. CI = Confidence interval. NE = Not estimable.

^a Months are calculated as days from randomization date to event/censor date, divided by 30.5.

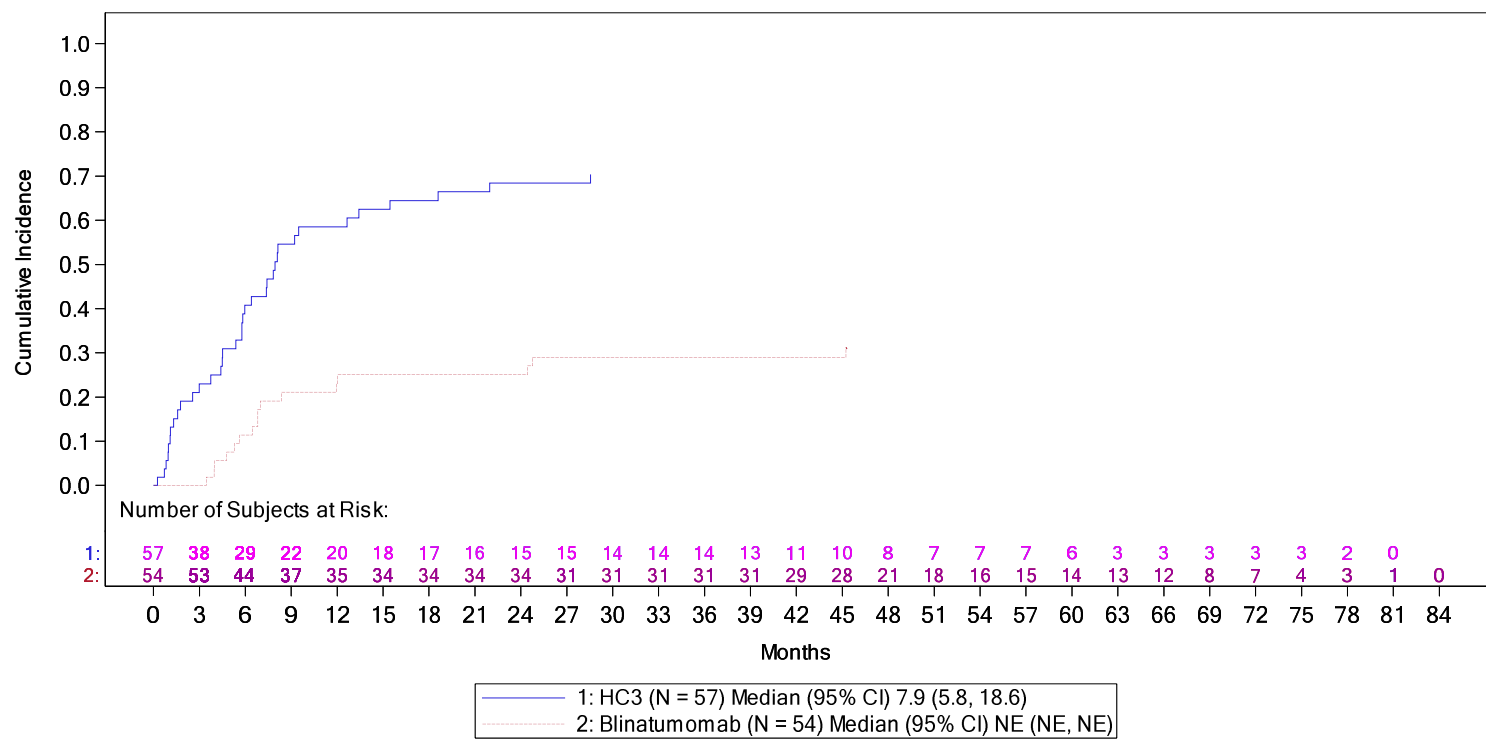
^b The subdistribution hazard ratio estimates are obtained from the subdistribution Cox model. A hazard ratio < 1.0 indicates a lower average event rate and a longer relapse free time for Blinatumomab relative to HC3.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-cif-dth-fas.sas

Output: t14-04-005-001-cif-dth-fas.rtf (Date generated: 04SEP2025:16:55) Source data: a215up.adsl, a215up.adtteff

Figure 14-4.3.1. Cumulative Incidence of Relapse with Death due to other causes as a Competing Event (Full Analysis Set)



Program: /userdata/stat/amg/103/onc/20120215/analysis/final_update/figures/f-inc-rlp-dth-fas.sas
Output: f14-04-003-001-inc-rlp-dth-fas.rtf (Date Generated: 05APR23 09:39) Source Data: adam.adsl, adam.adtteff

Anhang 4-G2.6: Rate der alloHSZT

Anhang 4-G2.6.1: Rate der alloHSZT in CR

**Table 14-4.3.6. Rate of alloHSCT in Complete Remission
(Full Analysis Set)**

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference
Subjects receiving transplant prior to relapse - n (%)	39 (68.4)	51 (94.4)	26.0
Unstratified odds ratio ^a			7.85
(95% CI)			(2.16, 28.54)
p-value			0.0018
Stratified odds ratio ^{a, b}			7.62
(95% CI)			(2.11, 27.51)
p-value			0.0019
Unstratified risk ratio ^a			1.38
(95% CI)			(1.14, 1.67)
p-value			0.0008
Stratified risk ratio ^{a, b, c}			1.24
(95% CI)			(1.03, 1.50)
p-value			0.0262
Absolute risk reduction			0.26
(95% CI)			(0.12, 0.40)
p-value			0.0002

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. alloHSCT = allogeneic hematopoietic stem cell transplantation. CI = Confidence interval. NE = Not estimable.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^b Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^c The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-allo-hsct-cr-fas.sas

Output: t14-04-003-006-allo-hsct-cr-fas.rtf (Date generated: 14AUG2025:00:06) Source data: a215up.adsl, a215.adsl

Anhang 4-G2.6.2: Gesamtüberleben nach alloHSZT in CR

Table 14-4.4.1. Survival Status Following Allogeneic HSCT (HSCT Analysis Set)

	HC3 (N=39)	Blinatumomab (N=51)	Treatment Difference
Mortality following alloHSCT			
KM estimate - %			
At time 100 days ^a	5.13	3.92	
(95% CI)	(1.31, 18.98)	(1.00, 14.78)	
Subject status			
Number of subjects with alloHSCT	39	51	
Events - n (%)	20 (51.3)	10 (19.6)	
Death from any cause	20 (51.3)	10 (19.6)	
Censored - n (%)	19 (48.7)	41 (80.4)	
Alive	19 (48.7)	41 (80.4)	
Unstratified log-rank test			
n	39	51	
Normal score ^d			-7.967
p-value			0.0029

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. alloHSCT = allogeneic hematopoietic stem cell transplantation. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Days are calculated from alloHSCT date to death/censor date.

^b Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-hsct-has.sas

Output: t14-04-004-001-tte-hsct-has.rtf (Date generated: 13AUG2025:04:43) Source data: a215up.adsl, a215up.adtteff

Table 14-4.4.1. Survival Status Following Allogeneic HSCT (HSCT Analysis Set)

	HC3 (N=39)	Blinatumomab (N=51)	Treatment Difference
Stratified log-rank test ^c			
n	39	51	
Normal score ^d			-7.924
p-value			0.0024
Time to event (KM) (days) ^a			
Median	1558.00	NE	
95% CI (median)	(431.00, NE)	(NE, NE)	
Q1, Q3	267.00, NE	NE, NE	
Min, Max	22.0, 1558.0	63.0, 1379.0	
Time to censoring (days) ^{a,b}			
Median	1619.00	1742.00	
95% CI (median)	(1294.00, 1830.00)	(1476.00, 1979.00)	
Q1, Q3	1322.50, 1836.00	1387.00, 2020.00	
Min, Max	1042.0, 2387.0	91.0, 2459.0	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. alloHSCT = allogeneic hematopoietic stem cell transplantation. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Days are calculated from alloHSCT date to death/censor date.

^b Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-hsct-has.sas

Output: t14-04-004-001-tte-hsct-has.rtf (Date generated: 13AUG2025:04:43) Source data: a215up.adsl, a215up.adtteff

Table 14-4.4.1. Survival Status Following Allogeneic HSCT (HSCT Analysis Set)

	HC3 (N=39)	Blinatumomab (N=51)	Treatment Difference
Unstratified hazard ratio ^e			0.33
(95% CI)			(0.16, 0.71)
p-value			0.0046
Stratified hazard ratio ^{c,e}			0.30
(95% CI)			(0.13, 0.69)
p-value			0.0042

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. alloHSCT = allogeneic hematopoietic stem cell transplantation. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Days are calculated from alloHSCT date to death/censor date.

^b Time to censoring measures follow-up time by reversing the status indicator for censored and events.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

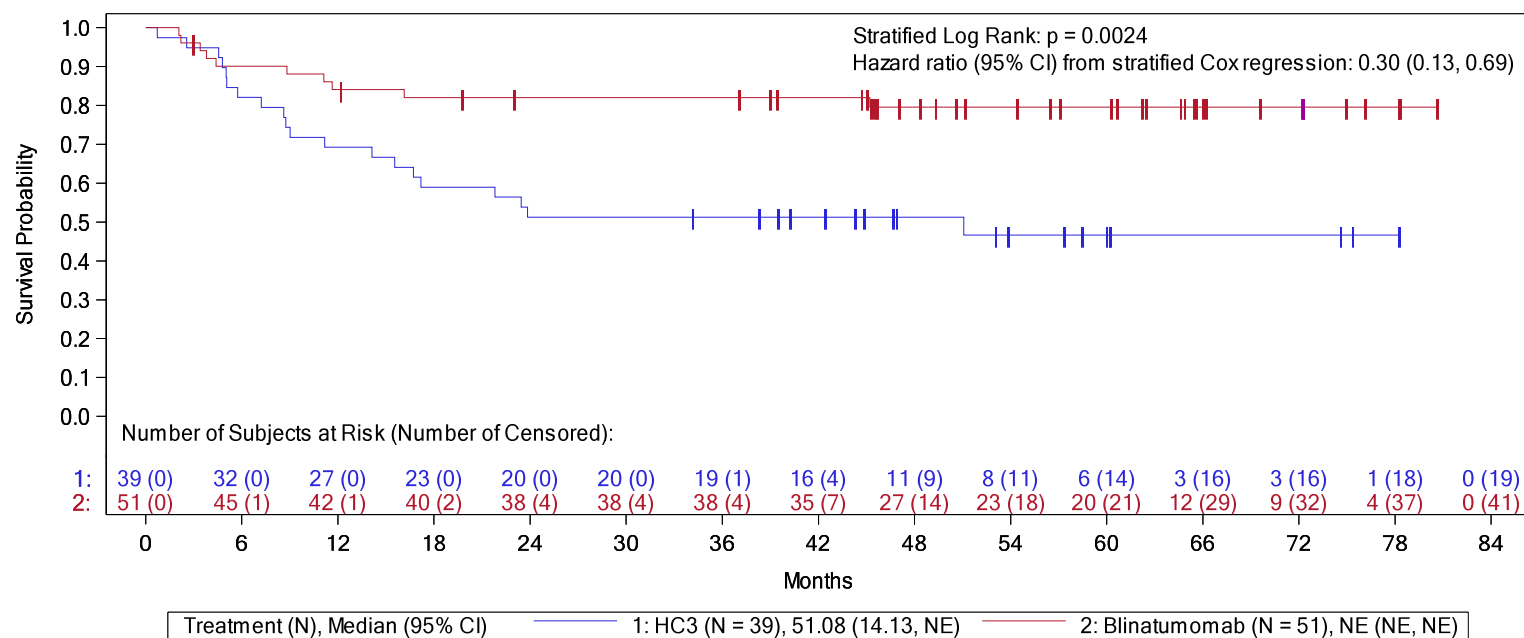
^d A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-hsct-has.sas

Output: t14-04-004-001-tte-hsct-has.rtf (Date generated: 13AUG2025:04:43) Source data: a215up.adsl, a215up.adtteff

Figure 14-4.6.1. Kaplan-Meier plot for Survival Status Following Allogeneic HSCT (HSCT Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Months are calculated from alloHSCT date to death/censor date.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ss-allohsct-has.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-04-006-001-km-ss-allohsct-has.rtf

(Date Generated: 24OCT2025 : 04:04) Source Data: a215up.adsl, a215up.adtteeff

Anhang 4-G2.7: Sicherheitsrelevante Endpunkte

Anhang 4-G2.7.1: Sicherheit: Gesamtraten

Table 14-6.11.1. Time to First Onset of Treatment-emergent Adverse Event (Safety Analysis Set)

	HC3 (N=52)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	50 (96.2)	54 (100.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			13.4444
p-value			0.0005
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			13.8323
p-value			0.0002

Page 1 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event/censor date, divided by 30.5.

^e The 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 HC3.

Program:

/userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

as

Output: t14-06-011-001-ae-tte-ont-teae-saf.rtf (Date generated: 18MAY2025:23:56) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.1. Time to First Onset of Treatment-emergent Adverse Event (Safety Analysis Set)

	HC3 (N=52)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.13	0.03	
95% CI (median)	(0.07, 0.16)	(NE, NE)	
Q1, Q3	0.07, 0.23	0.03, 0.07	
Min, Max	0.0, 0.5	0.0, 1.6	
Unstratified hazard ratio ^e (95% CI)			2.15 (1.44, 3.20)
p-value			0.0002
Stratified hazard ratio ^{c,e} (95% CI)			2.19 (1.45, 3.31)
p-value			0.0002

Page 2 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event/censor date, divided by 30.5.

^e The 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 HC3.

Program:

/userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-001-ae-tte-ont-teae-saf.rtf (Date generated: 18MAY2025:23:56) Source data: a215up.adsl, adam.adtteae

**Table 14-6.11.2. Time to First Onset of Serious Treatment-emergent Adverse Events
(Safety Analysis Set)**

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	24 (46.2)	15 (27.8)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-6.177
p-value			0.0438
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-6.585
p-value			0.0288

Page 1 of 2

N = Number of subjects in the 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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-002-sae-tte-ont-teae-saf.rtf (Date generated: 05AUG2025:04:00) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.2. Time to First Onset of Serious Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(0.56, NE)	(NE, NE)	
Q1, Q3	0.38, NE	1.84, NE	
Min, Max	0.1, 1.2	0.1, 1.9	
Unstratified hazard ratio ^e			0.52
(95% CI)			(0.27, 1.00)
p-value			0.0495
Stratified hazard ratio ^{c, e}			0.50
(95% CI)			(0.26, 0.96)
p-value			0.0366

Page 2 of 2

N = Number of subjects in the 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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-002-sae-tte-ont-teae-saf.rtf (Date generated: 05AUG2025:04:00) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.3. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	43 (82.7)	33 (61.1)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-14.960
p-value			0.0002
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-14.276
p-value			0.0003

Page 1 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-003-ae-tte-ont-teae-grade3-saf.rtf (Date generated: 05AUG2025:04:00) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.3. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.26	1.70	
95% CI (median)	(0.20, 0.33)	(1.31, 1.90)	
Q1, Q3	0.13, 0.44	0.46, NE	
Min, Max	0.0, 0.5	0.0, 1.9	
Unstratified hazard ratio ^e			0.41
(95% CI)			(0.25, 0.66)
p-value			0.0002
Stratified hazard ratio ^{c, e}			0.41
(95% CI)			(0.25, 0.67)
p-value			0.0003

Page 2 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-003-ae-tte-ont-teae-grade3-saf.rtf (Date generated: 05AUG2025:04:00) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.4. Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.981
p-value			0.1632
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.947
p-value			0.1674

Page 1 of 2

N = Number of subjects in the analysis set. n = Number 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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-004-ae-tte-ont-teae-trtdisc-saf.rtf (Date generated: 05AUG2025:04:00) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.4. Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
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 2

N = Number of subjects in the analysis set. n = Number 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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-saf.sas

Output: t14-06-011-004-ae-tte-ont-teae-trtdisc-saf.rtf (Date generated: 05AUG2025:04:00) Source data: a215up.adsl, adam.adtteae

**Table 14-6.15.1. Time to First Onset of Treatment-emergent Adverse Events
Excluding Disease Progression
(Safety Analysis Set)**

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	50 (96.2)	54 (100.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			13.444
p-value			0.0005
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			13.832
p-value			0.0002

Page 1 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-edp-saf.sas

Output: t14-06-015-001-ae-tte-ont-teae-edp-saf.rtf (Date generated: 25AUG2025:23:26) Source data: a215up.adsl, adam.adtteae

Table 14-6.15.1. Time to First Onset of Treatment-emergent Adverse Events Excluding Disease Progression (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.13	0.03	
95% CI (median)	(0.07, 0.16)	(NE, NE)	
Q1, Q3	0.07, 0.23	0.03, 0.07	
Min, Max	0.0, 0.5	0.0, 1.6	
Unstratified hazard ratio ^e			2.15
(95% CI)			(1.44, 3.20)
p-value			0.0002
Stratified hazard ratio ^{c, e}			2.19
(95% CI)			(1.45, 3.31)
p-value			0.0002

Page 2 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-edp-saf.sas

Output: t14-06-015-001-ae-tte-ont-teae-edp-saf.rtf (Date generated: 25AUG2025:23:26) Source data: a215up.adsl, adam.adtteae

Table 14-6.15.2. Time to First Onset of Serious Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	23 (44.2)	15 (27.8)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-5.558
p-value			0.0661
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-5.942
p-value			0.0458

Page 1 of 2

N = Number of subjects in the 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 excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-edp-saf.sas

Output: t14-06-015-002-sae-tte-ont-teae-edp-saf.rtf (Date generated: 25AUG2025:23:26) Source data: a215up.adsl, adam.adtteae

Table 14-6.15.2. Time to First Onset of Serious Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(0.56, NE)	(NE, NE)	
Q1, Q3	0.38, NE	1.84, NE	
Min, Max	0.1, 1.2	0.1, 1.9	
Unstratified hazard ratio ^e			0.55
(95% CI)			(0.29, 1.06)
p-value			0.0728
Stratified hazard ratio ^{c, e}			0.52
(95% CI)			(0.27, 1.02)
p-value			0.0559

Page 2 of 2

N = Number of subjects in the 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 excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-edp-saf.sas

Output: t14-06-015-002-sae-tte-ont-teae-edp-saf.rtf (Date generated: 25AUG2025:23:26) Source data: a215up.adsl, adam.adtteae

Table 14-6.15.3. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	43 (82.7)	33 (61.1)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-14.960
p-value			0.0002
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-14.276
p-value			0.0003

Page 1 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of grade 3 or above treatment emergent adverse event excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-edp-saf.sas

Output: t14-06-015-003-ae-tte-ont-teae-grade3-edp-saf.rtf (Date generated: 25AUG2025:23:26)

Source data: a215up.adsl, adam.adtteae

Table 14-6.15.3. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.26	1.70	
95% CI (median)	(0.20, 0.33)	(1.31, 1.90)	
Q1, Q3	0.13, 0.44	0.46, NE	
Min, Max	0.0, 0.5	0.0, 1.9	
Unstratified hazard ratio ^e			0.41
(95% CI)			(0.25, 0.66)
p-value			0.0002
Stratified hazard ratio ^{c, e}			0.41
(95% CI)			(0.25, 0.67)
p-value			0.0003

Page 2 of 2

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of grade 3 or above treatment emergent adverse event excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-edp-saf.sas

Output: t14-06-015-003-ae-tte-ont-teae-grade3-edp-saf.rtf (Date generated: 25AUG2025:23:26)

Source data: a215up.adsl, adam.adtteae

Table 14-6.15.4. Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.981
p-value			0.1632
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.947
p-value			0.1674

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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 leading to discontinuation of study treatment excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-trtdisc-edp-saf.sas

Output: t14-06-015-004-ae-tte-ont-teae-trtdisc-edp-saf.rtf (Date generated: 04DEC2025:22:51)

Source data: a215up.adsl, adam.adtteae

Table 14-6.15.4. Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c, e} (95% CI)			NE (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 leading to discontinuation of study treatment excluding disease progression events.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

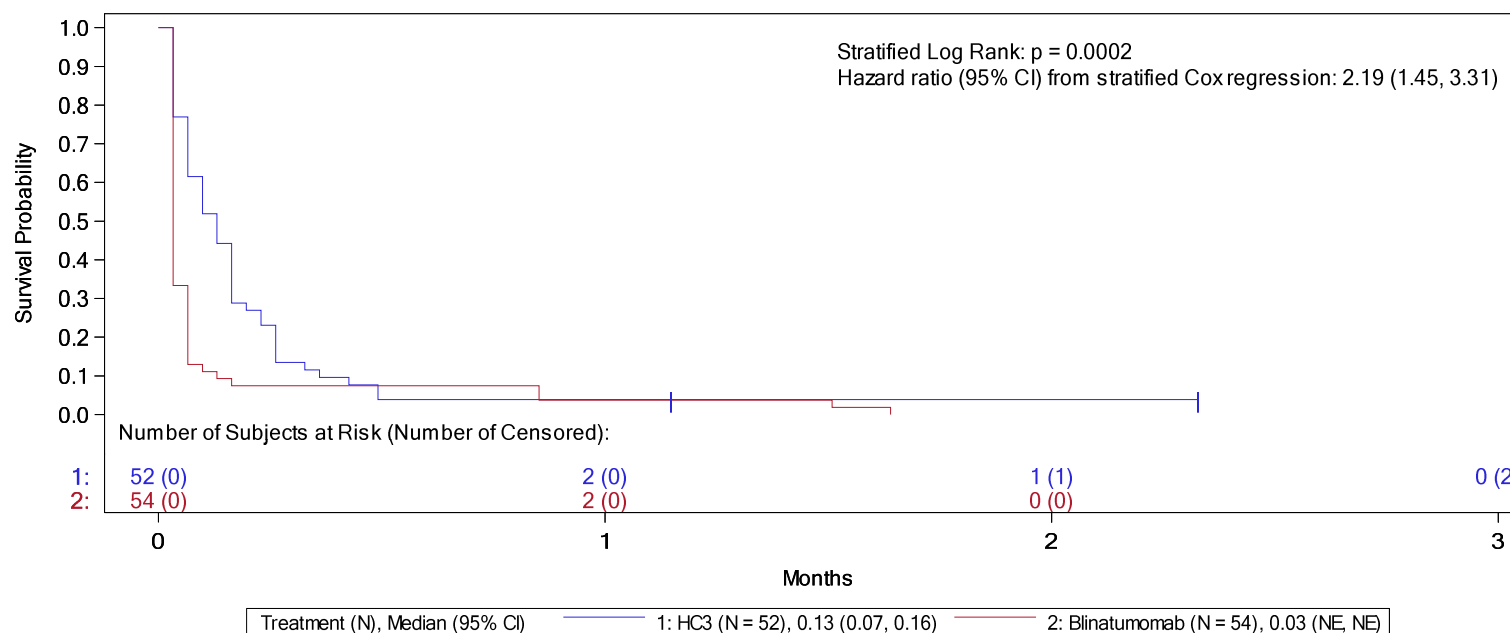
^e The hazard ratio estimates are obtained from the Cox Proportional Hazard model. A hazard ratio <1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-trtdisc-edp-saf.sas

Output: t14-06-015-004-ae-tte-ont-teae-trtdisc-edp-saf.rtf (Date generated: 04DEC2025:22:51)

Source data: a215up.adsl, adam.adtteae

Figure 14-6.11.6. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events (Safety Analysis Set)



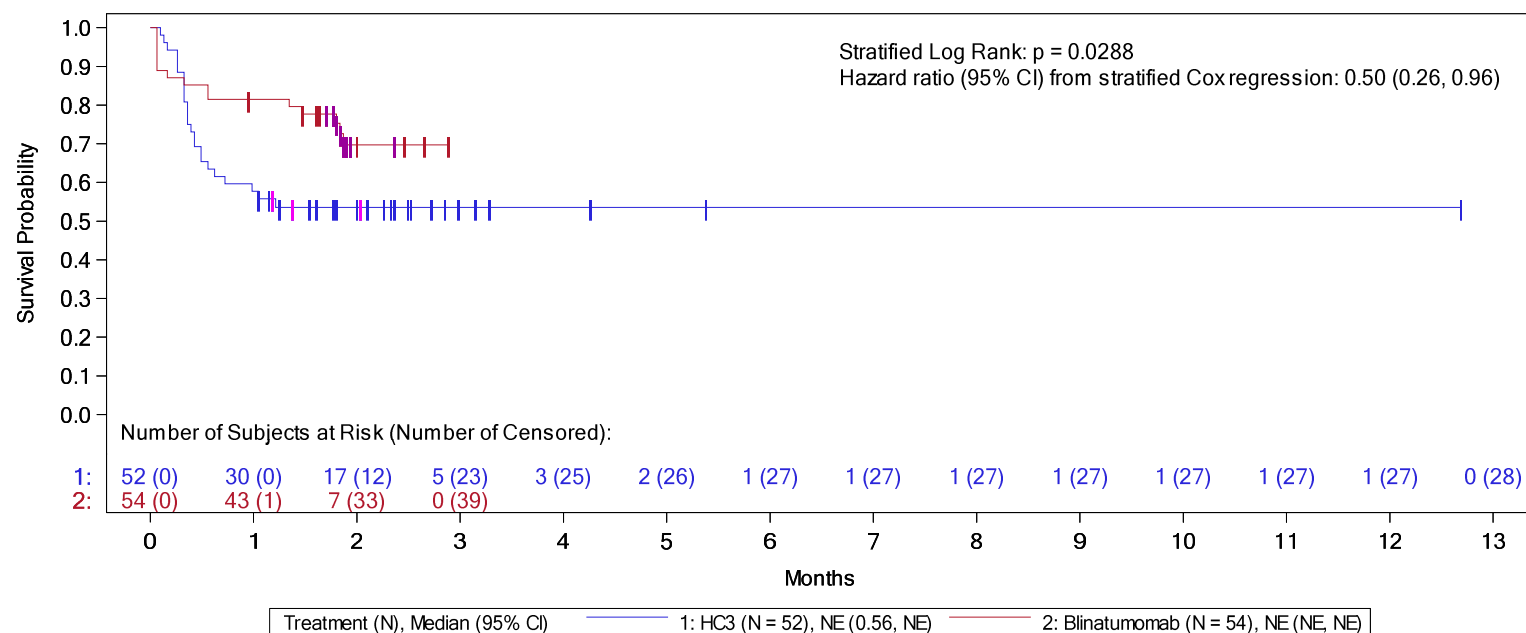
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-011-006-km-ae-ont-teae-saf.rtf (Date Generated: 23OCT2025 : 03:30) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.11.7. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

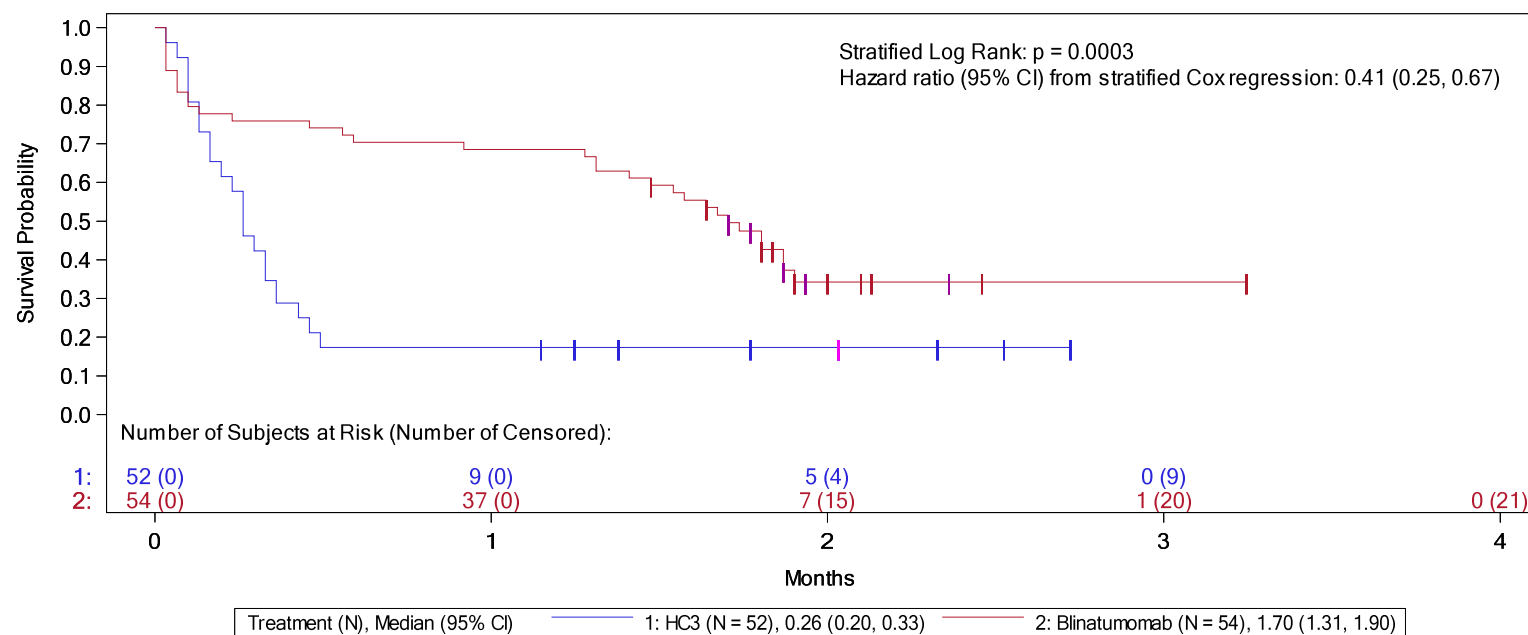
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-011-007-km-sae-ont-teae-saf.rtf (Date Generated:

23OCT2025 : 03:30) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.11.8. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events (Safety Analysis Set)



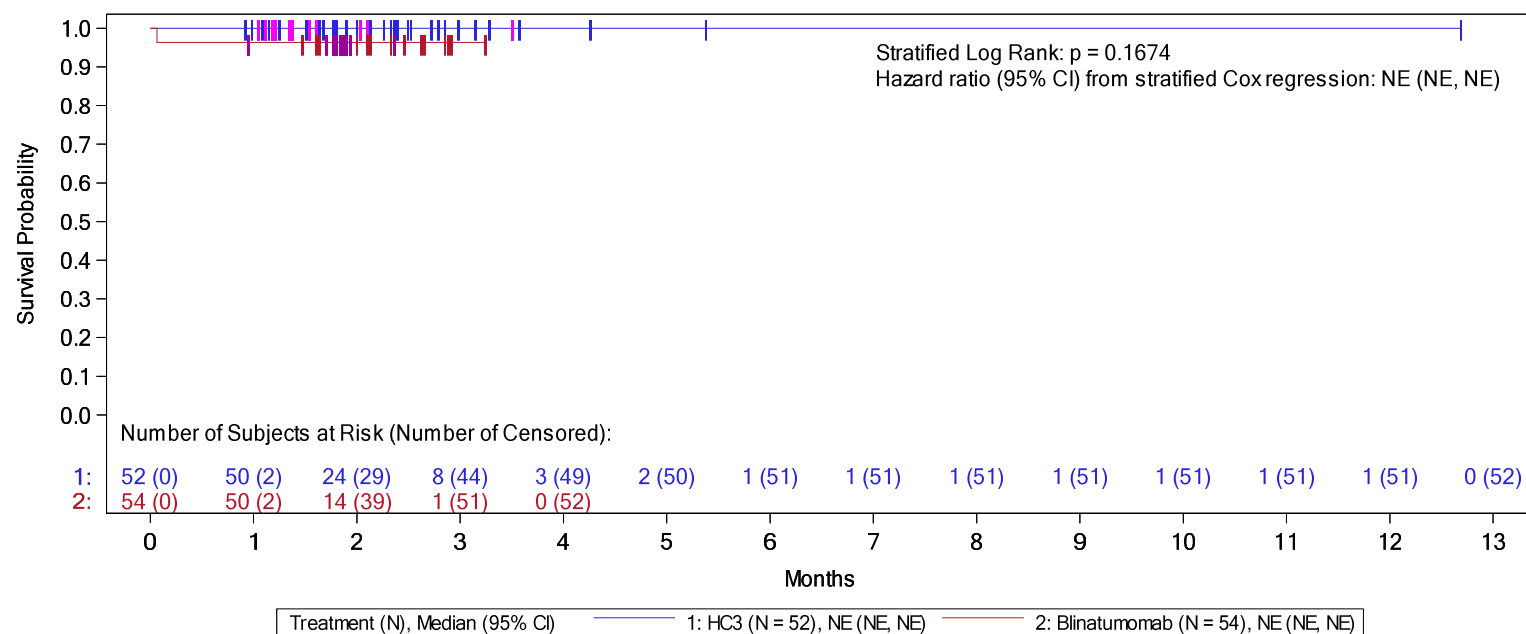
N = Number of subjects in the analysis set. CI = Confidence interval.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-011-008-km-ae-ont-teae-grade3-saf.rtf (Date Generated: 23OCT2025 : 03:30) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.11.9. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

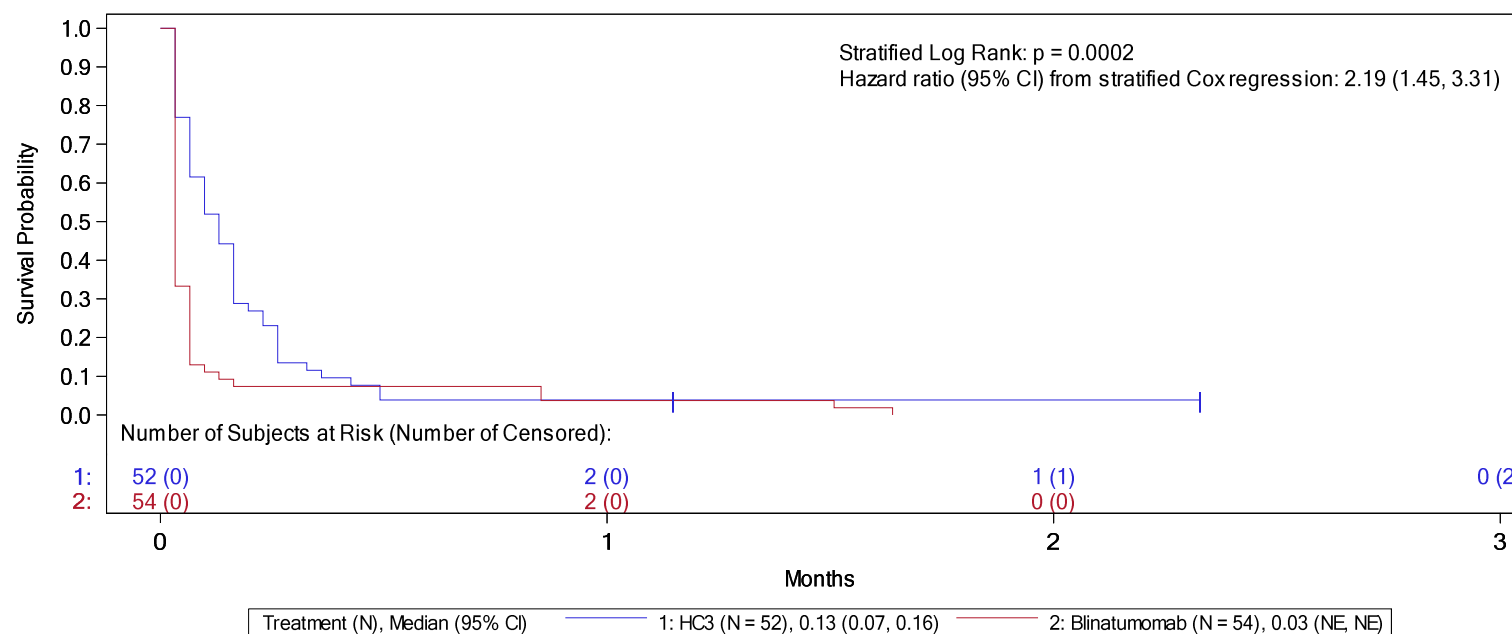
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-011-009-km-ae-ont-teae-trtdisc-saf.rtf (Date Generated:

23OCT2025 : 03:30) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.15.1. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

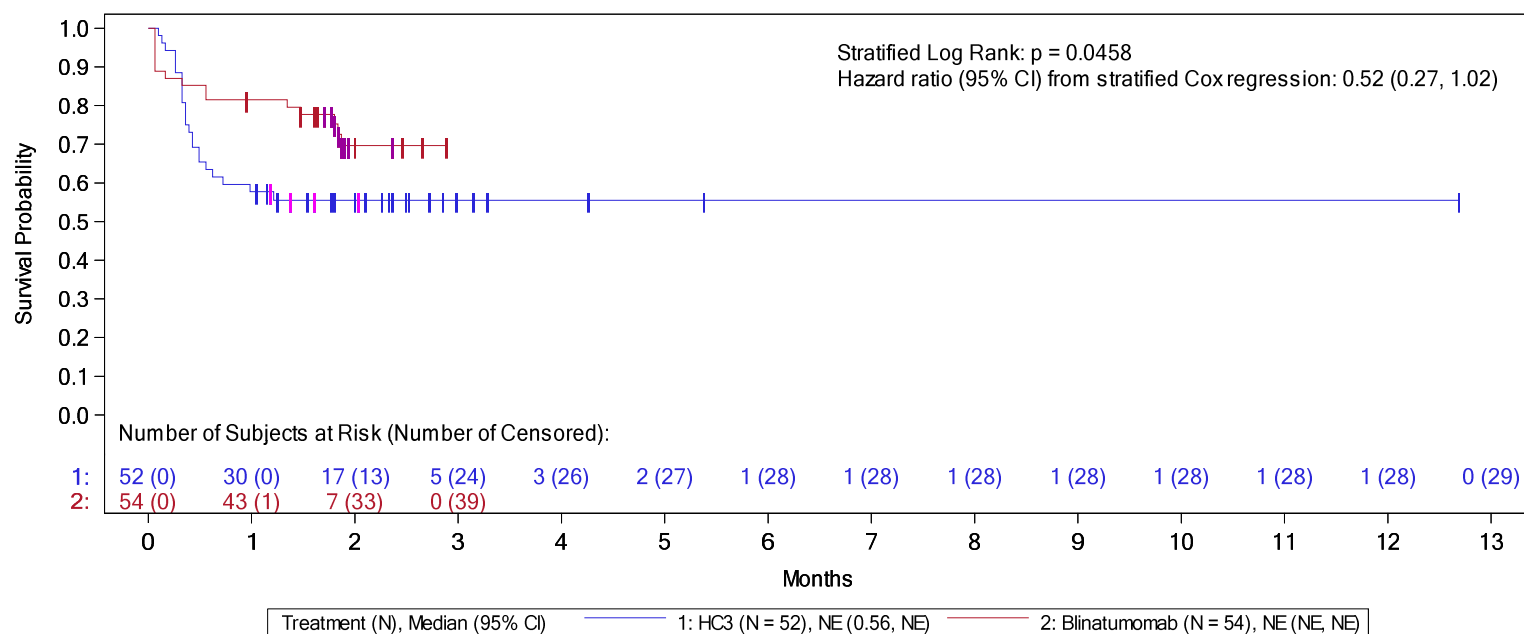


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-edp-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-015-001-km-ae-ont-teae-edp-saf.rtf (Date Generated: 23OCT2025 : 05:19) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.15.2. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

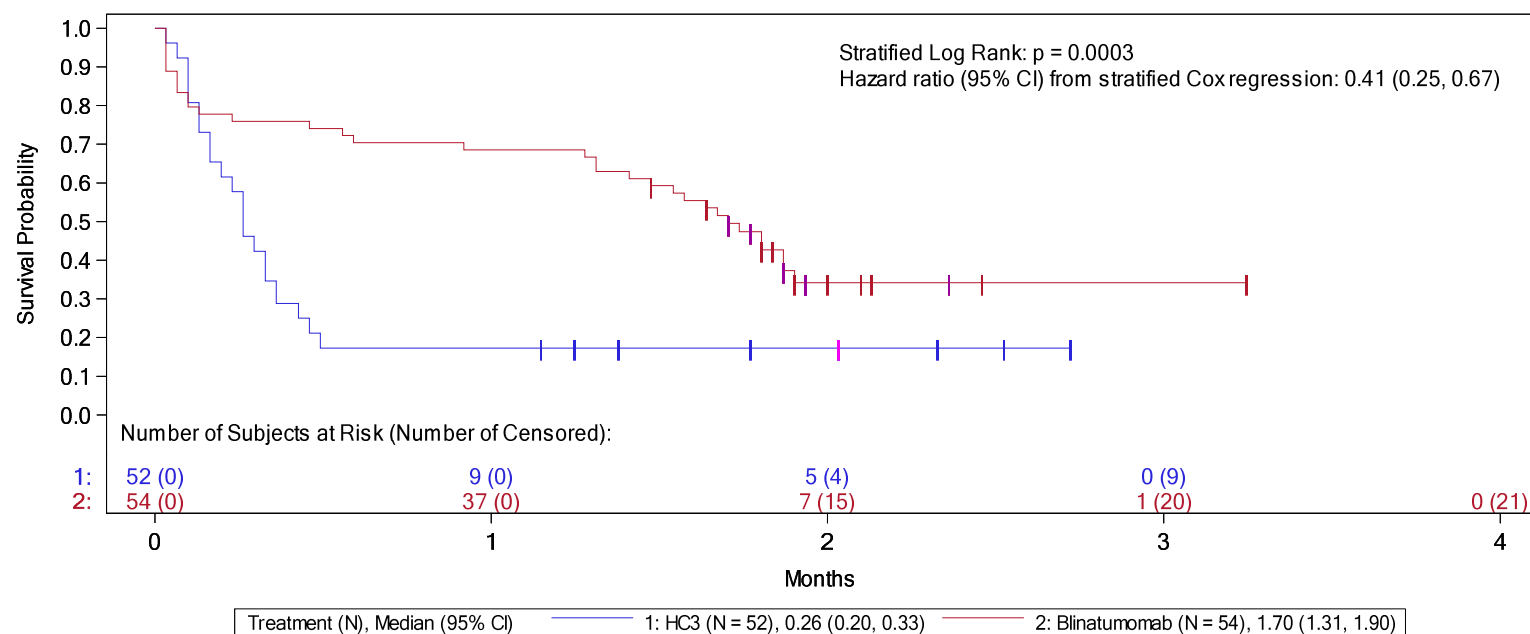


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-edp-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-015-002-km-sae-ont-teae-edp-saf.rtf (Date Generated: 23OCT2025 : 05:19) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.15.3. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

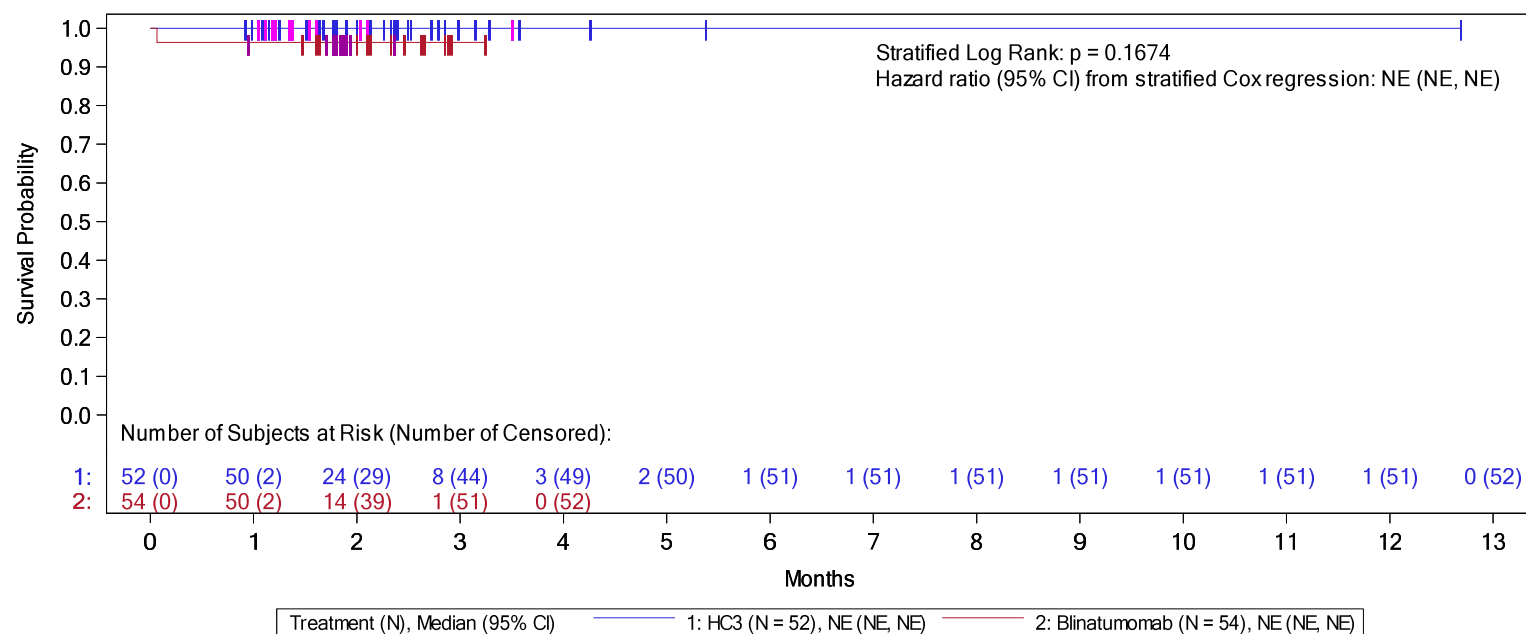


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-edp-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-015-003-km-ae-ont-teae-grade3-edp-saf.rtf (Date Generated: 23OCT2025 : 05:19) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.15.4. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment Excluding Disease Progression Events (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-teae-trtdisc-edp-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-015-004-km-ae-ont-teae-trtdisc-edp-saf.rtf (Date

Generated: 05DEC2025 : 03:14) Source Data: a215up.adsl, adam.adtteae

Anhang 4-G2.7.2: Sicherheit: UE von besonderem Interesse

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Capillary leak syndrome (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	0 (0.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-0.553
p-value			0.2658
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-0.500
p-value			0.3173

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.2, 1.2		
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Cytokine release syndrome (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	2 (3.7)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.491
p-value			0.5709
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.593
p-value			0.4918

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.0, 0.1	
Unstratified hazard ratio ^e (95% CI)			1.98 (0.18, 21.79)
p-value			0.5783
Stratified hazard ratio ^{c,e} (95% CI)			2.27 (0.21, 25.15)
p-value			0.5037

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Decreased immunoglobulins (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	9 (16.7)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			1.233
p-value			0.5223
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			1.078
p-value			0.5758

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.8	
Unstratified hazard ratio ^e			1.40
(95% CI)			(0.50, 3.95)
p-value			0.5193
Stratified hazard ratio ^{c,e}			1.34
(95% CI)			(0.48, 3.79)
p-value			0.5772

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Elevated liver enzymes (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	15 (28.8)	7 (13.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-4.905
p-value			0.0337
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-4.909
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 treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.64, NE	NE, NE	
Min, Max	0.0, 0.8	0.0, 1.9	
Unstratified hazard ratio ^e (95% CI)			0.39 (0.16, 0.97)
p-value			0.0418
Stratified hazard ratio ^{c,e} (95% CI)			0.39 (0.16, 0.96)
p-value			0.0398

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Embolic and thrombotic events (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	4 (7.4)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			1.996
p-value			0.0459
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			2.013
p-value			0.0437

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.9	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Infections			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	18 (34.6)	25 (46.3)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.920
p-value			0.7760
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-0.157
p-value			0.9608

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	1.90	
95% CI (median)	(NE, NE)	(1.70, NE)	
Q1, Q3	0.66, NE	1.41, NE	
Min, Max	0.0, 1.2	0.1, 1.9	
Unstratified hazard ratio ^e (95% CI)			1.09 (0.60, 2.01)
p-value			0.7728
Stratified hazard ratio ^{c,e} (95% CI)			0.99 (0.54, 1.82)
p-value			0.9659

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Infusion reaction with duration (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	2 (3.8)	26 (48.1)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			12.782
p-value			<0.0001
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			12.572
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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(0.07, NE)	
Q1, Q3	NE, NE	0.03, NE	
Min, Max	0.1, 0.1	0.0, 0.1	
Unstratified hazard ratio ^e			16.92
(95% CI)			(4.01, 71.40)
p-value			0.0001
Stratified hazard ratio ^{c,e}			16.38
(95% CI)			(3.88, 69.24)
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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Lymphopenia (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.491
p-value			0.3264
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.490
p-value			0.3272

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Medication errors (Broad)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.491
p-value			0.3264
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.490
p-value			0.3272

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	15 (28.8)	26 (48.1)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			6.512
p-value			0.0379
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			6.570
p-value			0.0331

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(0.20, NE)	
Q1, Q3	0.93, NE	0.10, NE	
Min, Max	0.0, 1.5	0.0, 1.7	
Unstratified hazard ratio ^e			1.96
(95% CI)			(1.03, 3.70)
p-value			0.0390
Stratified hazard ratio ^{c,e}			2.01
(95% CI)			(1.05, 3.83)
p-value			0.0340

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Neutropenia (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	28 (53.8)	12 (22.2)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-9.732
p-value			0.0016
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-9.268
p-value			0.0027

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.51	NE	
95% CI (median)	(0.36, NE)	(NE, NE)	
Q1, Q3	0.33, NE	NE, NE	
Min, Max	0.1, 1.4	0.0, 1.6	
Unstratified hazard ratio ^e (95% CI)			0.35 (0.17, 0.69)
p-value			0.0024
Stratified hazard ratio ^{c,e} (95% CI)			0.37 (0.18, 0.72)
p-value			0.0038

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

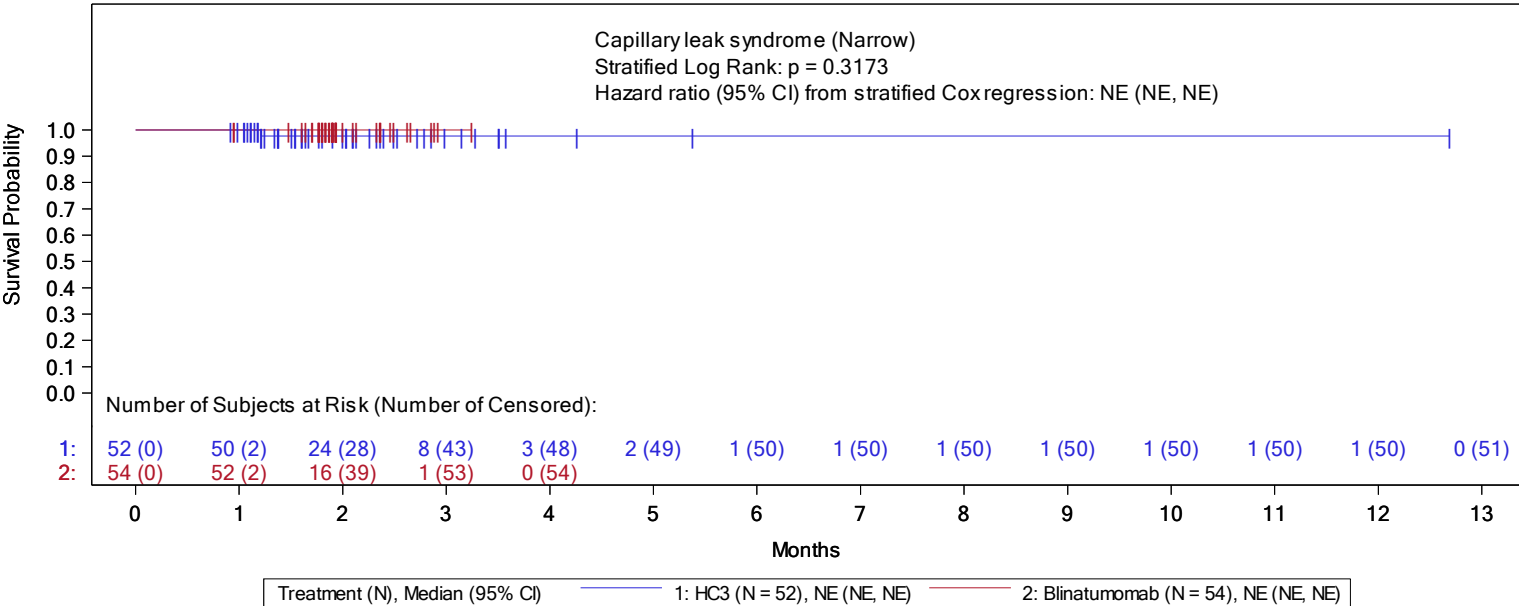
^e The hazard ratio estimates are obtained from the Cox Proportional Hazard model. A hazard ratio <1.0 indicates a lower average event rate and a longer survival for Blinatumomab relative to HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-005-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



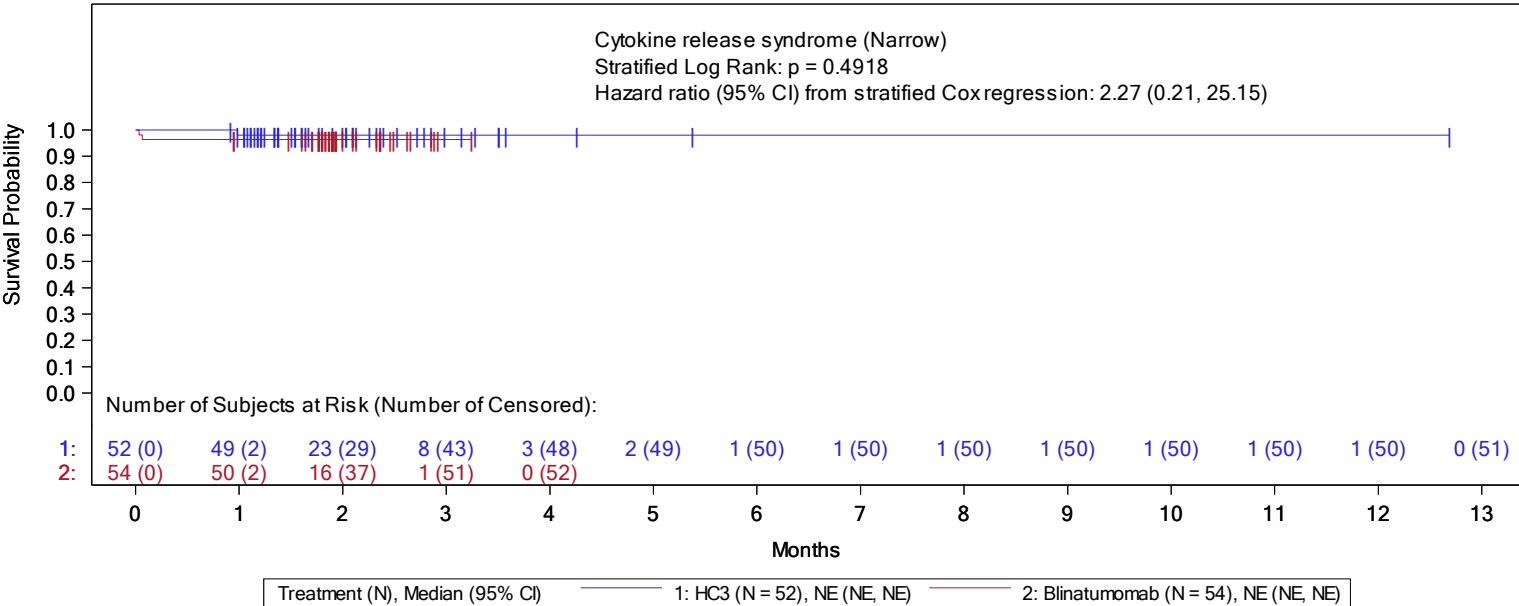
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



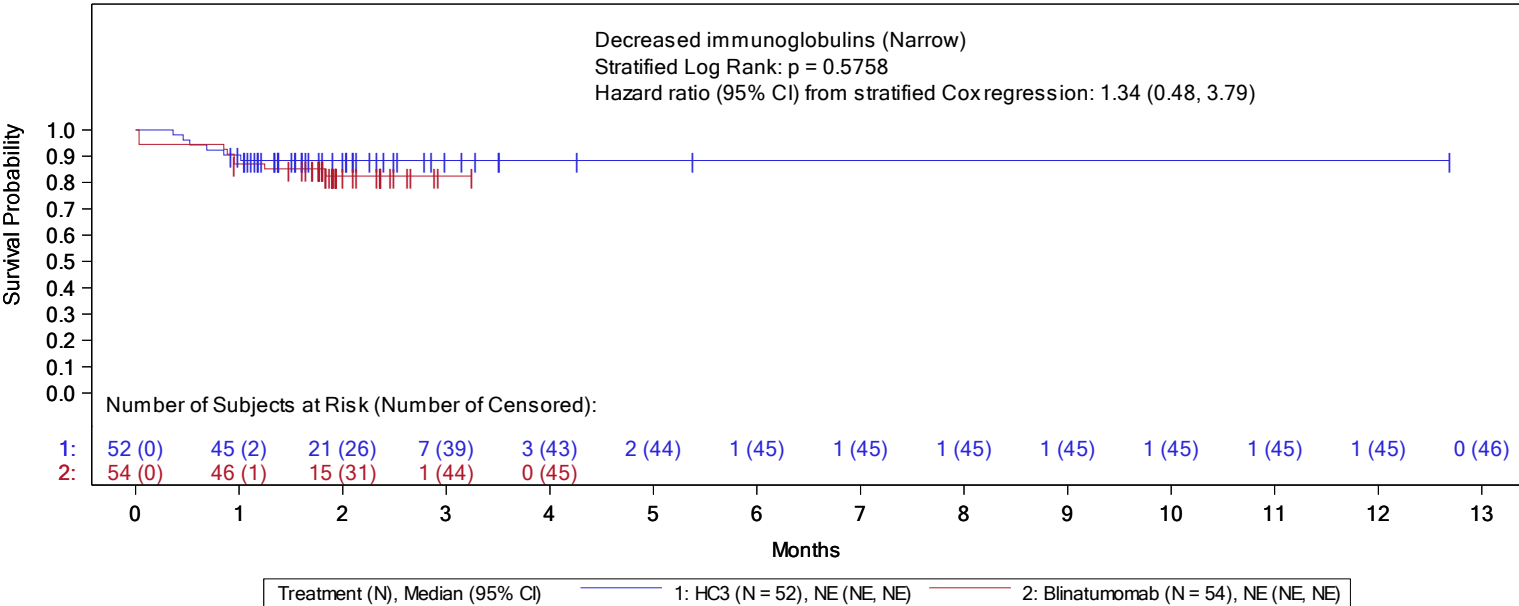
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



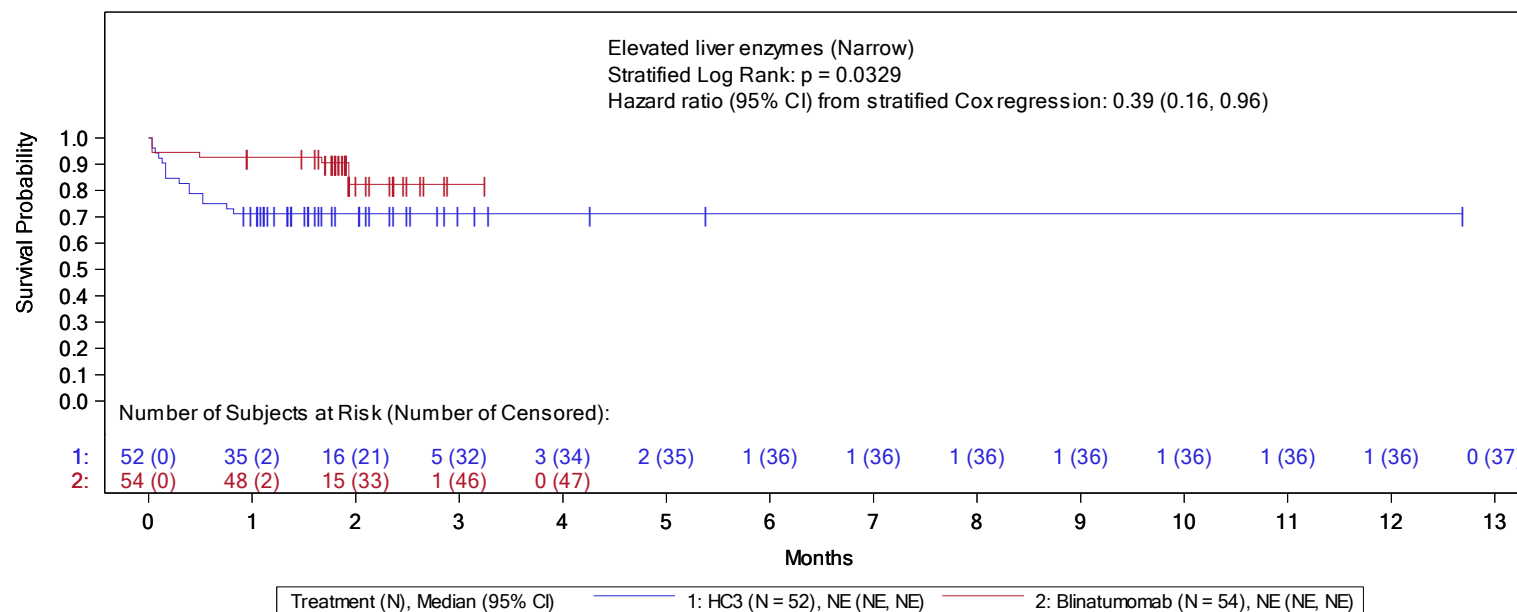
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



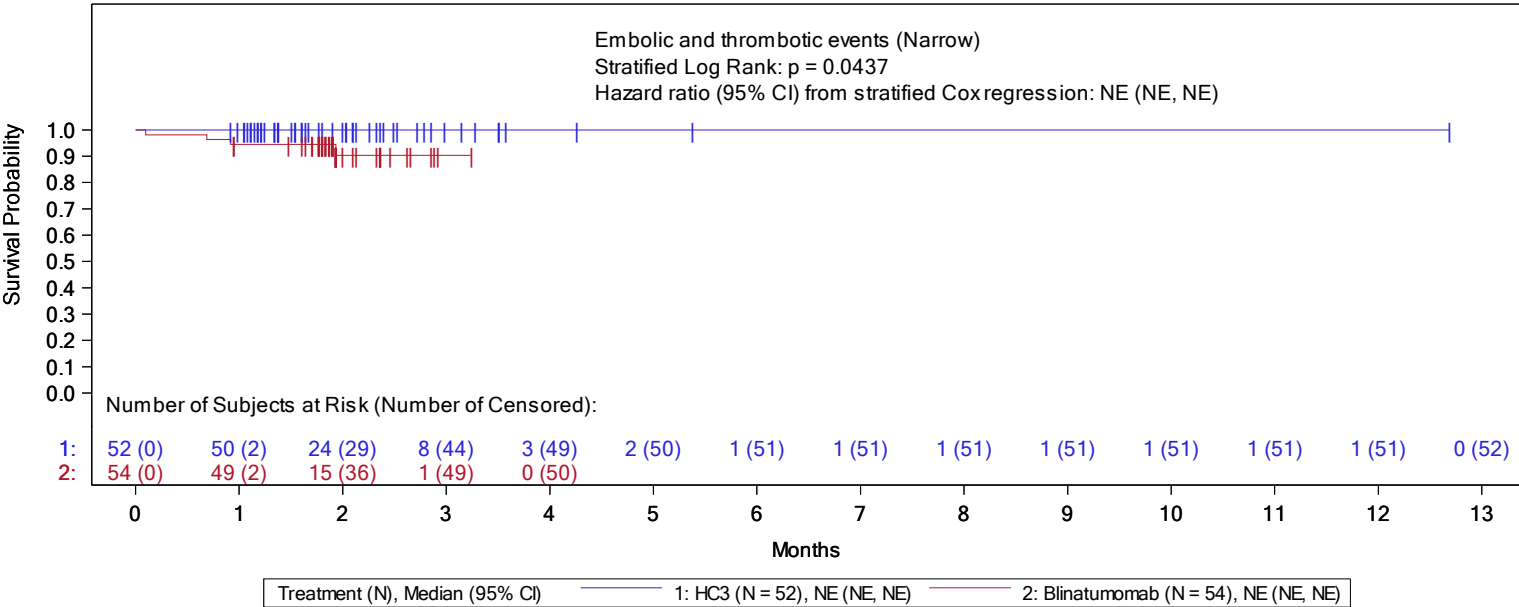
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

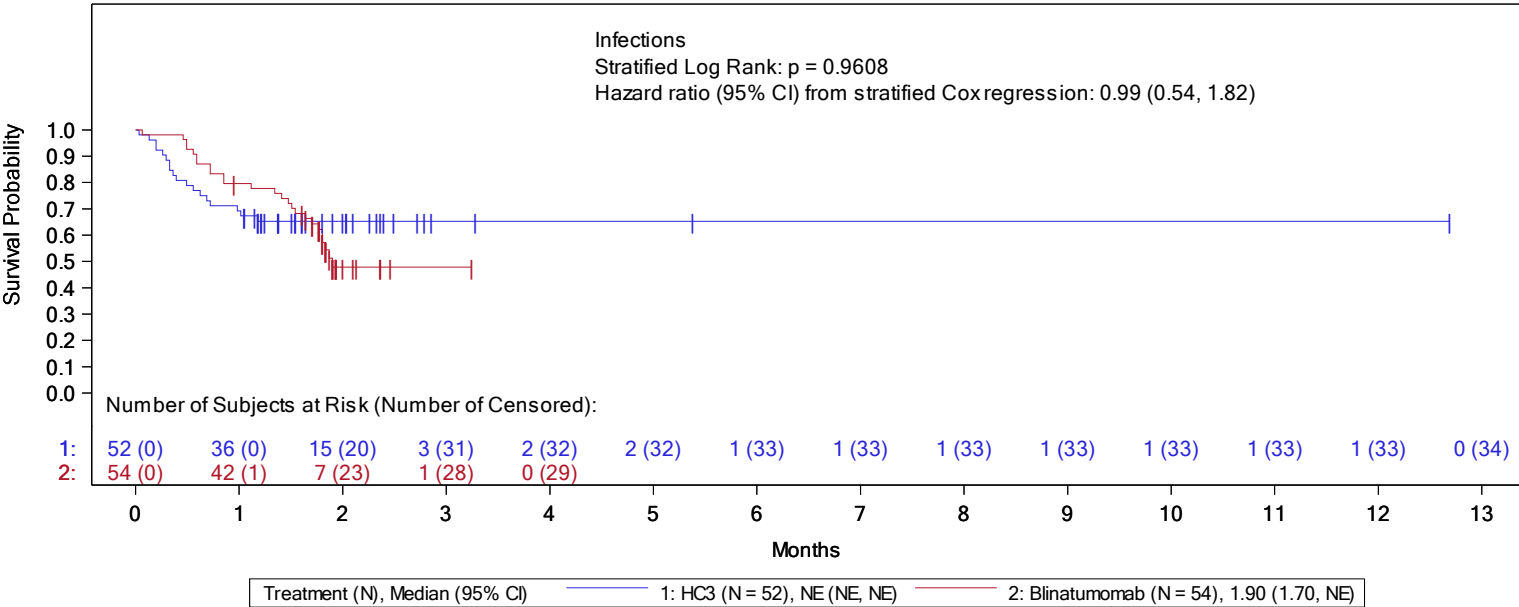
Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



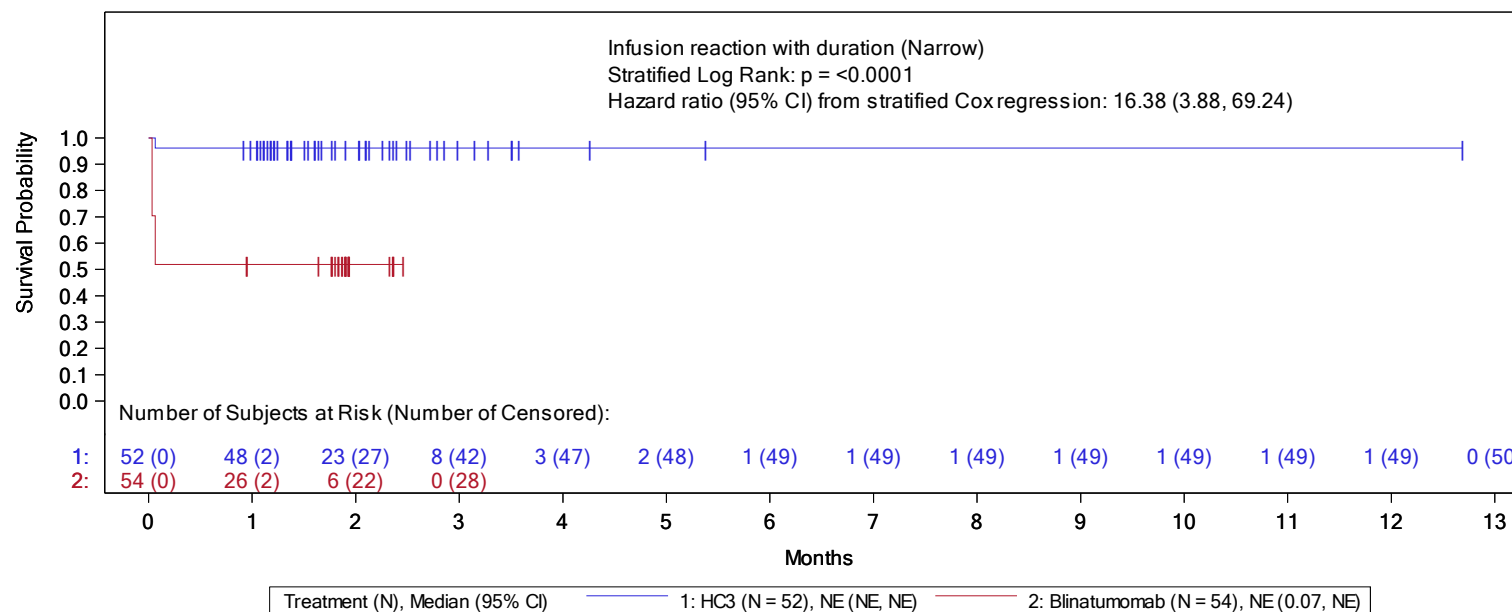
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



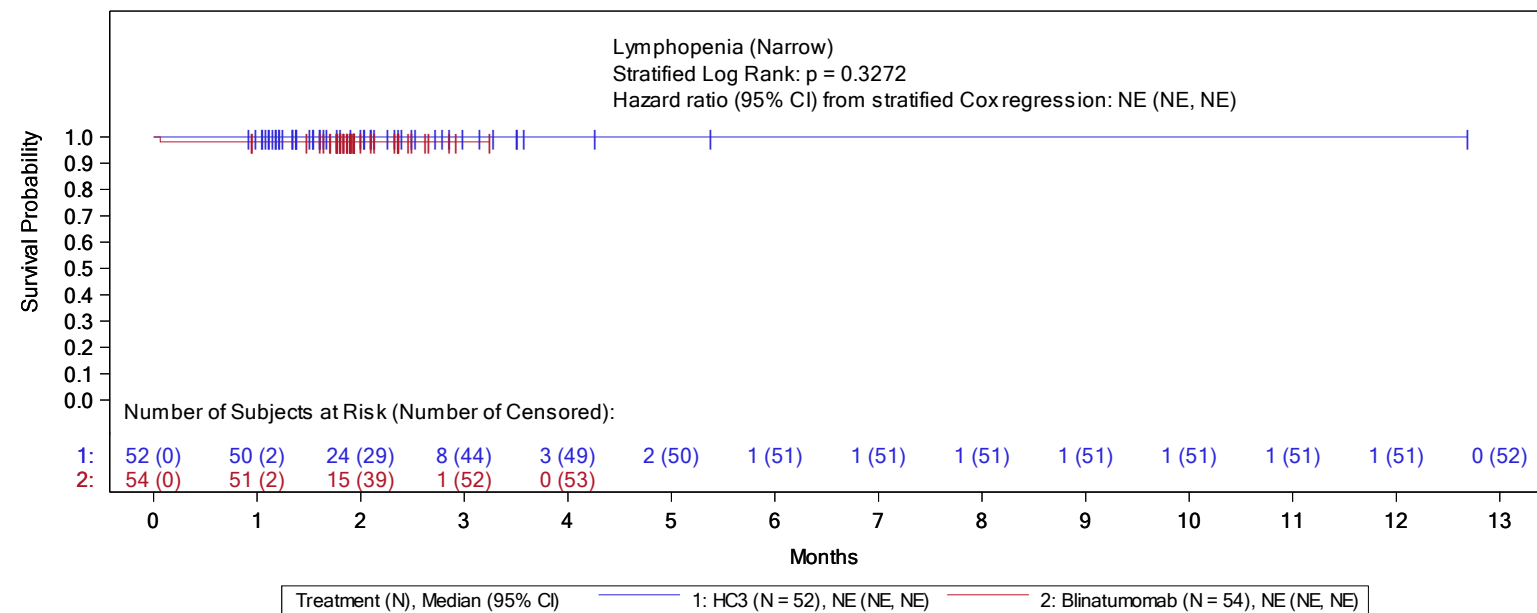
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

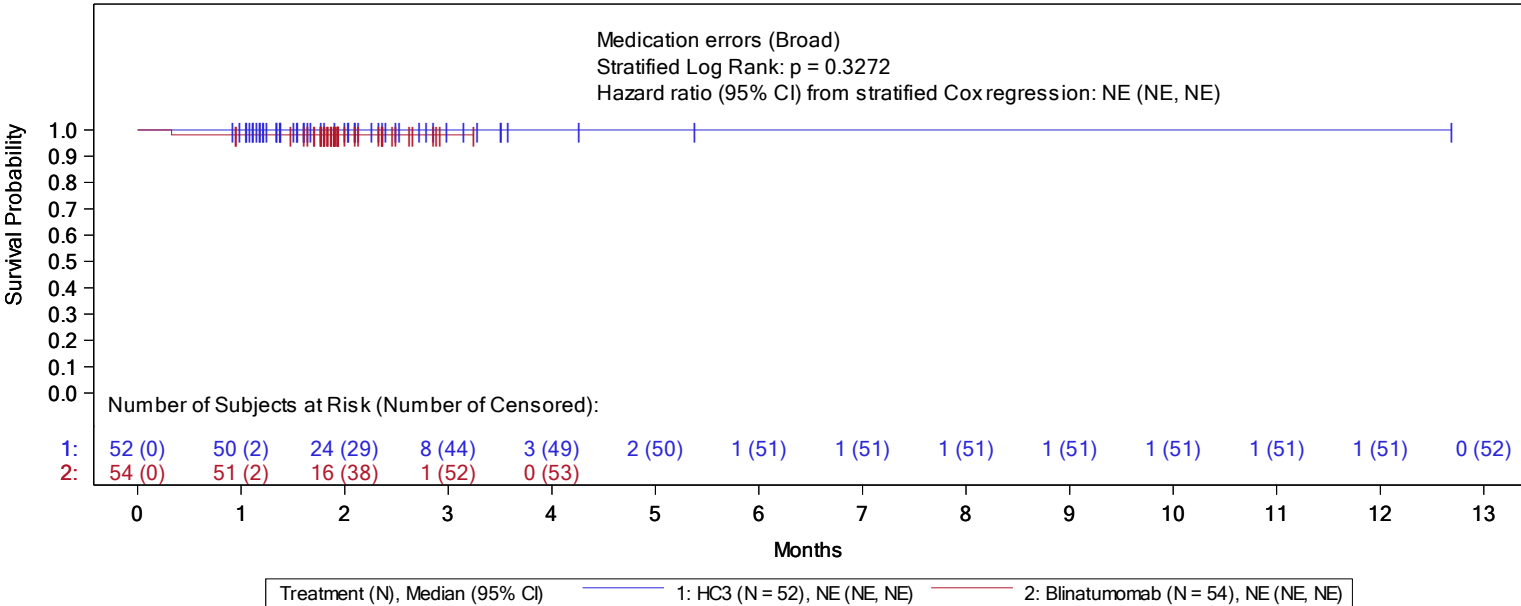
Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



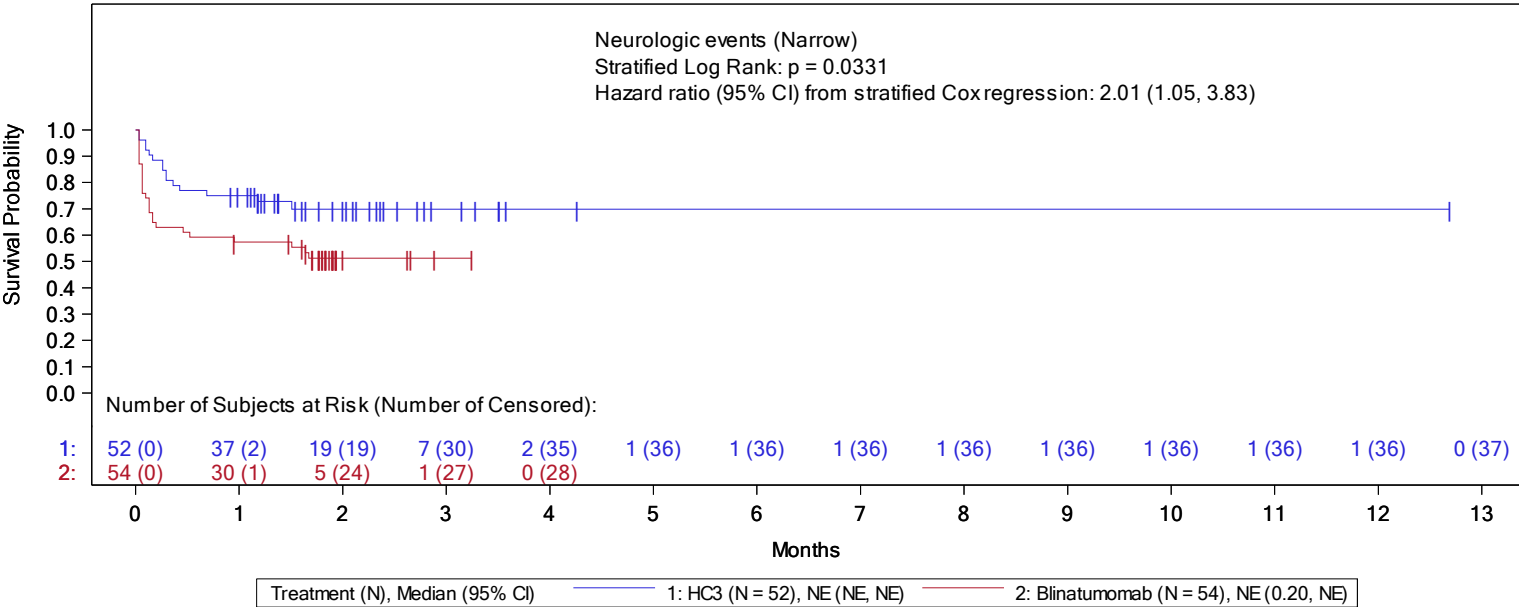
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



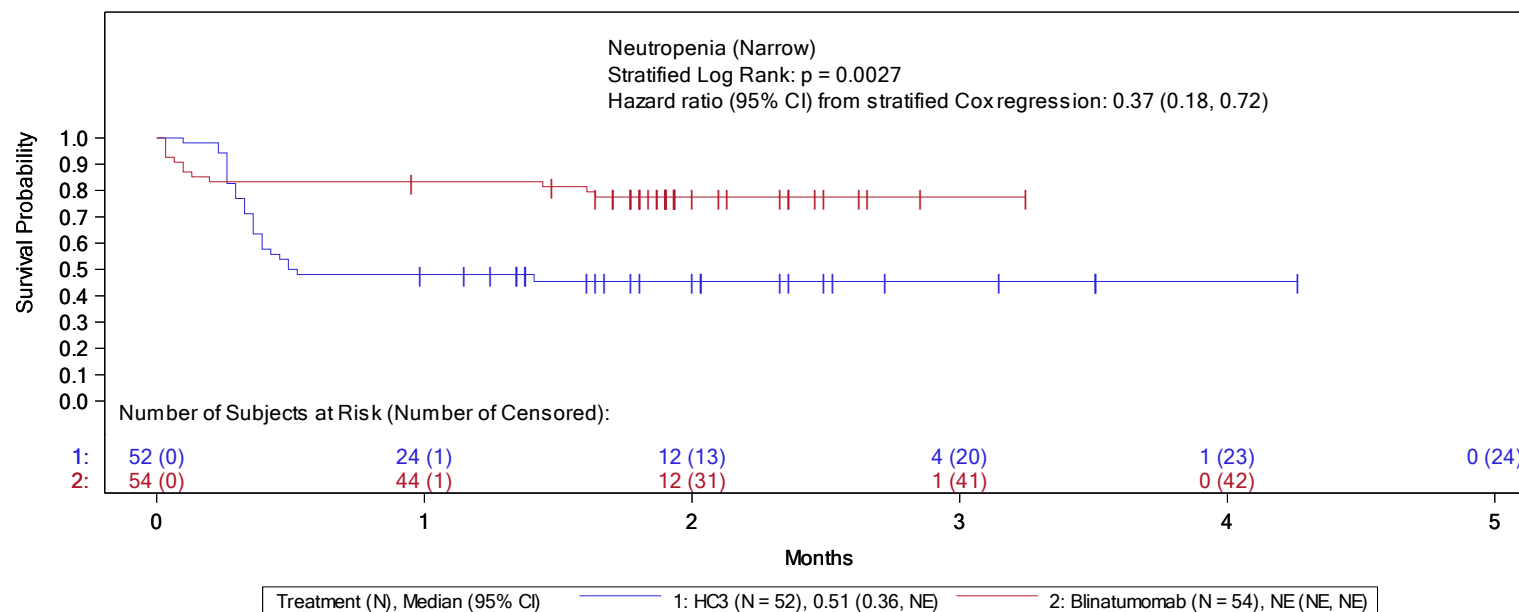
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier plot for Time to First Onset of Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Anhang 4-G2.7.3: Sicherheit: SUE von besonderem Interesse

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Capillary leak syndrome (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	0 (0.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-0.553
p-value			0.2658
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-0.500
p-value			0.3173

Page 1 of 16

N = Number of subjects in the 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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.2, 1.2		
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 serious treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Decreased immunoglobulins (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.397
p-value			0.4173
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.414
p-value			0.4008

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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		1.8, 1.8	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 serious treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Elevated liver enzymes (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	0 (0.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-0.509
p-value			0.3082
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-0.510
p-value			0.3074

Page 5 of 16

N = Number of subjects in the 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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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		
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 serious treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Infections			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	4 (7.4)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-1.502
p-value			0.3376
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-1.514
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 serious treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.6, 1.8	
Unstratified hazard ratio ^e (95% CI)			0.54 (0.15, 1.93)
p-value			0.3450
Stratified hazard ratio ^{c,e} (95% CI)			0.54 (0.15, 1.92)
p-value			0.3400

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Infusion reaction with duration (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.491
p-value			0.3264
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.500
p-value			0.3173

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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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 serious treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Medication errors (Broad)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.491
p-value			0.3264
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.490
p-value			0.3272

Page 11 of 16

N = Number of subjects in the 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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 serious treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	5 (9.3)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			1.987
p-value			0.1013
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			1.826
p-value			0.1204

Page 13 of 16

N = Number of subjects in the 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 HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.7	0.1, 0.2	
Unstratified hazard ratio ^e (95% CI)			5.05 (0.59, 43.25)
p-value			0.1392
Stratified hazard ratio ^{c,e} (95% CI)			4.82 (0.56, 41.74)
p-value			0.1529

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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 HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Neutropenia (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	12 (23.1)	0 (0.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-6.413
p-value			0.0002
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-6.296
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 serious treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

Table 14-6.11.6. Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.5		
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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.

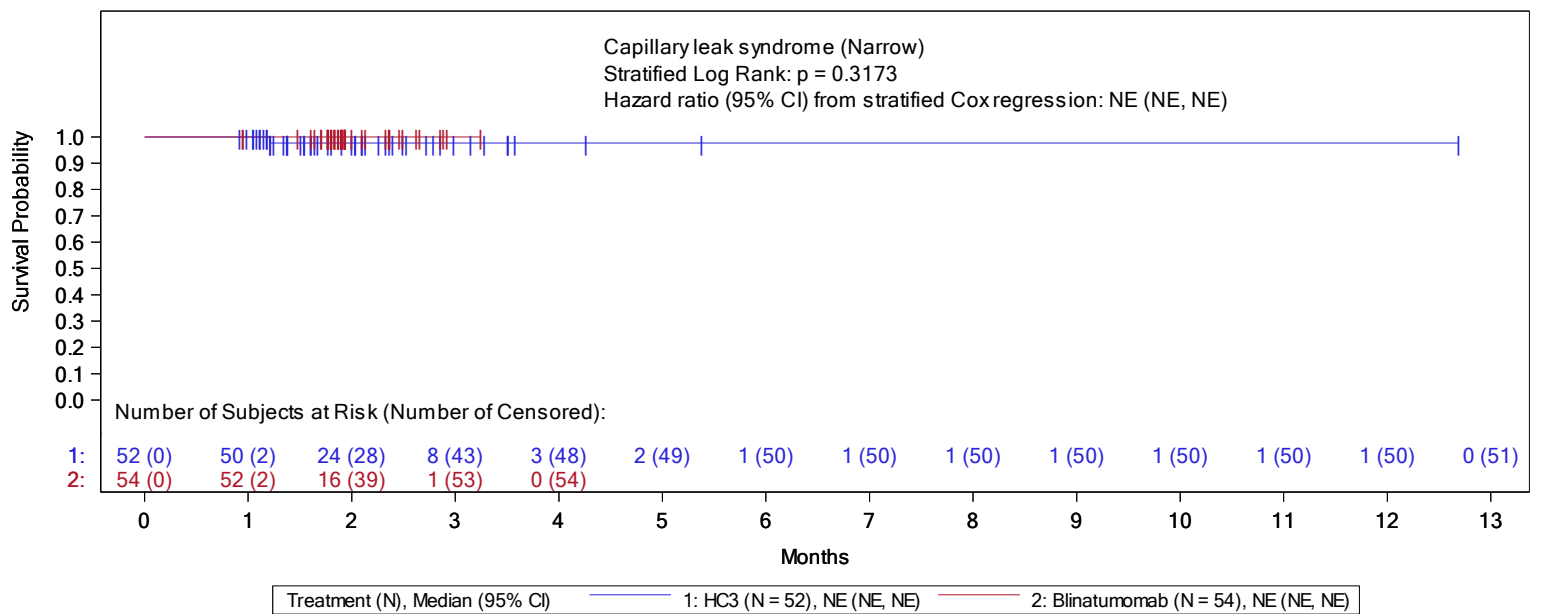
^a Events are first onset of serious treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-006-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 11AUG2025:04:54)

Source data: a215up.adsl, adam.adtteae

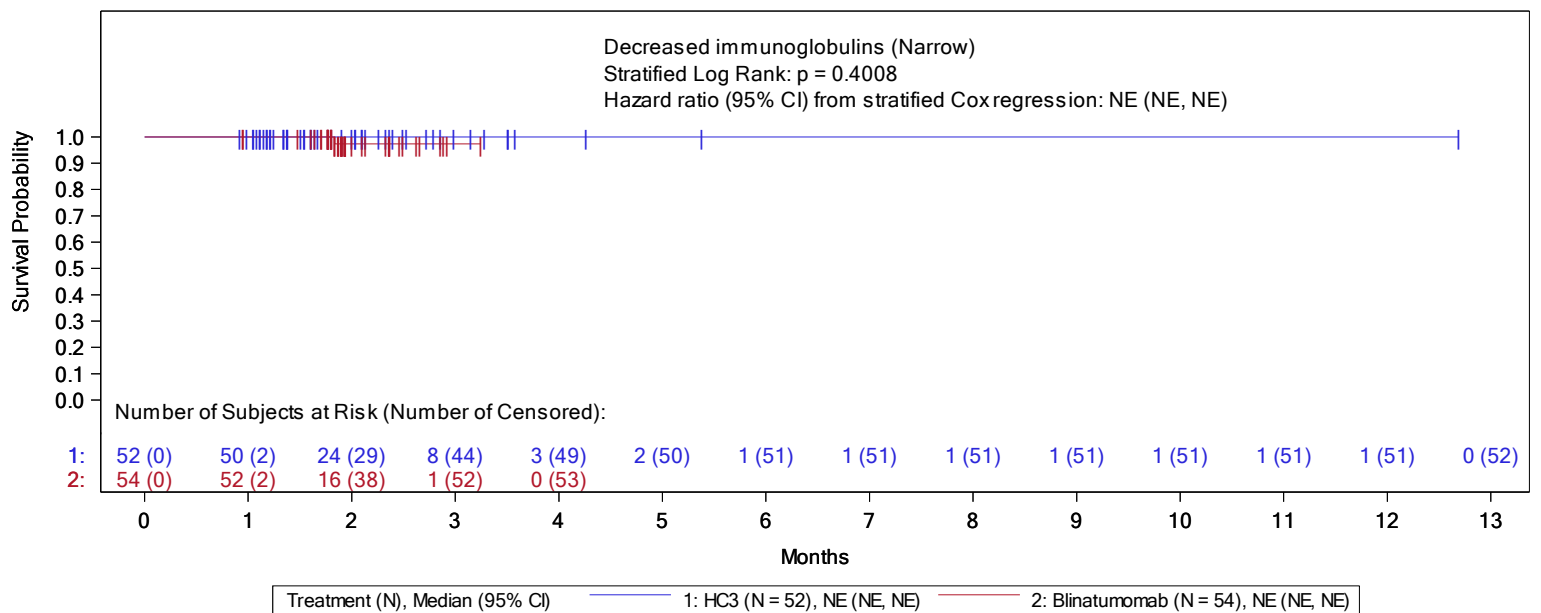
Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

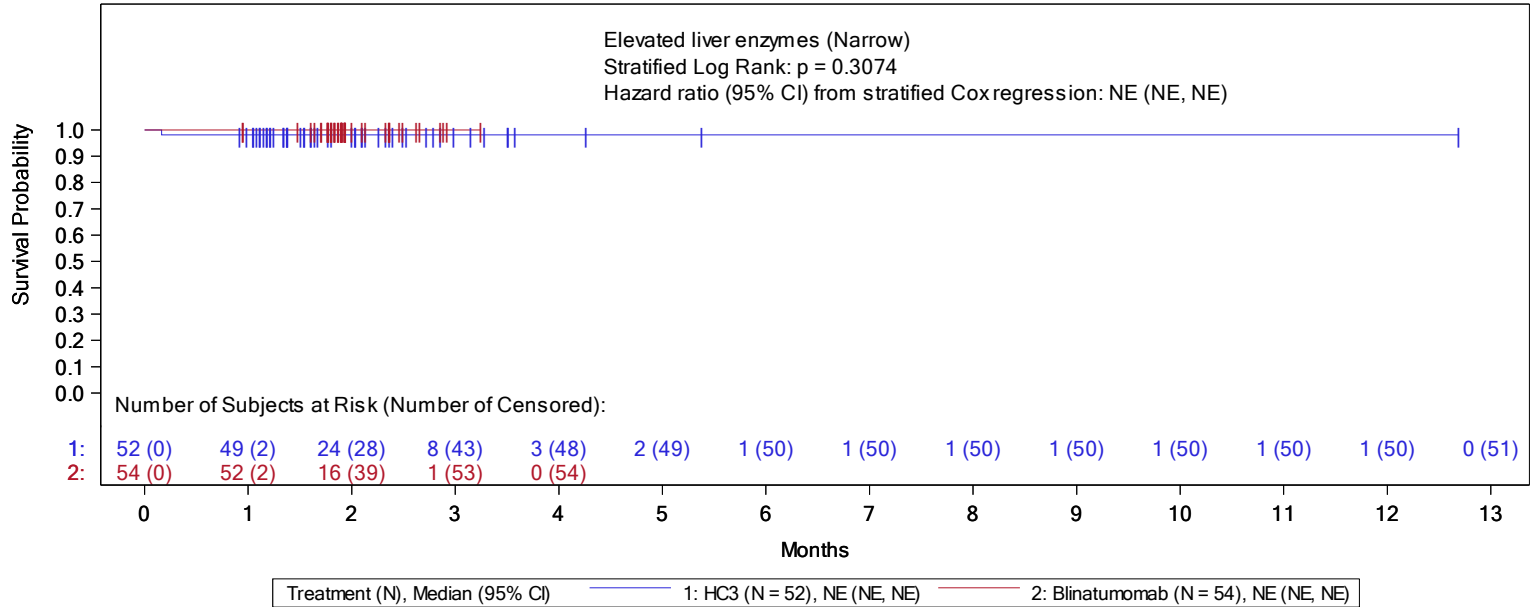
Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



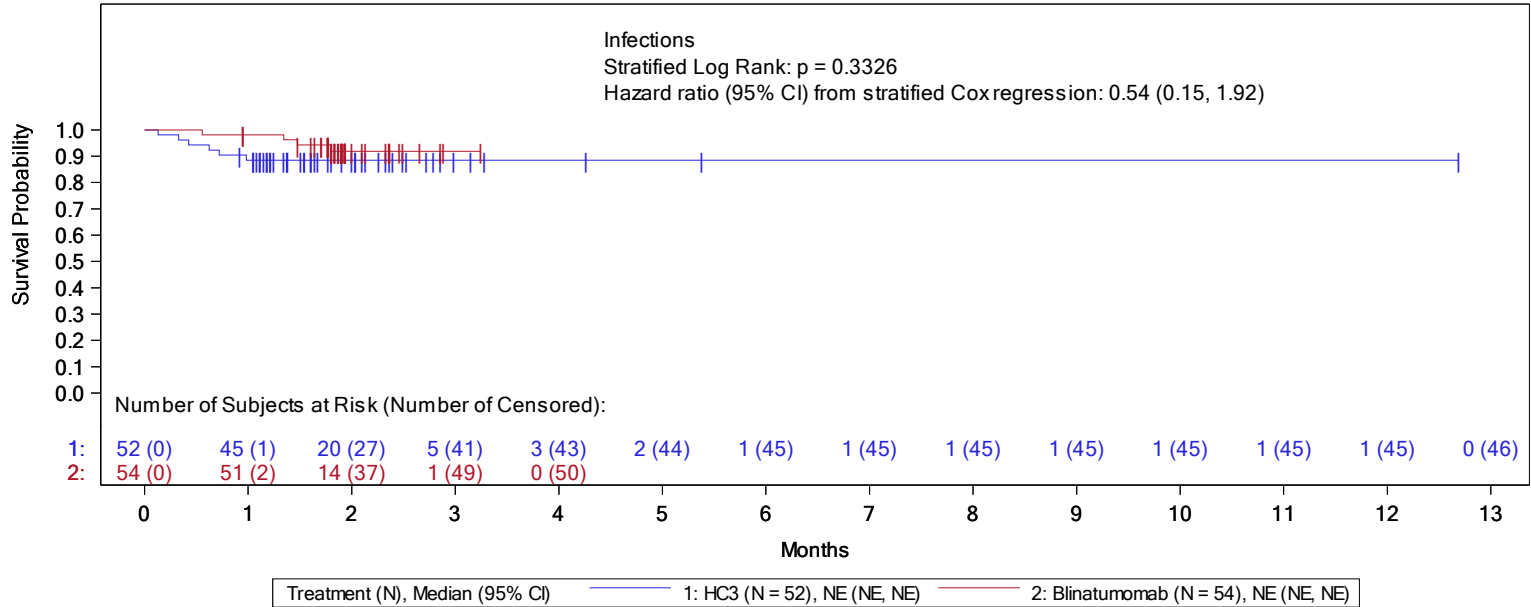
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

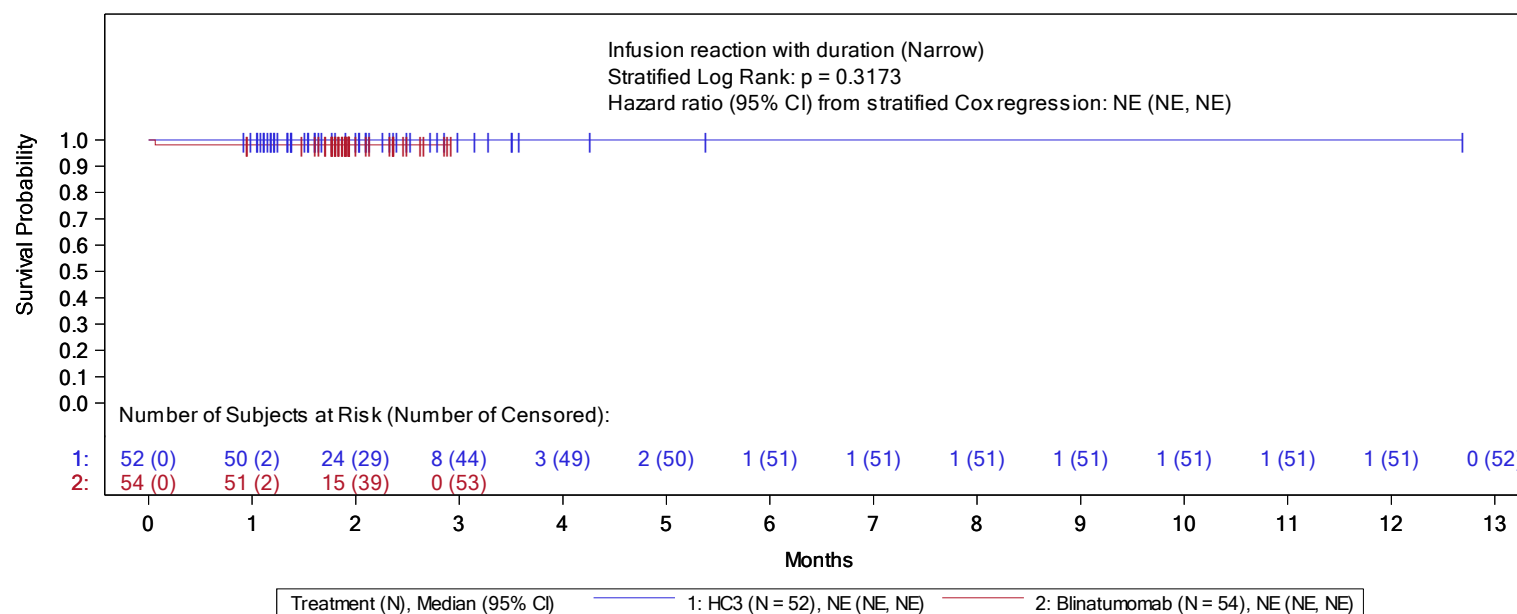
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated:

24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



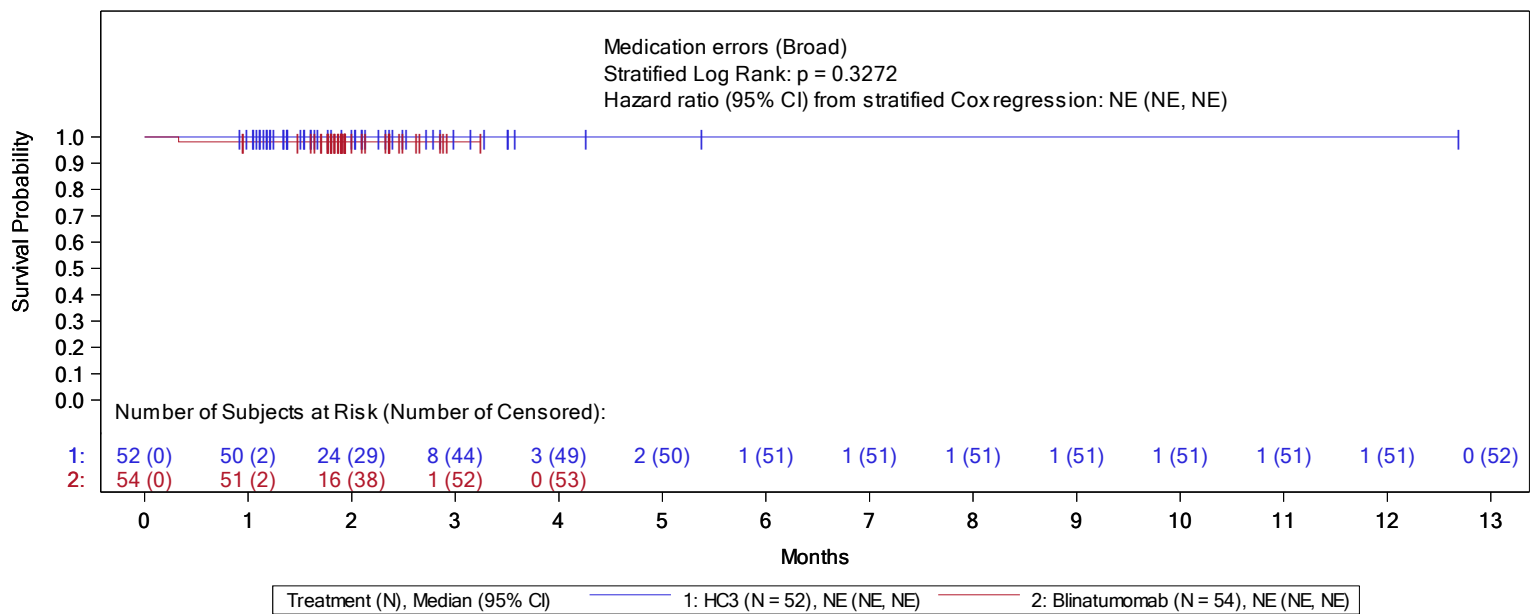
N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

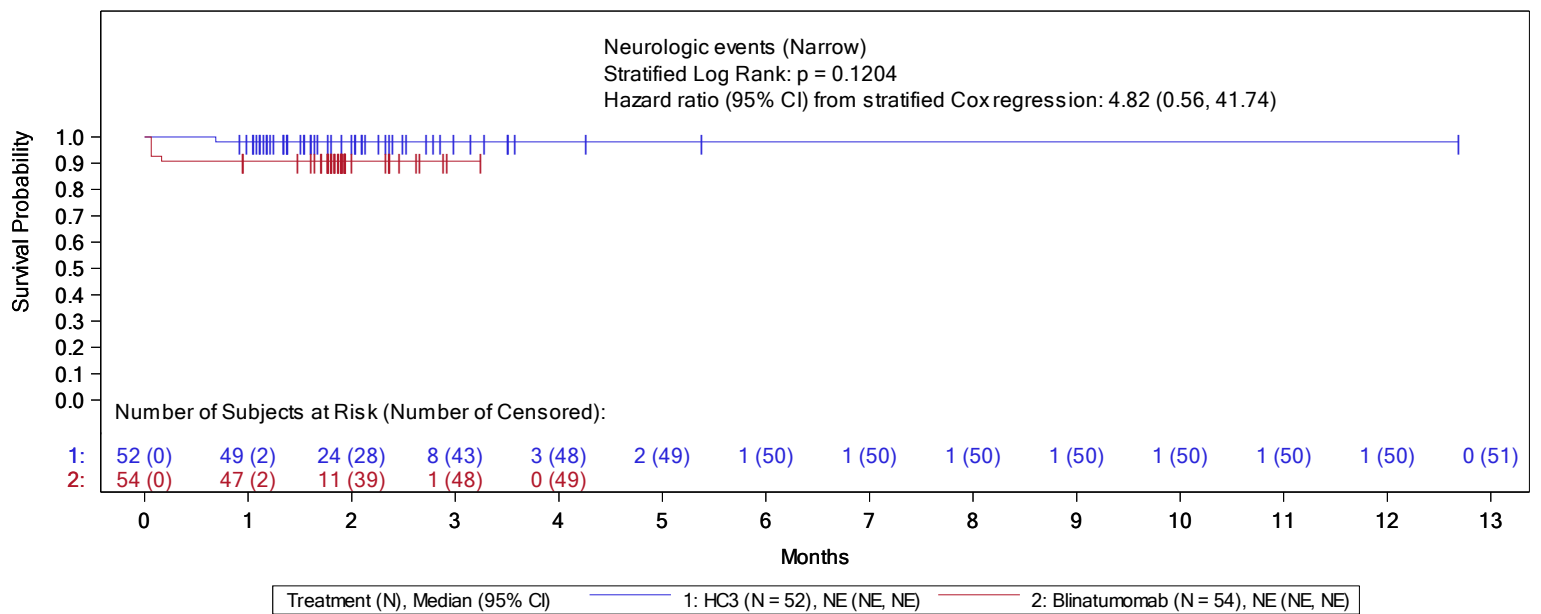
Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

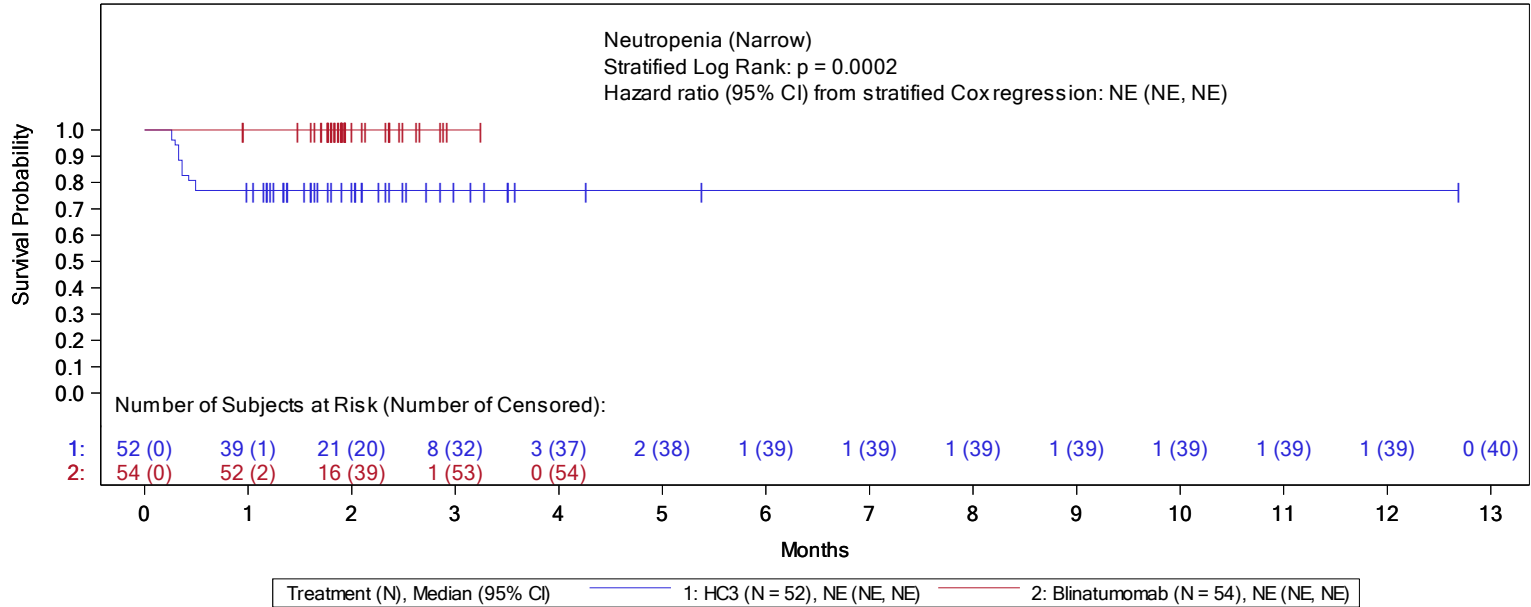
Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.17. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-017-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Anhang 4-G2.7.4: Sicherheit: Schwere UE von besonderem Interesse

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Capillary leak syndrome (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	0 (0.0)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-0.553
p-value			0.2658
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-0.500
p-value			0.3173

Page 1 of 16

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE= Not estimable.

^a Events are first onset of grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.2, 1.2		
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Decreased immunoglobulins (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-0.122
p-value			0.8609
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-0.086
p-value			0.9022

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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 grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.8, 1.8	
Unstratified hazard ratio ^e			0.78
(95% CI)			(0.05, 12.66)
p-value			0.8612
Stratified hazard ratio ^{c,e}			0.84
(95% CI)			(0.05, 13.57)
p-value			0.9024

Page 4 of 16

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE= Not estimable.

^a Events are first onset of grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Elevated liver enzymes (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	9 (17.3)	3 (5.6)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-3.301
p-value			0.0559
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-3.187
p-value			0.0642

Page 5 of 16

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE= Not estimable.

^a Events are first onset of grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.8	0.0, 1.9	
Unstratified hazard ratio ^e			0.30
(95% CI)			(0.08, 1.11)
p-value			0.0715
Stratified hazard ratio ^{c,e}			0.31
(95% CI)			(0.08, 1.15)
p-value			0.0798

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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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Embolic and thrombotic events (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.991
p-value			0.1612
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			1.040
p-value			0.1404

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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 grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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		0.9, 1.9	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Infections			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	11 (20.4)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			1.605
p-value			0.4290
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			1.345
p-value			0.5055

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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 grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(2.00, NE)	
Q1, Q3	NE, NE	2.00, NE	
Min, Max	0.1, 1.0	0.5, 2.0	
Unstratified hazard ratio ^e (95% CI)			1.50 (0.55, 4.08)
p-value			0.4320
Stratified hazard ratio ^{c,e} (95% CI)			1.40 (0.51, 3.84)
p-value			0.5074

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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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Lymphopenia (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.491
p-value			0.3264
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.490
p-value			0.3272

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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 grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	3 (5.6)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			0.847
p-value			0.3913
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			0.852
p-value			0.3790

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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 grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.1, 1.8	
Unstratified hazard ratio ^e			2.61
(95% CI)			(0.27, 25.37)
p-value			0.4074
Stratified hazard ratio ^{c,e}			2.73
(95% CI)			(0.28, 26.84)
p-value			0.3901

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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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Neutropenia (Narrow)			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	27 (51.9)	11 (20.4)	
Unstratified log-rank test			
n	52	54	
Normal score ^b			-9.656
p-value			0.0013
Stratified log-rank test ^c			
n	52	54	
Normal score ^b			-9.326
p-value			0.0020

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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 grade 3 and above treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

11AUG2025:04:54) Source data: a215up.adsl, adam.adtteae

Table 14-6.11.7. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.51	NE	
95% CI (median)	(0.36, NE)	(NE, NE)	
Q1, Q3	0.33, NE	NE, NE	
Min, Max	0.1, 0.5	0.0, 1.6	
Unstratified hazard ratio ^e			0.33
(95% CI)			(0.16, 0.67)
p-value			0.0021
Stratified hazard ratio ^{c,e}			0.34
(95% CI)			(0.17, 0.69)
p-value			0.0029

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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 grade 3 and above treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

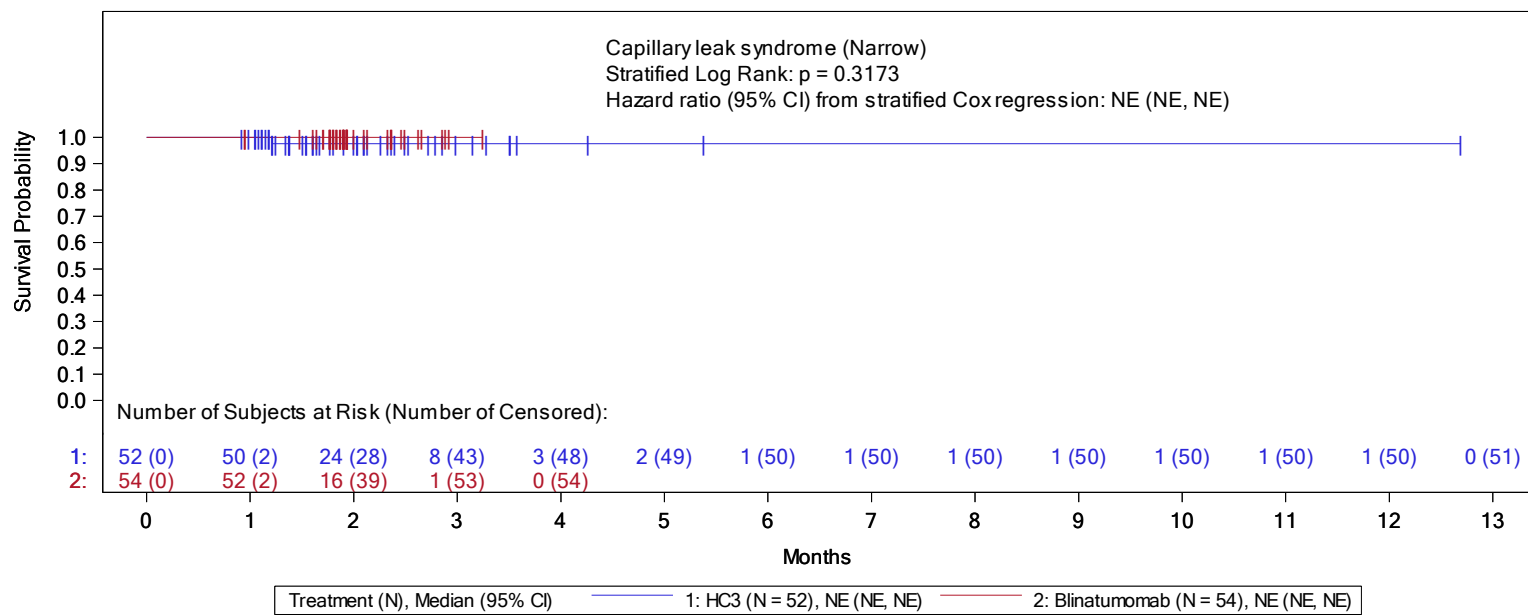
Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-ont-teae-eoi-saf.sas

Output: t14-06-011-007-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated:

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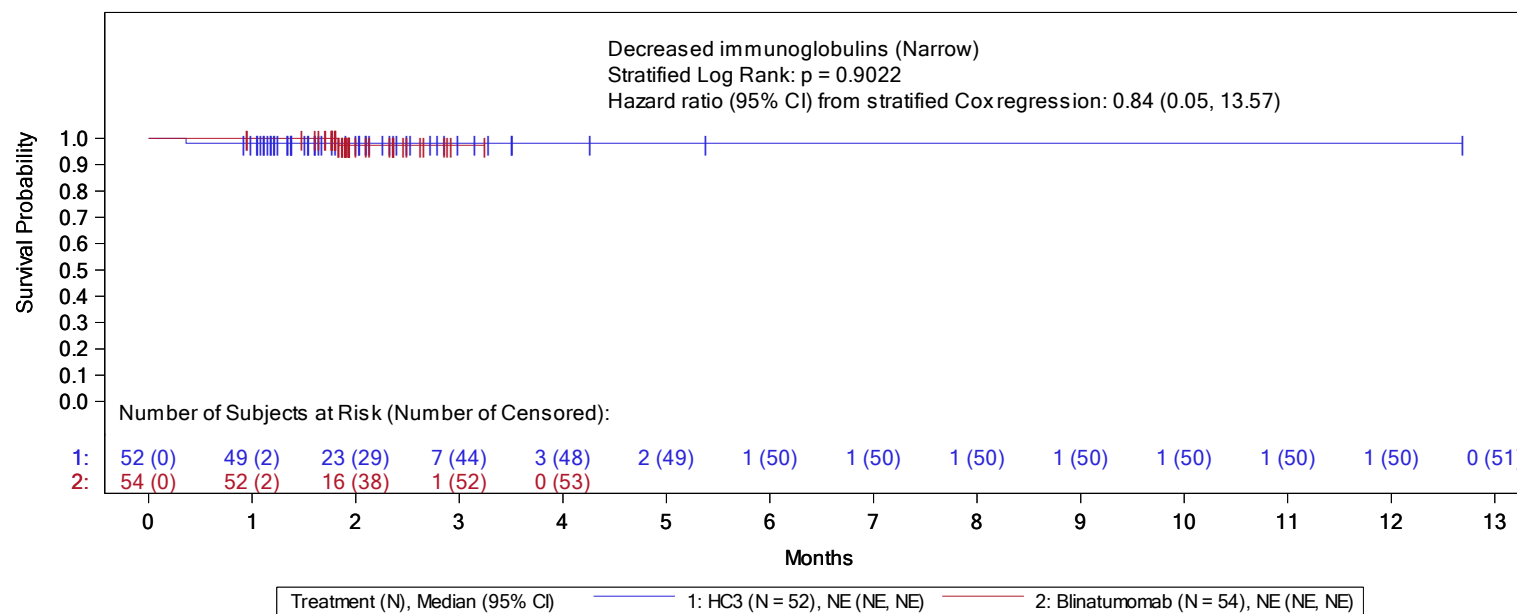
Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

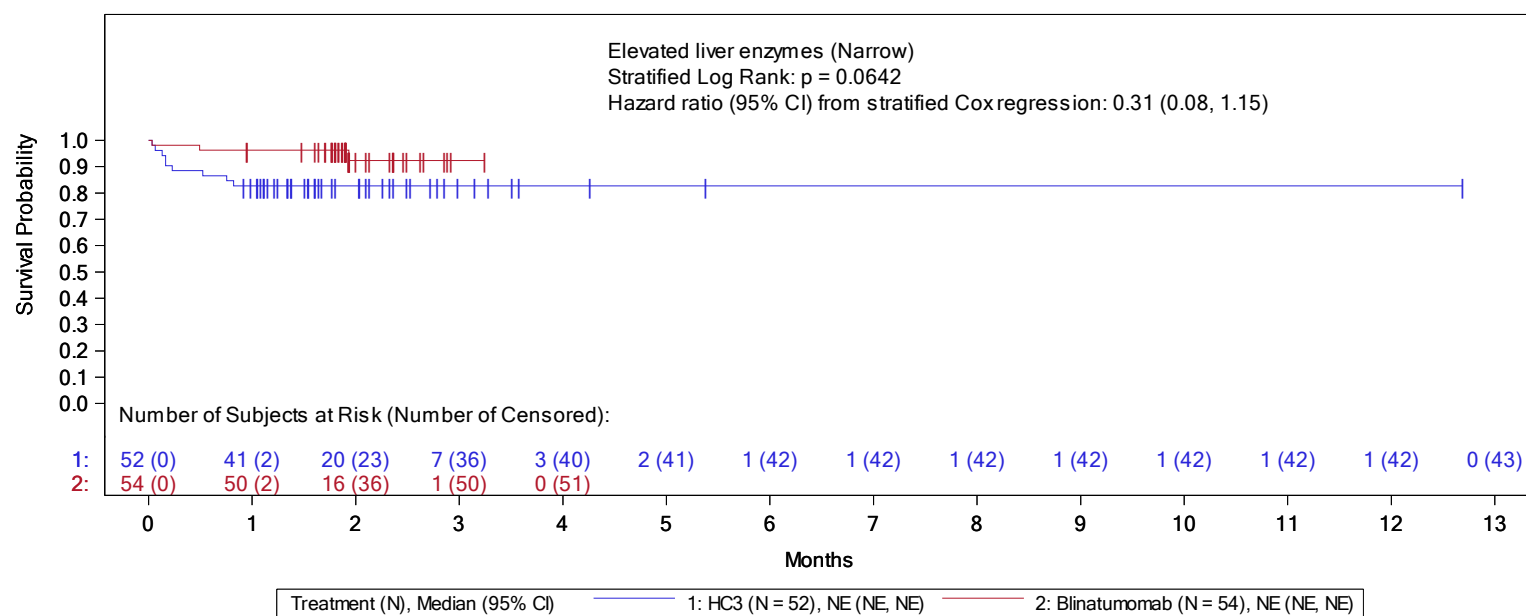
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025: 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

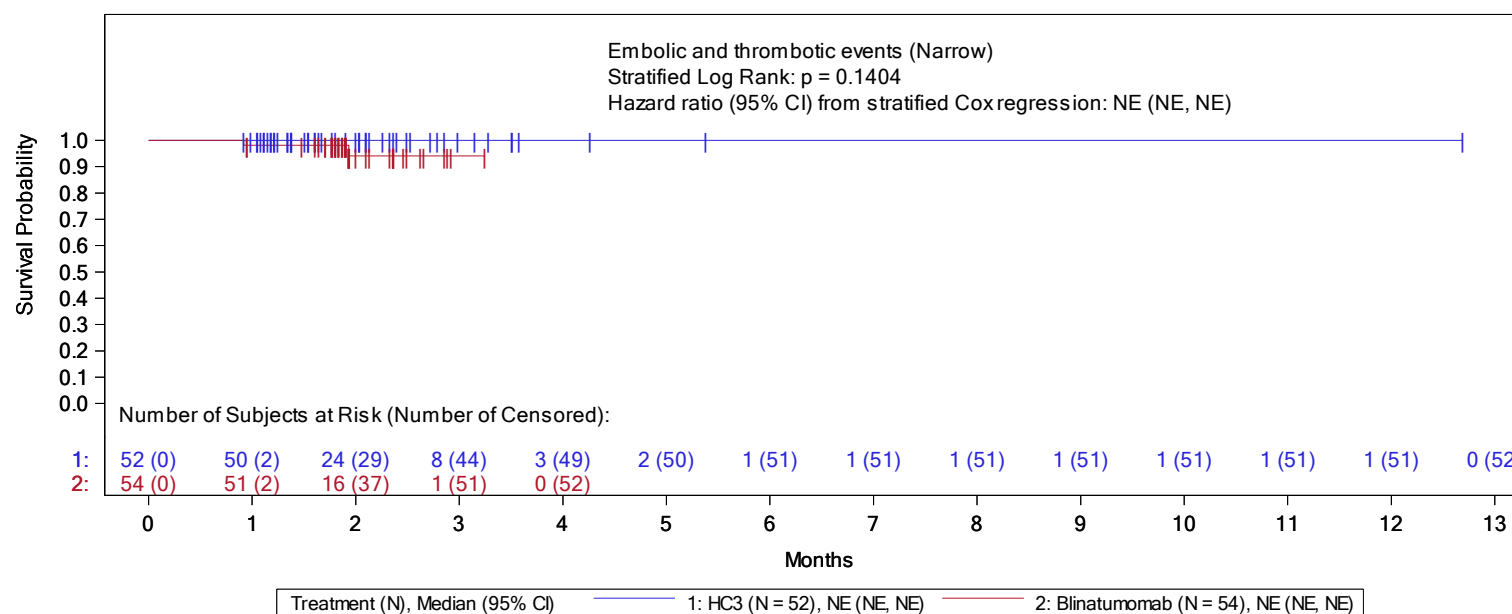
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025: 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

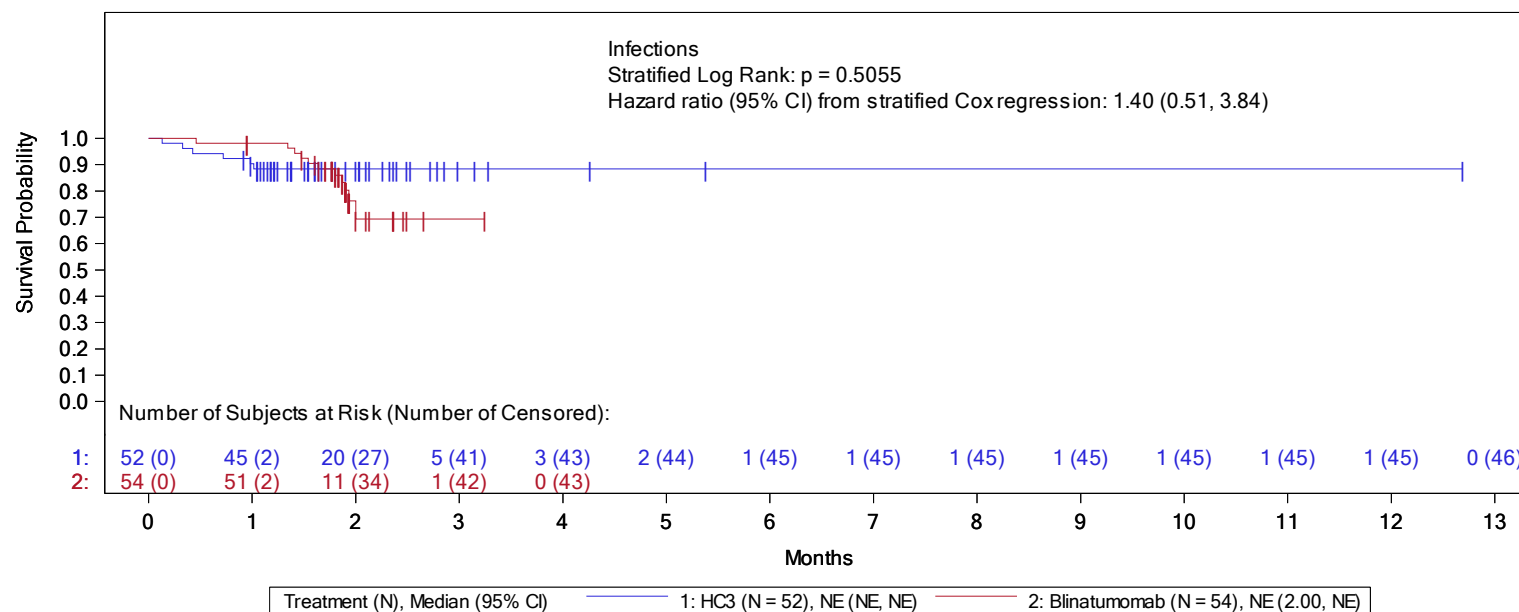
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025: 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

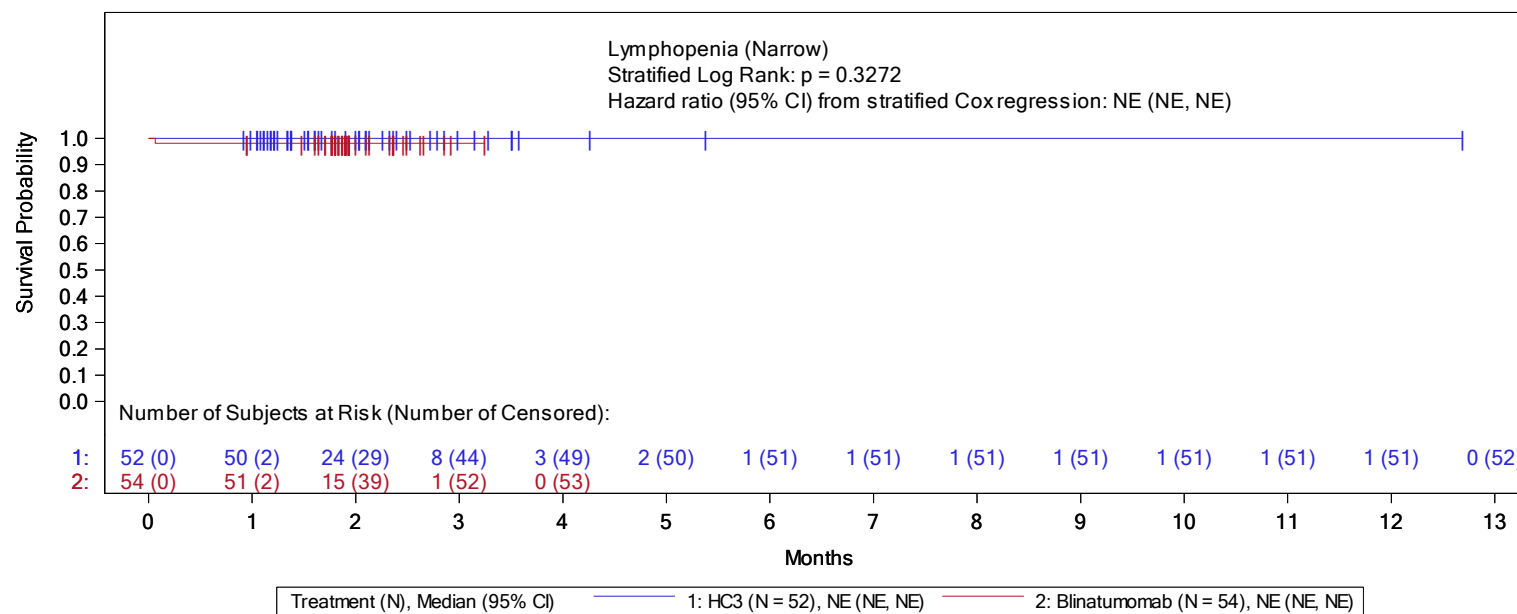
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025: 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

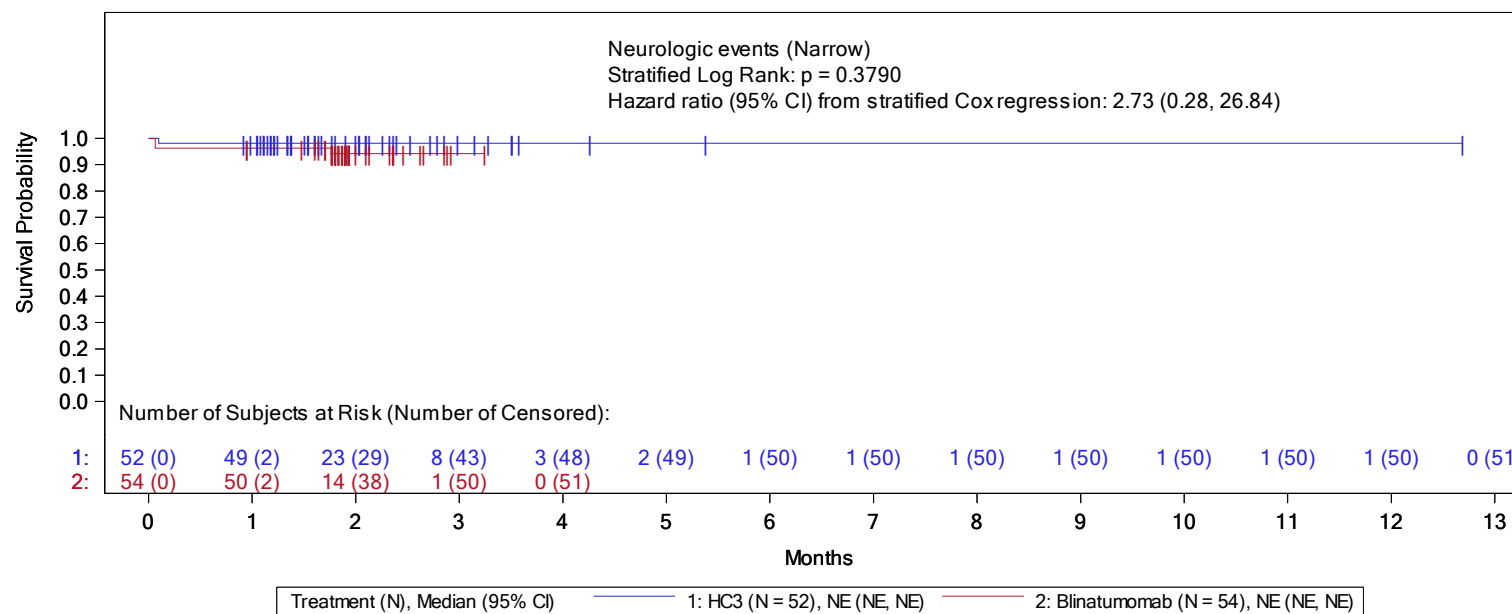
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025: 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

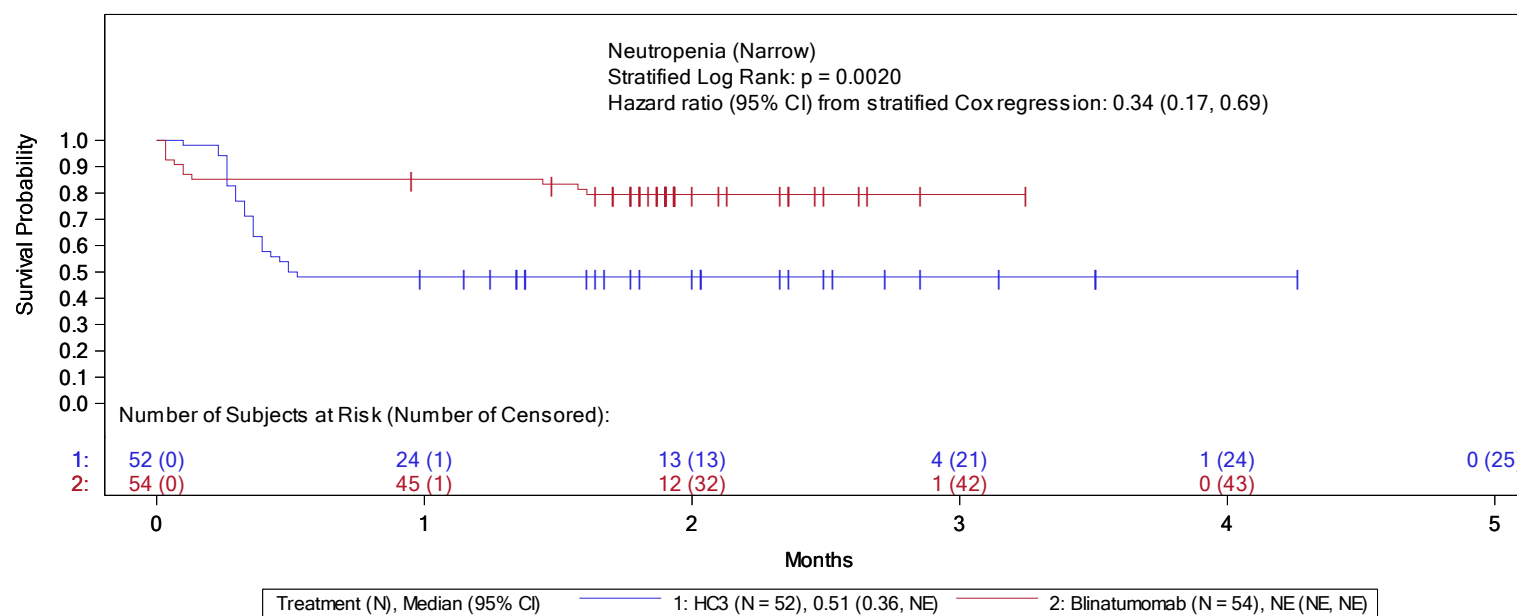
Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025: 05:34) Source Data: a215up.adsl, adam.adtteae

Figure 14-6.12.18. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-ae-ont-eoi-saf.sas

Output: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/output/f14-06-012-018-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date

Generated: 24OCT2025 : 05:34) Source Data: a215up.adsl, adam.adtteae

Anhang 4-G2.7.5: Sicherheit: Häufige 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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	39 (75.0)	20 (37.0)	
Unstratified log-rank test			
Normal score ^b			-14.96
p-value			<0.0001
Stratified log-rank test ^c			
Normal score ^b			-14.21
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.33	NE	
95% CI (median)	(0.26, 0.39)	(1.64, NE)	
Q1, Q3	0.26, NE	1.44, NE	
Min, Max	0.0, 0.5	0.0, 1.7	
Unstratified hazard ratio ^e			0.32
(95% CI)			(0.18, 0.56)
p-value			<0.0001
Stratified hazard ratio ^{c,e}			0.33
(95% CI)			(0.19, 0.58)
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.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Anaemia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	24 (46.2)	13 (24.1)	
Unstratified log-rank test			
Normal score ^b			-7.54
p-value			0.0109
Stratified log-rank test ^c			
Normal score ^b			-7.69
p-value			0.0080

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(0.43, NE)	(NE, NE)	
Q1, Q3	0.30, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 1.7	
Unstratified hazard ratio ^e			0.42
(95% CI)			(0.21, 0.84)
p-value			0.0138
Stratified hazard ratio ^{c,e}			0.40
(95% CI)			(0.20, 0.81)
p-value			0.0108

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	16 (30.8)	5 (9.3)	
Unstratified log-rank test			
Normal score ^b			-6.23
p-value			0.0058
Stratified log-rank test ^c			
Normal score ^b			-6.11
p-value			0.0067

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.48, NE	NE, NE	
Min, Max	0.2, 1.4	0.1, 1.6	
Unstratified hazard ratio ^e			0.26
(95% CI)			(0.10, 0.73)
p-value			0.0099
Stratified hazard ratio ^{c,e}			0.27
(95% CI)			(0.10, 0.74)
p-value			0.0111

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Thrombocytopenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	13 (25.0)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			-5.52
p-value			0.0063
Stratified log-rank test ^c			
Normal score ^b			-5.65
p-value			0.0035

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.08, NE	NE, NE	
Min, Max	0.2, 1.1	0.1, 1.9	
Unstratified hazard ratio ^e			0.23
(95% CI)			(0.08, 0.72)
p-value			0.0116
Stratified hazard ratio ^{c,e}			0.18
(95% CI)			(0.05, 0.64)
p-value			0.0082

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	13 (25.0)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			-5.99
p-value			0.0024
Stratified log-rank test ^c			
Normal score ^b			-5.74
p-value			0.0036

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.15, NE	NE, NE	
Min, Max	0.1, 1.1	1.4, 1.6	
Unstratified hazard ratio ^e			0.18
(95% CI)			(0.05, 0.62)
p-value			0.0069
Stratified hazard ratio ^{c,e}			0.19
(95% CI)			(0.05, 0.66)
p-value			0.0091

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Eye disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	9 (17.3)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			-3.46
p-value			0.0439
Stratified log-rank test ^c			
Normal score ^b			-3.38
p-value			0.0488

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.3	0.1, 1.6	
Unstratified hazard ratio ^e			0.28
(95% CI)			(0.08, 1.05)
p-value			0.0586
Stratified hazard ratio ^{c,e}			0.29
(95% CI)			(0.08, 1.07)
p-value			0.0637

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	39 (75.0)	39 (72.2)	
Unstratified log-rank test			
Normal score ^b			-8.29
p-value			0.0446
Stratified log-rank test ^c			
Normal score ^b			-8.61
p-value			0.0307

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.21	1.51	
95% CI (median)	(0.16, 0.26)	(1.02, 1.70)	
Q1, Q3	0.10, 1.18	0.33, 1.93	
Min, Max	0.0, 1.2	0.0, 2.0	
Unstratified hazard ratio ^e			0.63
(95% CI)			(0.40, 0.99)
p-value			0.0437
Stratified hazard ratio ^{c,e}			0.61
(95% CI)			(0.38, 0.97)
p-value			0.0374

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Nausea			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	9 (17.3)	23 (42.6)	
Unstratified log-rank test			
Normal score ^b			6.16
p-value			0.0268
Stratified log-rank test ^c			
Normal score ^b			5.95
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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	2.03	
95% CI (median)	(NE, NE)	(1.67, NE)	
Q1, Q3	NE, NE	1.51, NE	
Min, Max	0.0, 1.0	0.0, 2.0	
Unstratified hazard ratio ^e			2.35
(95% CI)			(1.08, 5.10)
p-value			0.0313
Stratified hazard ratio ^{c,e}			2.29
(95% CI)			(1.05, 4.98)
p-value			0.0362

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Vomiting			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	11 (21.2)	17 (31.5)	
Unstratified log-rank test			
Normal score ^b			2.06
p-value			0.4288
Stratified log-rank test ^c			
Normal score ^b			2.06
p-value			0.4264

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(2.03, NE)	
Q1, Q3	1.48, NE	1.57, NE	
Min, Max	0.0, 1.5	0.0, 2.0	
Unstratified hazard ratio ^e			1.36
(95% CI)			(0.63, 2.92)
p-value			0.4314
Stratified hazard ratio ^{c,e}			1.35
(95% CI)			(0.63, 2.90)
p-value			0.4421

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Diarrhoea			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	9 (17.3)	12 (22.2)	
Unstratified log-rank test			
Normal score ^b			0.38
p-value			0.8653
Stratified log-rank test ^c			
Normal score ^b			0.38
p-value			0.8665

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	1.90, NE	
Min, Max	0.1, 0.7	0.1, 1.9	
Unstratified hazard ratio ^e			1.07
(95% CI)			(0.45, 2.56)
p-value			0.8734
Stratified hazard ratio ^{c,e}			1.08
(95% CI)			(0.45, 2.58)
p-value			0.8671

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Stomatitis			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	28 (53.8)	12 (22.2)	
Unstratified log-rank test			
Normal score ^b			-13.02
p-value			<0.0001
Stratified log-rank test ^c			
Normal score ^b			-13.22
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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.79	NE	
95% CI (median)	(0.26, NE)	(NE, NE)	
Q1, Q3	0.21, NE	2.00, NE	
Min, Max	0.0, 1.1	0.3, 2.0	
Unstratified hazard ratio ^e			0.24
(95% CI)			(0.12, 0.48)
p-value			<0.0001
Stratified hazard ratio ^{c,e}			0.22
(95% CI)			(0.11, 0.45)
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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Abdominal pain			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	11 (21.2)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			-2.79
p-value			0.1834
Stratified log-rank test ^c			
Normal score ^b			-2.52
p-value			0.2285

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.9	
Unstratified hazard ratio ^e			0.53
(95% CI)			(0.20, 1.37)
p-value			0.1889
Stratified hazard ratio ^{c,e}			0.56
(95% CI)			(0.22, 1.45)
p-value			0.2334

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Constipation			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	7 (13.5)	5 (9.3)	
Unstratified log-rank test			
Normal score ^b			-1.42
p-value			0.4079
Stratified log-rank test ^c			
Normal score ^b			-1.58
p-value			0.3562

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.9	
Unstratified hazard ratio ^e			0.62
(95% CI)			(0.20, 1.95)
p-value			0.4114
Stratified hazard ratio ^{c,e}			0.58
(95% CI)			(0.18, 1.86)
p-value			0.3617

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	19 (36.5)	48 (88.9)	
Unstratified log-rank test			
Normal score ^b			22.47
p-value			<0.0001
Stratified log-rank test ^c			
Normal score ^b			23.49
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	0.07	
95% CI (median)	(1.48, NE)	(0.03, 0.07)	
Q1, Q3	0.44, NE	0.03, 1.28	
Min, Max	0.1, 1.5	0.0, 1.9	
Unstratified hazard ratio ^e			4.90
(95% CI)			(2.86, 8.39)
p-value			<0.0001
Stratified hazard ratio ^{c,e}			6.44
(95% CI)			(3.54, 11.72)
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	10 (19.2)	44 (81.5)	
Unstratified log-rank test			
Normal score ^b			21.97
p-value			<0.0001
Stratified log-rank test ^c			
Normal score ^b			22.97
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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	0.07	
95% CI (median)	(NE, NE)	(0.03, 0.07)	
Q1, Q3	NE, NE	0.03, 1.57	
Min, Max	0.3, 1.5	0.0, 1.9	
Unstratified hazard ratio ^e			7.76
(95% CI)			(3.88, 15.53)
p-value			<0.0001
Stratified hazard ratio ^{c,e}			11.57
(95% CI)			(5.13, 26.07)
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Mucosal inflammation			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	4 (7.7)	9 (16.7)	
Unstratified log-rank test			
Normal score ^b			1.54
p-value			0.3831
Stratified log-rank test ^c			
Normal score ^b			1.47
p-value			0.4037

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.3	1.3, 1.9	
Unstratified hazard ratio ^e			1.69
(95% CI)			(0.52, 5.50)
p-value			0.3849
Stratified hazard ratio ^{c,e}			1.65
(95% CI)			(0.50, 5.40)
p-value			0.4085

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Hepatobiliary disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	10 (19.2)	5 (9.3)	
Unstratified log-rank test			
Normal score ^b			-2.90
p-value			0.1314
Stratified log-rank test ^c			
Normal score ^b			-2.86
p-value			0.1378

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.9	
Unstratified hazard ratio ^e			0.44
(95% CI)			(0.15, 1.30)
p-value			0.1397
Stratified hazard ratio ^{c,e}			0.45
(95% CI)			(0.15, 1.32)
p-value			0.1472

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Immune system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	15 (27.8)	
Unstratified log-rank test			
Normal score ^b			5.89
p-value			0.0052
Stratified log-rank test ^c			
Normal score ^b			5.59
p-value			0.0079

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(2.10, NE)	
Q1, Q3	NE, NE	1.87, NE	
Min, Max	0.7, 1.0	0.0, 2.1	
Unstratified hazard ratio ^e			4.95
(95% CI)			(1.43, 17.13)
p-value			0.0115
Stratified hazard ratio ^{c,e}			4.64
(95% CI)			(1.34, 16.08)
p-value			0.0156

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Hypogammaglobulinaemia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	2 (3.8)	6 (11.1)	
Unstratified log-rank test			
Normal score ^b			1.93
p-value			0.1707
Stratified log-rank test ^c			
Normal score ^b			1.72
p-value			0.2191

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.0, 1.2	
Unstratified hazard ratio ^e			2.92
(95% CI)			(0.59, 14.48)
p-value			0.1897
Stratified hazard ratio ^{c,e}			2.64
(95% CI)			(0.53, 13.14)
p-value			0.2368

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	18 (34.6)	25 (46.3)	
Unstratified log-rank test			
Normal score ^b			0.92
p-value			0.7760
Stratified log-rank test ^c			
Normal score ^b			-0.16
p-value			0.9608

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	1.90	
95% CI (median)	(NE, NE)	(1.70, NE)	
Q1, Q3	0.66, NE	1.41, NE	
Min, Max	0.0, 1.2	0.1, 1.9	
Unstratified hazard ratio ^e			1.09
(95% CI)			(0.60, 2.01)
p-value			0.7728
Stratified hazard ratio ^{c,e}			0.99
(95% CI)			(0.54, 1.82)
p-value			0.9659

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Injury, poisoning and procedural complications			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	9 (16.7)	
Unstratified log-rank test			
Normal score ^b			0.64
p-value			0.7400
Stratified log-rank test ^c			
Normal score ^b			0.58
p-value			0.7601

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.1	0.3, 1.8	
Unstratified hazard ratio ^e			1.19
(95% CI)			(0.42, 3.36)
p-value			0.7405
Stratified hazard ratio ^{c,e}			1.18
(95% CI)			(0.41, 3.34)
p-value			0.7603

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Investigations			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	22 (42.3)	22 (40.7)	
Unstratified log-rank test			
Normal score ^b			-1.19
p-value			0.7142
Stratified log-rank test ^c			
Normal score ^b			-1.02
p-value			0.7484

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(0.46, NE)	(1.54, NE)	
Q1, Q3	0.30, NE	0.49, NE	
Min, Max	0.0, 1.0	0.0, 1.8	
Unstratified hazard ratio ^e			0.90
(95% CI)			(0.50, 1.63)
p-value			0.7337
Stratified hazard ratio ^{c,e}			0.91
(95% CI)			(0.50, 1.67)
p-value			0.7694

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Platelet count decreased			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	8 (15.4)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			-1.51
p-value			0.4265
Stratified log-rank test ^c			
Normal score ^b			-1.33
p-value			0.4787

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.1	0.3, 1.8	
Unstratified hazard ratio ^e			0.66
(95% CI)			(0.24, 1.84)
p-value			0.4321
Stratified hazard ratio ^{c,e}			0.70
(95% CI)			(0.25, 1.93)
p-value			0.4856

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Alanine aminotransferase increased			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	7 (13.5)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			-1.66
p-value			0.3135
Stratified log-rank test ^c			
Normal score ^b			-1.43
p-value			0.3867

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.8	0.0, 0.5	
Unstratified hazard ratio ^e			0.54
(95% CI)			(0.16, 1.84)
p-value			0.3256
Stratified hazard ratio ^{c,e}			0.59
(95% CI)			(0.17, 2.02)
p-value			0.4013

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	13 (25.0)	19 (35.2)	
Unstratified log-rank test			
Normal score ^b			3.08
p-value			0.2697
Stratified log-rank test ^c			
Normal score ^b			3.59
p-value			0.1941

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.90, NE)	
Q1, Q3	1.41, NE	0.49, NE	
Min, Max	0.1, 1.4	0.0, 1.9	
Unstratified hazard ratio ^e			1.49
(95% CI)			(0.74, 3.03)
p-value			0.2669
Stratified hazard ratio ^{c,e}			1.60
(95% CI)			(0.78, 3.28)
p-value			0.1992

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Hypokalaemia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	5 (9.6)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			0.83
p-value			0.6307
Stratified log-rank test ^c			
Normal score ^b			0.84
p-value			0.6213

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.8	0.0, 1.7	
Unstratified hazard ratio ^e			1.32
(95% CI)			(0.42, 4.17)
p-value			0.6348
Stratified hazard ratio ^{c,e}			1.34
(95% CI)			(0.42, 4.28)
p-value			0.6231

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Musculoskeletal and connective tissue disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	15 (28.8)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			-5.20
p-value			0.0242
Stratified log-rank test ^c			
Normal score ^b			-5.15
p-value			0.0251

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.64, NE	NE, NE	
Min, Max	0.0, 1.1	0.0, 1.7	
Unstratified hazard ratio ^e			0.37
(95% CI)			(0.15, 0.91)
p-value			0.0303
Stratified hazard ratio ^{c,e}			0.37
(95% CI)			(0.15, 0.91)
p-value			0.0310

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Back pain			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			-1.92
p-value			0.1958
Stratified log-rank test ^c			
Normal score ^b			-1.89
p-value			0.2020

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.0, 1.7	
Unstratified hazard ratio ^e			0.41
(95% CI)			(0.10, 1.65)
p-value			0.2099
Stratified hazard ratio ^{c,e}			0.41
(95% CI)			(0.10, 1.67)
p-value			0.2146

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	12 (23.1)	24 (44.4)	
Unstratified log-rank test			
Normal score ^b			6.61
p-value			0.0249
Stratified log-rank test ^c			
Normal score ^b			6.71
p-value			0.0189

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(0.95, NE)	
Q1, Q3	NE, NE	0.13, NE	
Min, Max	0.0, 1.5	0.0, 1.7	
Unstratified hazard ratio ^e			2.18
(95% CI)			(1.09, 4.37)
p-value			0.0274
Stratified hazard ratio ^{c,e}			2.28
(95% CI)			(1.13, 4.62)
p-value			0.0215

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Headache			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	9 (17.3)	20 (37.0)	
Unstratified log-rank test			
Normal score ^b			5.30
p-value			0.0456
Stratified log-rank test ^c			
Normal score ^b			5.43
p-value			0.0386

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.64, NE)	
Q1, Q3	NE, NE	0.52, NE	
Min, Max	0.0, 1.5	0.0, 1.7	
Unstratified hazard ratio ^e			2.20
(95% CI)			(1.00, 4.84)
p-value			0.0503
Stratified hazard ratio ^{c,e}			2.25
(95% CI)			(1.02, 4.97)
p-value			0.0448

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Psychiatric disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	5 (9.6)	9 (16.7)	
Unstratified log-rank test			
Normal score ^b			1.83
p-value			0.3231
Stratified log-rank test ^c			
Normal score ^b			1.81
p-value			0.3316

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.9	
Unstratified hazard ratio ^e			1.72
(95% CI)			(0.58, 5.15)
p-value			0.3288
Stratified hazard ratio ^{c,e}			1.71
(95% CI)			(0.57, 5.13)
p-value			0.3373

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Renal and urinary disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	7 (13.5)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			-1.97
p-value			0.2317
Stratified log-rank test ^c			
Normal score ^b			-2.37
p-value			0.1389

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.1, 2.1	
Unstratified hazard ratio ^e			0.48
(95% CI)			(0.14, 1.64)
p-value			0.2420
Stratified hazard ratio ^{c,e}			0.40
(95% CI)			(0.11, 1.40)
p-value			0.1512

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	10 (19.2)	12 (22.2)	
Unstratified log-rank test			
Normal score ^b			-0.22
p-value			0.9240
Stratified log-rank test ^c			
Normal score ^b			-0.45
p-value			0.8426

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(2.16, NE)	
Q1, Q3	NE, NE	2.16, NE	
Min, Max	0.2, 1.3	0.4, 2.2	
Unstratified hazard ratio ^e			0.96
(95% CI)			(0.41, 2.22)
p-value			0.9181
Stratified hazard ratio ^{c,e}			0.92
(95% CI)			(0.39, 2.16)
p-value			0.8427

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Epistaxis			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	7 (13.5)	5 (9.3)	
Unstratified log-rank test			
Normal score ^b			-1.88
p-value			0.2657
Stratified log-rank test ^c			
Normal score ^b			-2.02
p-value			0.2293

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

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Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.3	1.4, 2.2	
Unstratified hazard ratio ^e			0.52
(95% CI)			(0.16, 1.67)
p-value			0.2726
Stratified hazard ratio ^{c,e}			0.49
(95% CI)			(0.15, 1.59)
p-value			0.2380

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Skin and subcutaneous tissue disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	14 (26.9)	24 (44.4)	
Unstratified log-rank test			
Normal score ^b			3.80
p-value			0.2133
Stratified log-rank test ^c			
Normal score ^b			3.31
p-value			0.2681

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.64, NE)	
Q1, Q3	1.11, NE	1.31, NE	
Min, Max	0.0, 1.2	0.1, 1.9	
Unstratified hazard ratio ^e			1.52
(95% CI)			(0.78, 2.94)
p-value			0.2172
Stratified hazard ratio ^{c,e}			1.46
(95% CI)			(0.75, 2.86)
p-value			0.2683

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Rash			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	5 (9.6)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			0.48
p-value			0.7800
Stratified log-rank test ^c			
Normal score ^b			0.60
p-value			0.7258

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

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Table 14-6.1.12. Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.2	0.1, 1.8	
Unstratified hazard ratio ^e			1.18
(95% CI)			(0.37, 3.73)
p-value			0.7803
Stratified hazard ratio ^{c,e}			1.23
(95% CI)			(0.39, 3.91)
p-value			0.7262

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Erythema			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	2 (3.8)	6 (11.1)	
Unstratified log-rank test			
Normal score ^b			1.47
p-value			0.2866
Stratified log-rank test ^c			
Normal score ^b			1.45
p-value			0.2923

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.4, 1.9	
Unstratified hazard ratio ^e			2.34
(95% CI)			(0.47, 11.67)
p-value			0.2990
Stratified hazard ratio ^{c,e}			2.31
(95% CI)			(0.46, 11.63)
p-value			0.3103

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Pruritus			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	5 (9.6)	6 (11.1)	
Unstratified log-rank test			
Normal score ^b			-0.14
p-value			0.9321
Stratified log-rank test ^c			
Normal score ^b			-0.28
p-value			0.8628

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.1	0.4, 1.9	
Unstratified hazard ratio ^e			0.95
(95% CI)			(0.29, 3.13)
p-value			0.9319
Stratified hazard ratio ^{c,e}			0.90
(95% CI)			(0.27, 3.01)
p-value			0.8629

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Vascular disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	11 (21.2)	16 (29.6)	
Unstratified log-rank test			
Normal score ^b			1.28
p-value			0.6154
Stratified log-rank test ^c			
Normal score ^b			1.49
p-value			0.5537

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	NE, NE	1.67, NE	
Min, Max	0.0, 1.3	0.0, 1.9	
Unstratified hazard ratio ^e			1.23
(95% CI)			(0.57, 2.66)
p-value			0.6050
Stratified hazard ratio ^{c,e}			1.26
(95% CI)			(0.58, 2.75)
p-value			0.5586

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Hypertension			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	4 (7.7)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			0.95
p-value			0.5612
Stratified log-rank test ^c			
Normal score ^b			0.99
p-value			0.5425

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 2.1	
Unstratified hazard ratio ^e			1.44
(95% CI)			(0.42, 4.98)
p-value			0.5626
Stratified hazard ratio ^{c,e}			1.47
(95% CI)			(0.42, 5.07)
p-value			0.5457

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Hypotension			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	4 (7.7)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			1.04
p-value			0.5244
Stratified log-rank test ^c			
Normal score ^b			1.02
p-value			0.5289

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-tte-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.3	0.0, 1.7	
Unstratified hazard ratio ^e			1.49
(95% CI)			(0.43, 5.13)
p-value			0.5264
Stratified hazard ratio ^{c,e}			1.47
(95% CI)			(0.42, 5.10)
p-value			0.5453

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

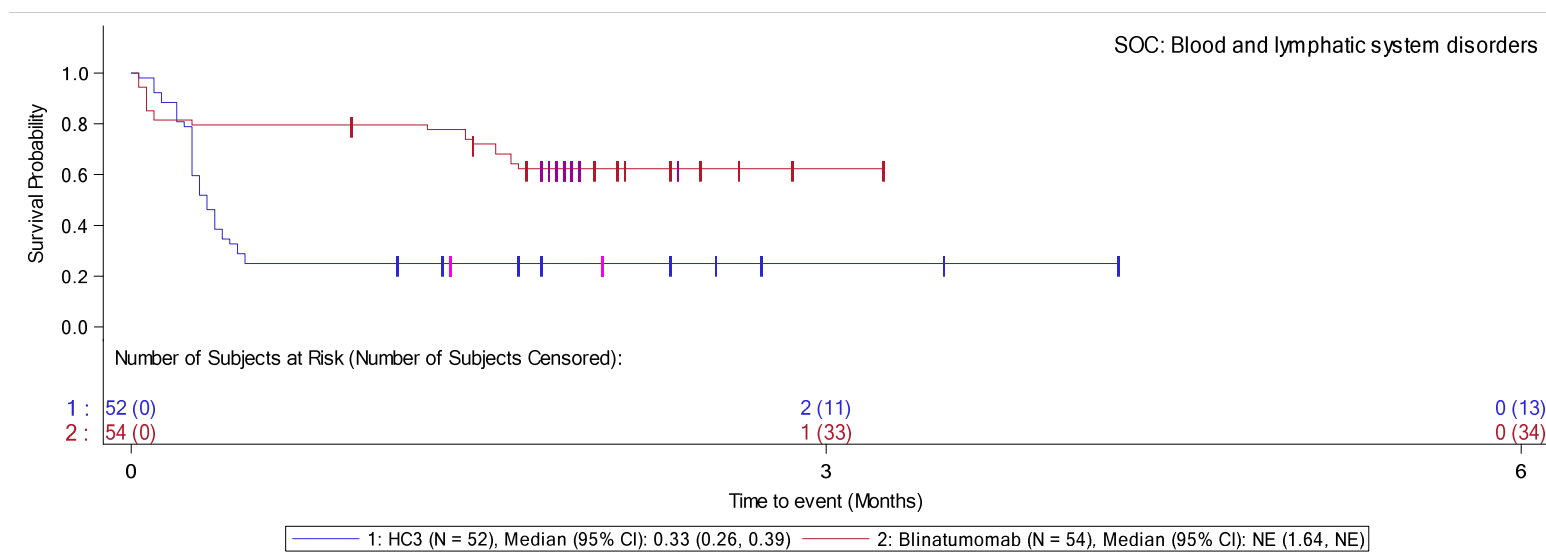
^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-teae-soc-pt-saf.sas

Output: t14-06-001-012-tte-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:16) Source data: a215up.adsl, a215.adae

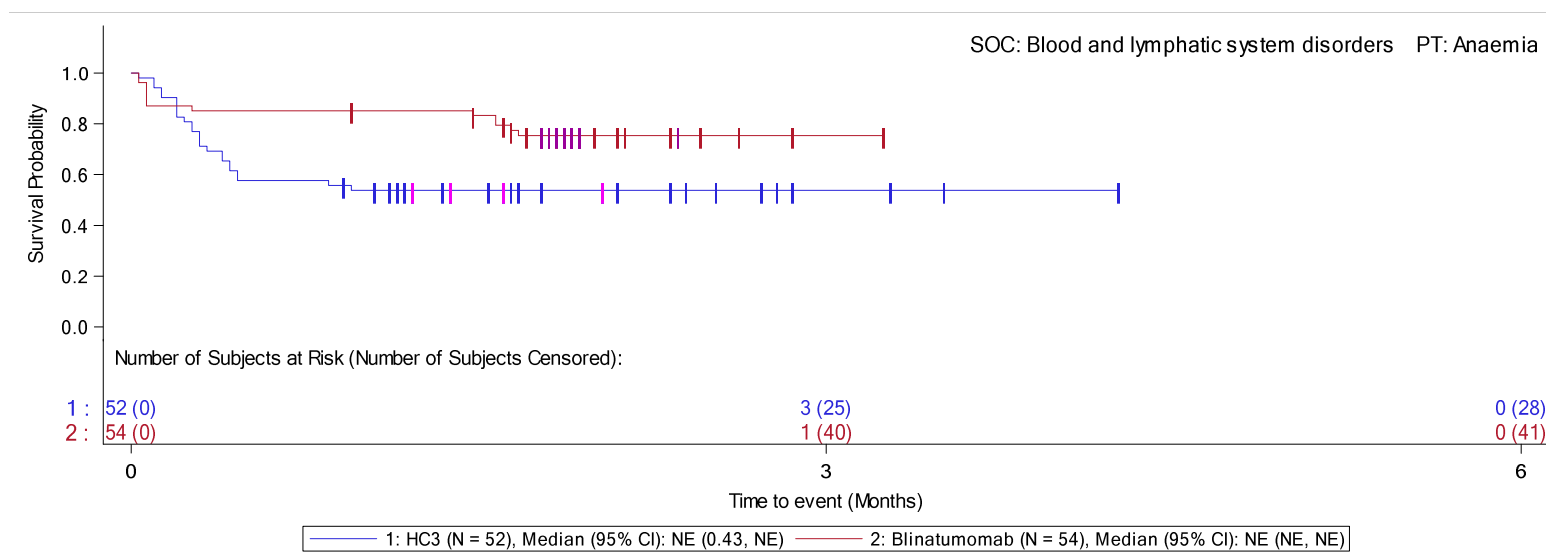
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
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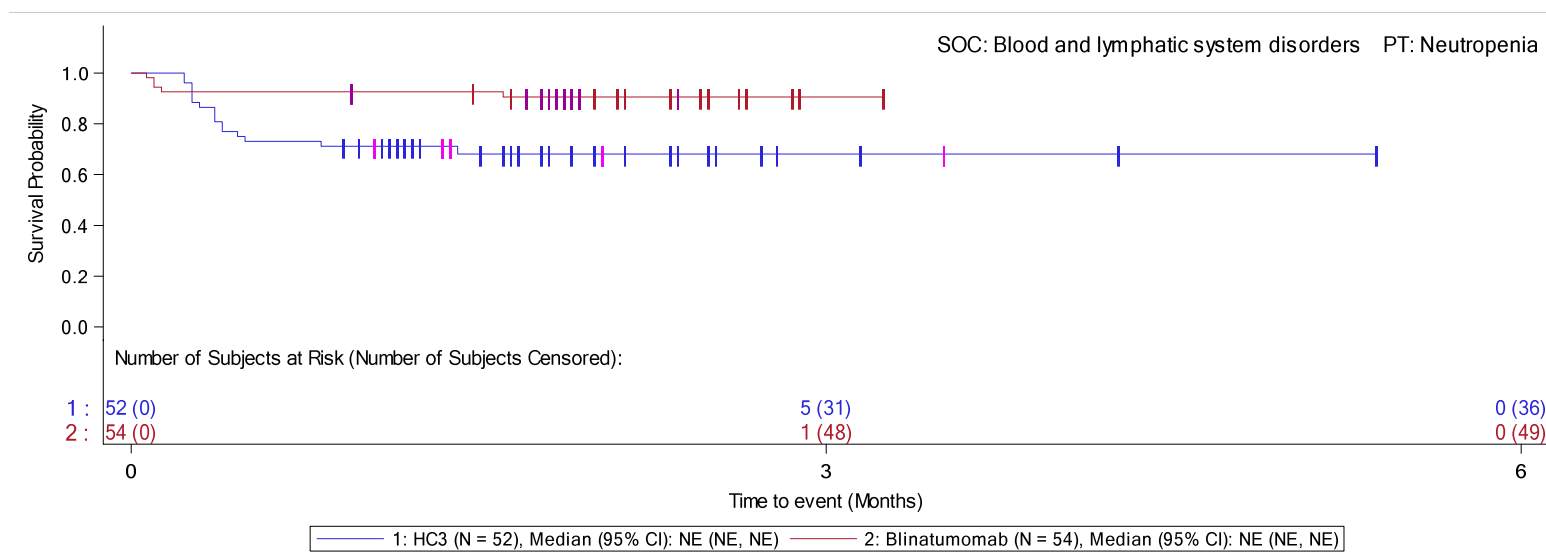
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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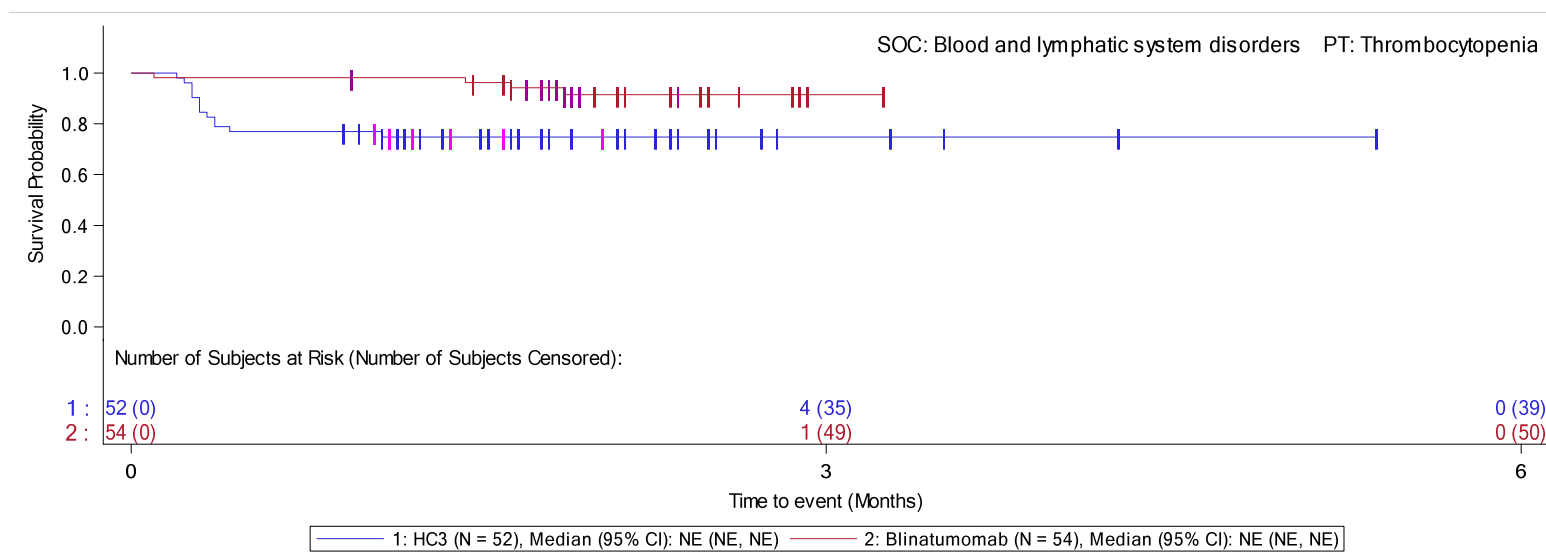
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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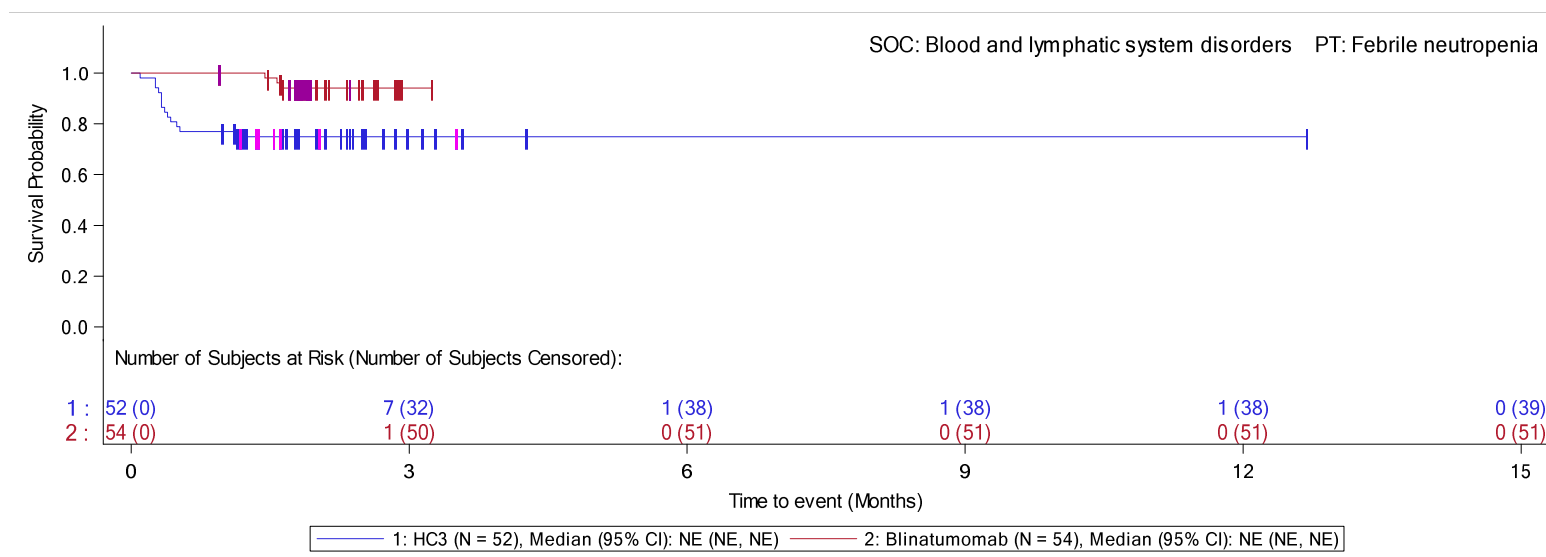
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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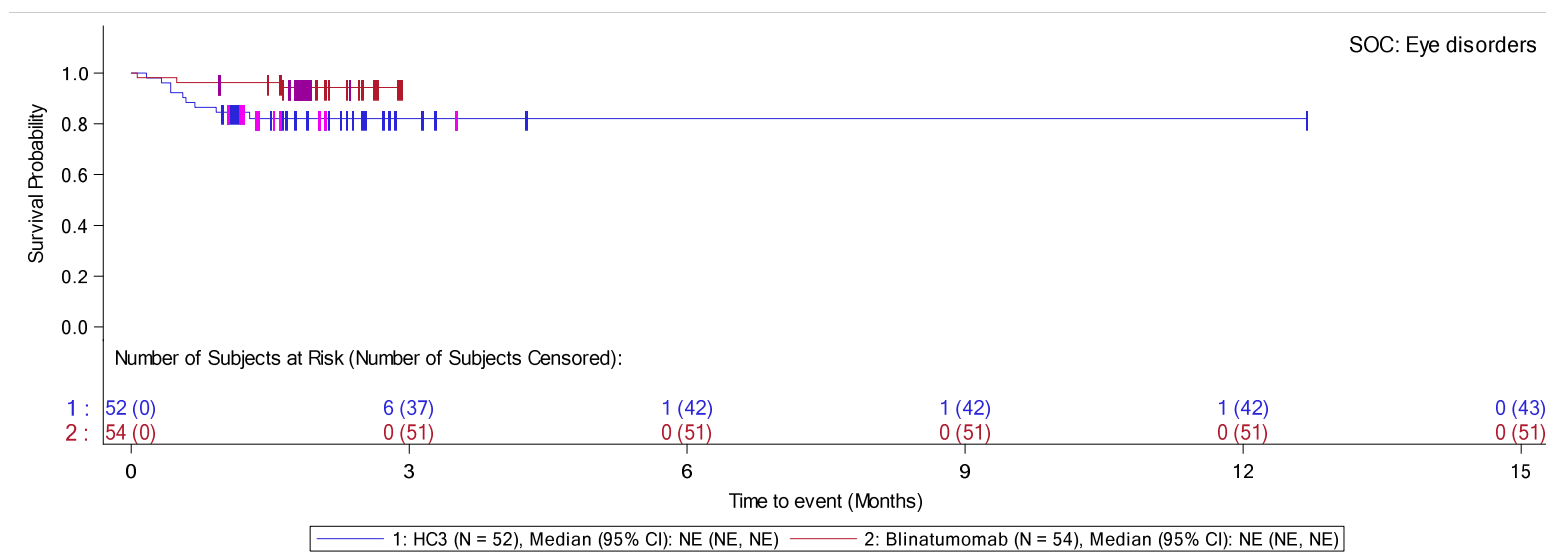
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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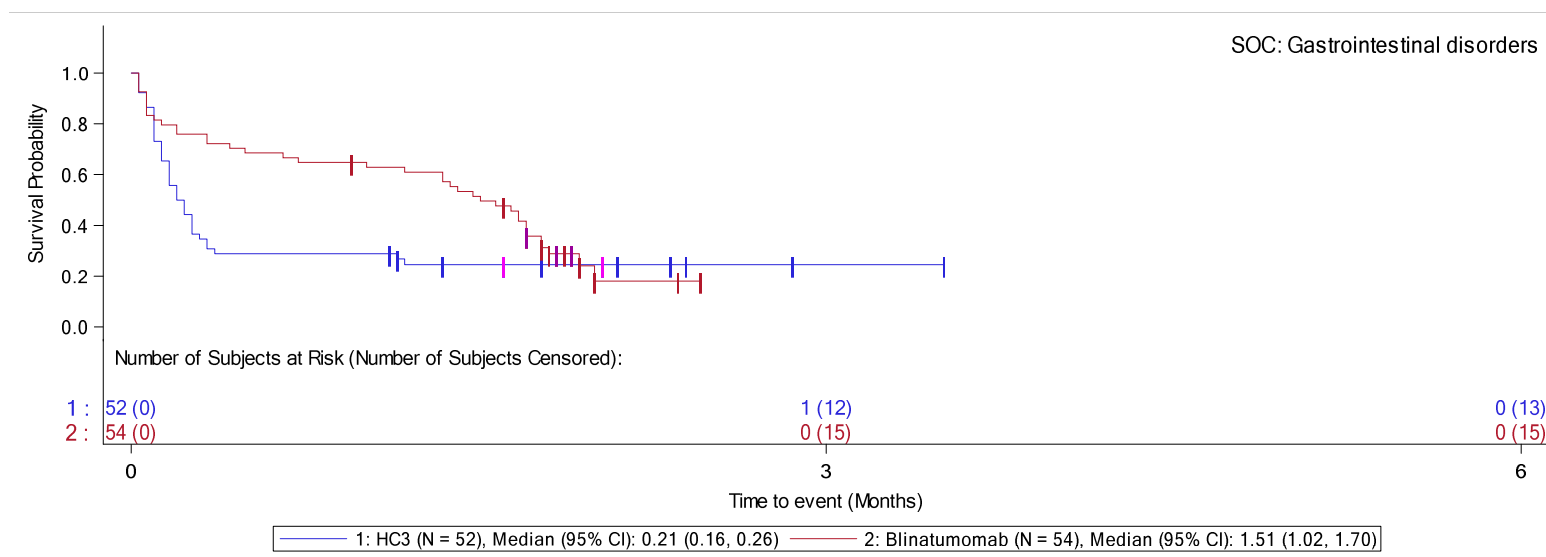
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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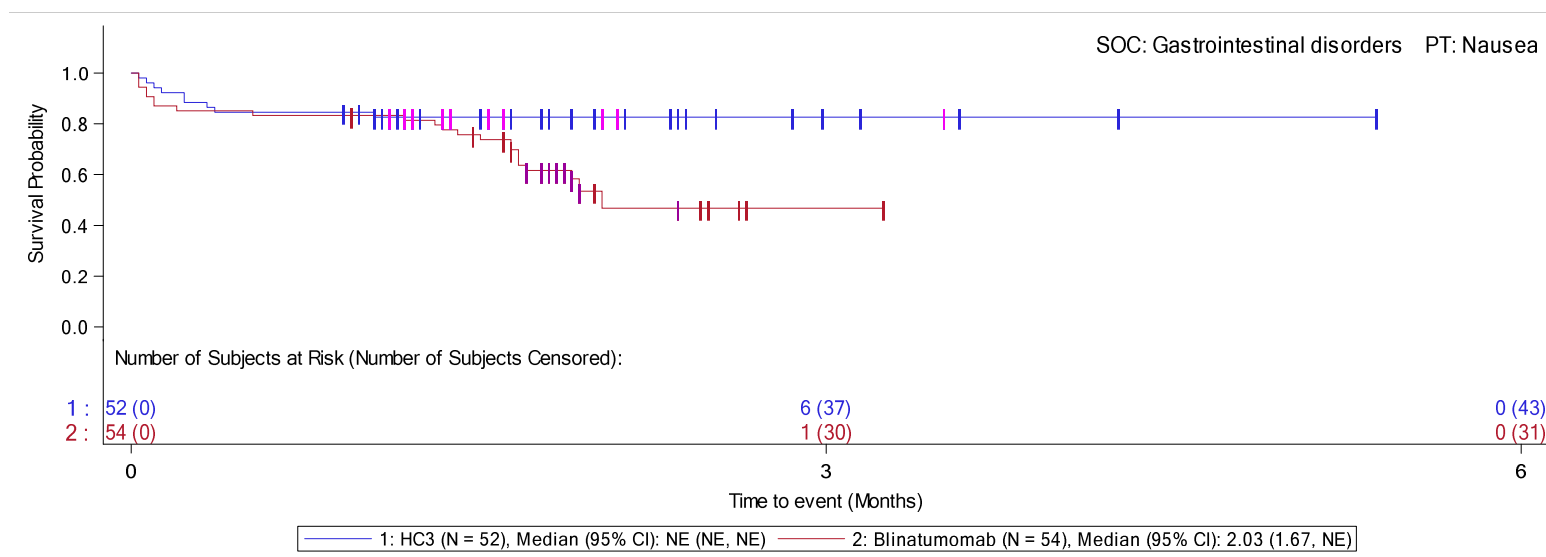
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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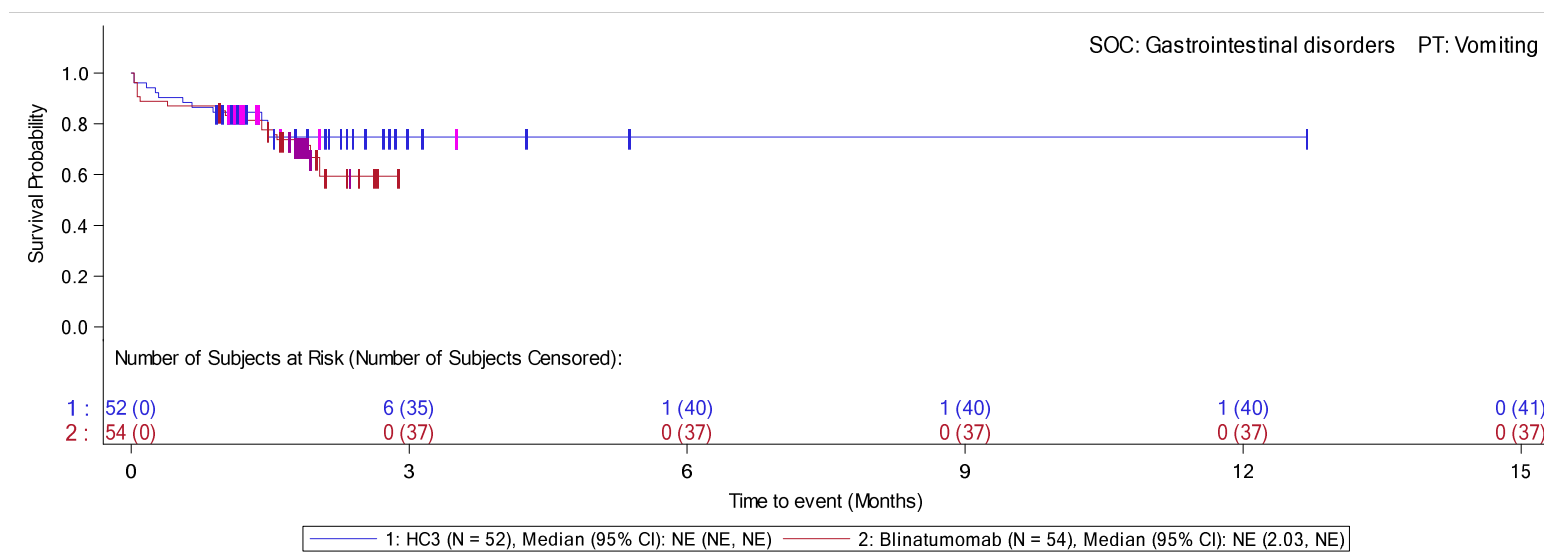
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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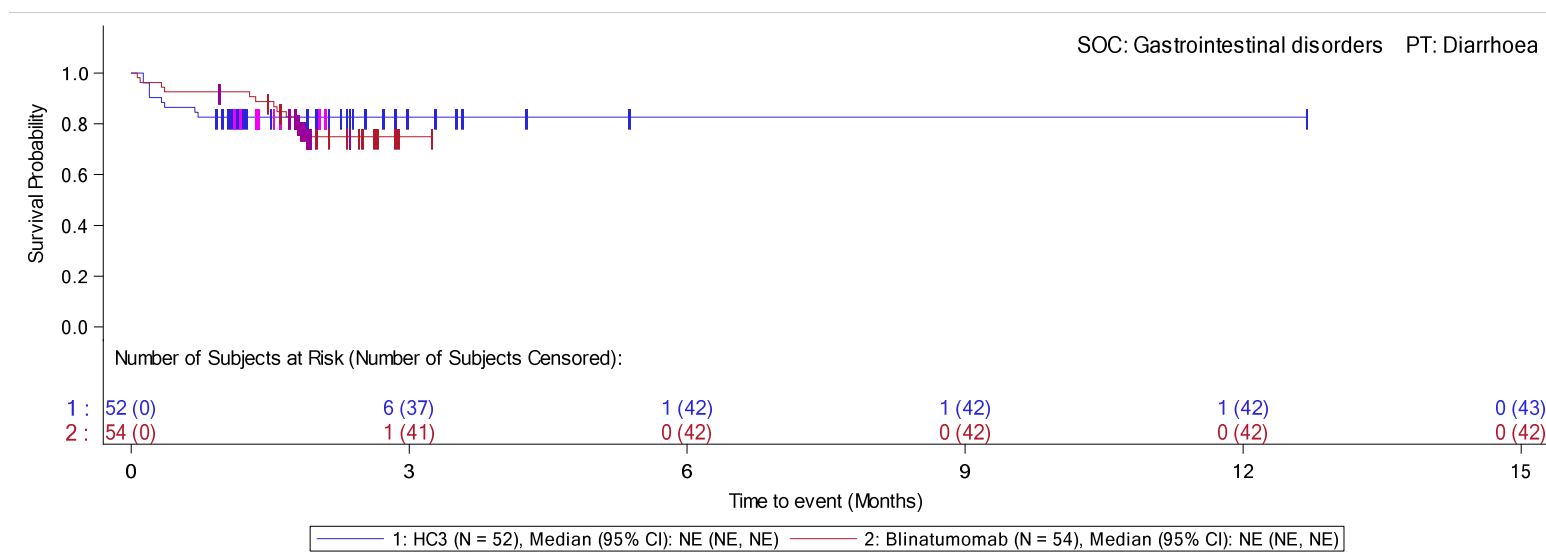
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
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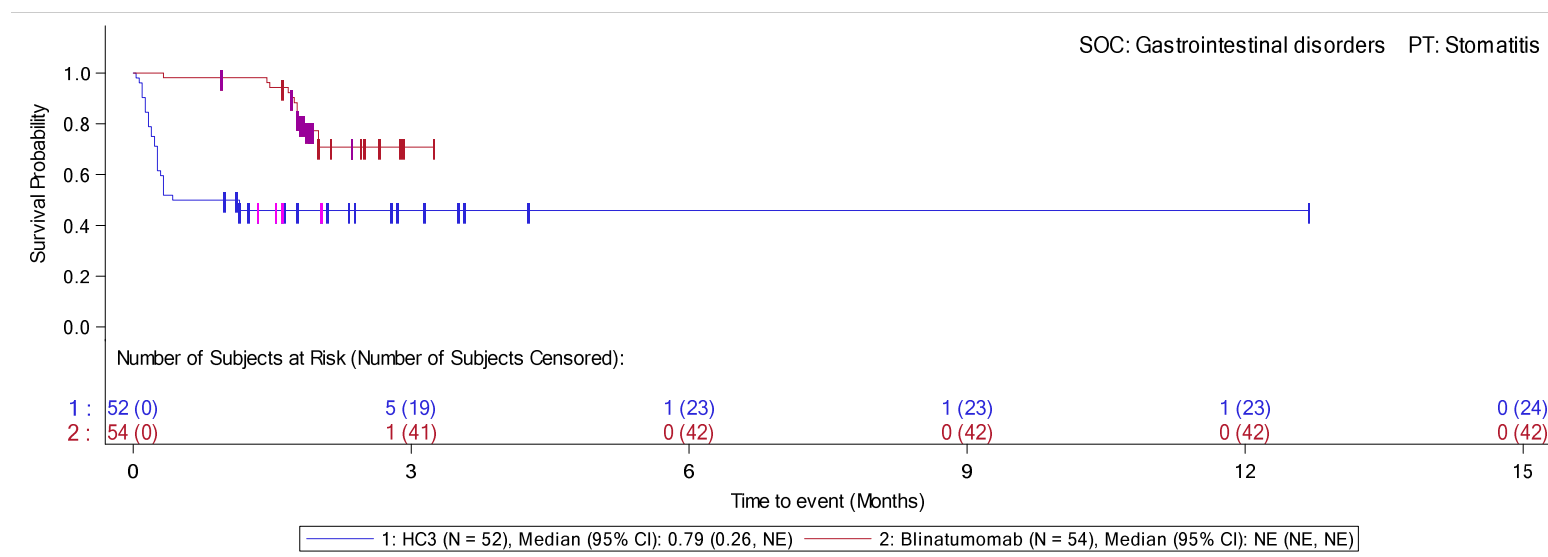
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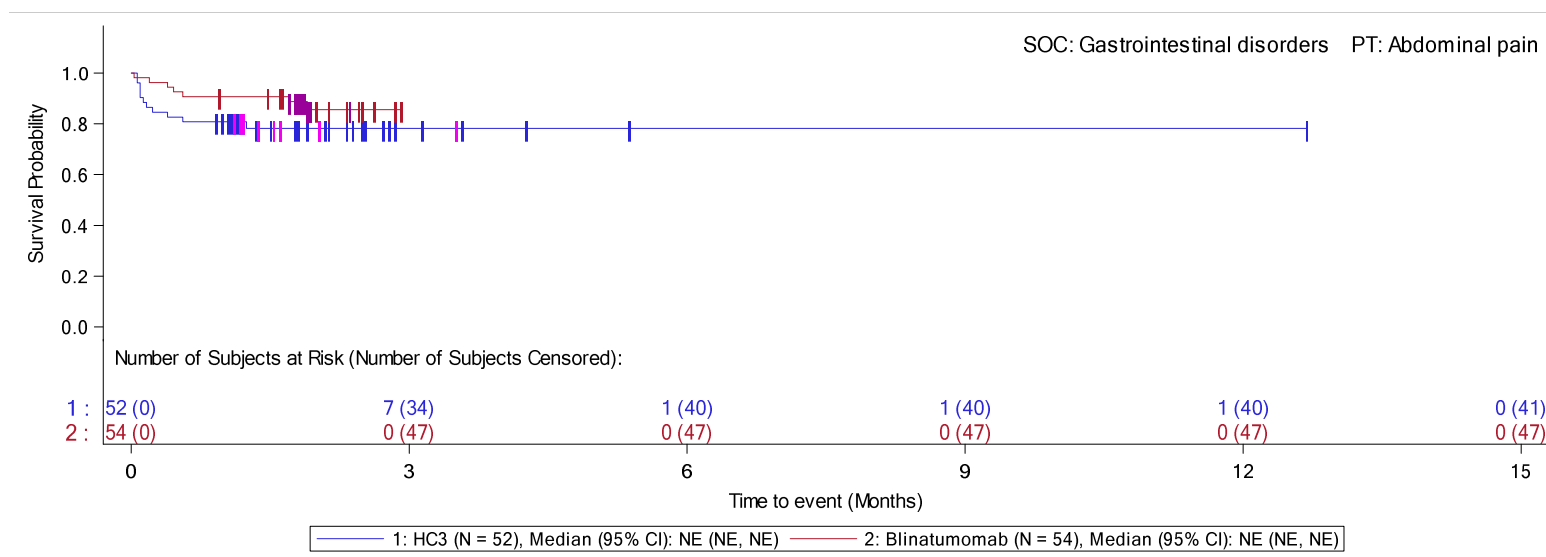
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
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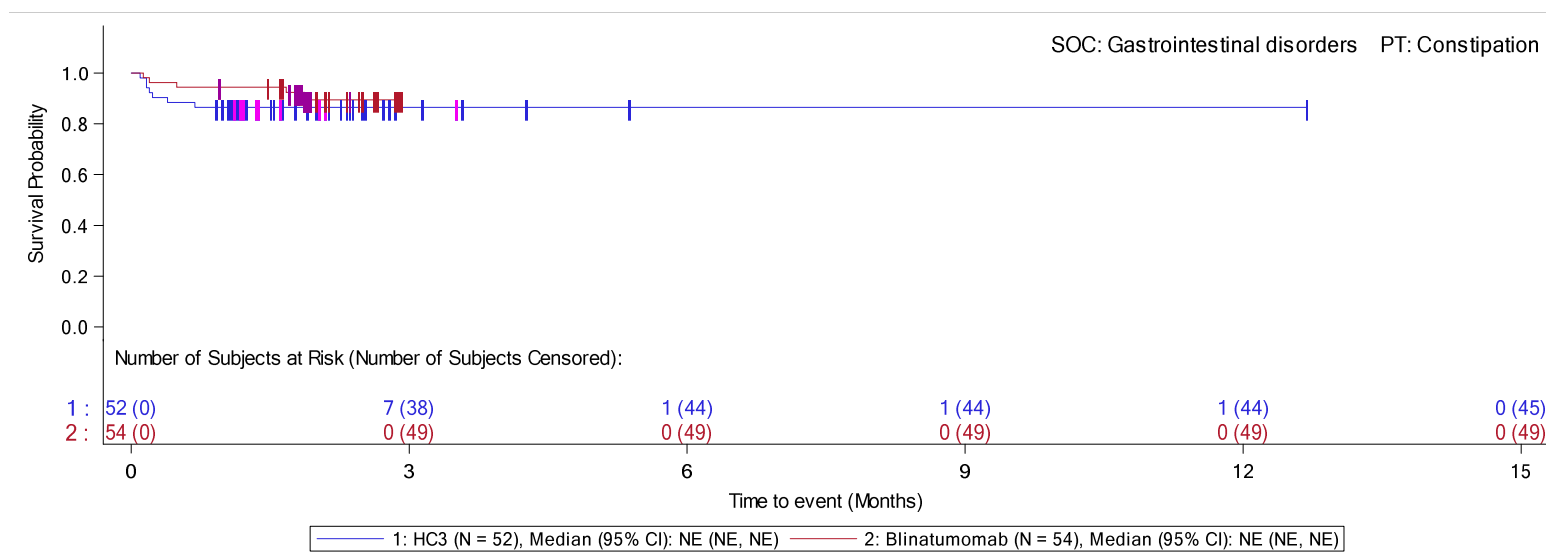
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
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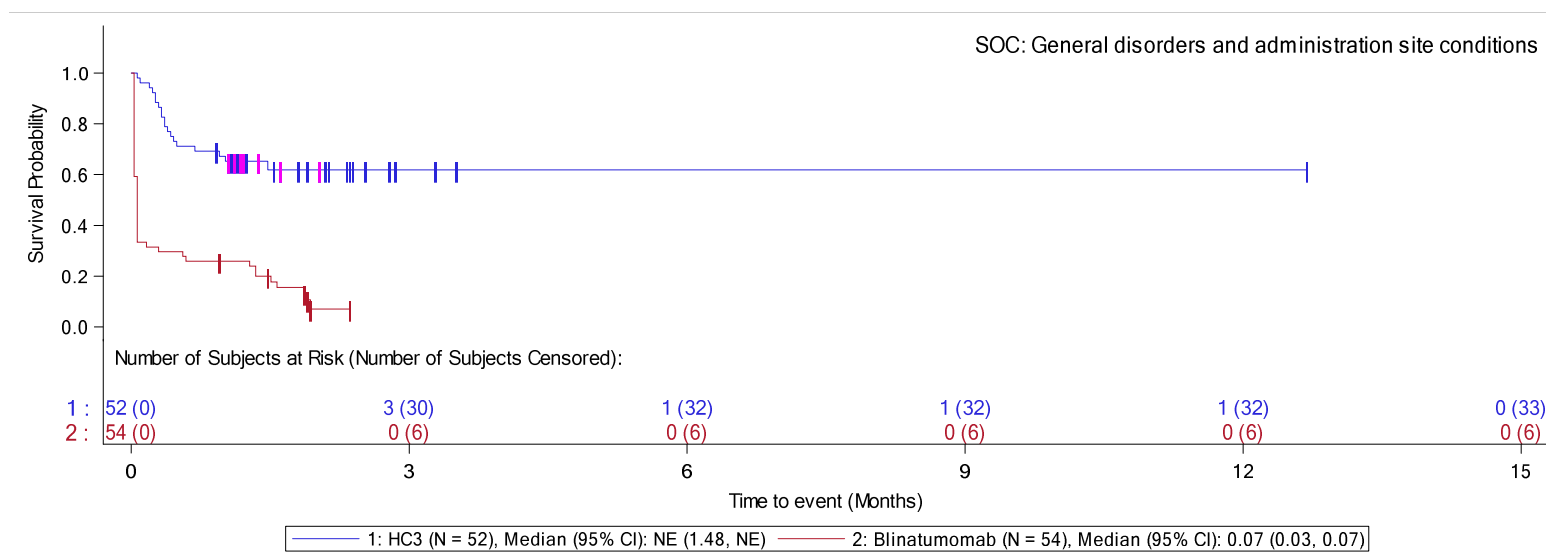
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-teae-soc-pt-saf.sas
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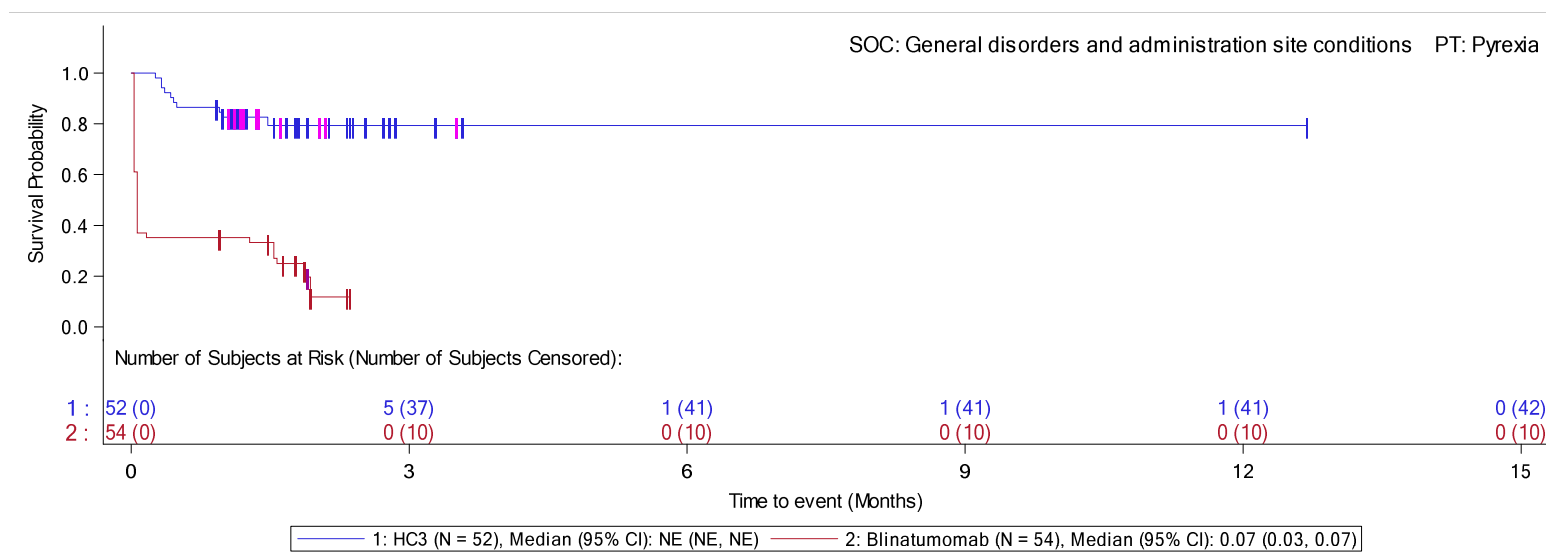
Figure 14-6.1.12. Kaplan-Meier plot for Time to First Onset of Any Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



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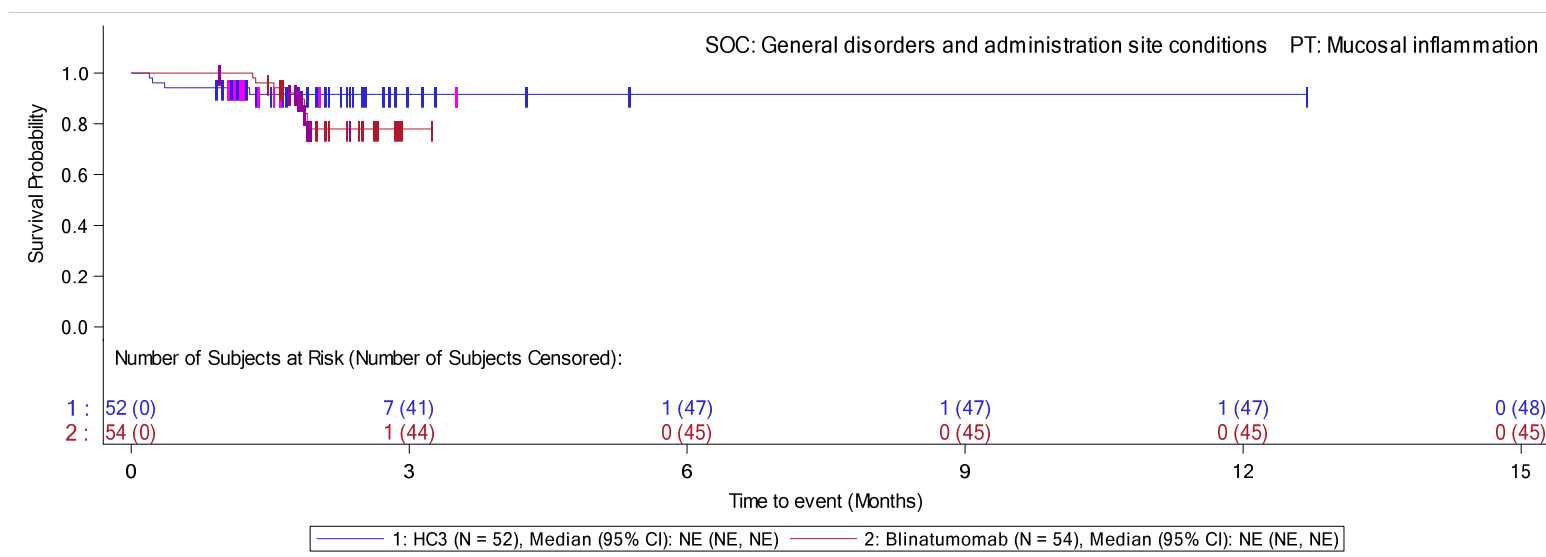
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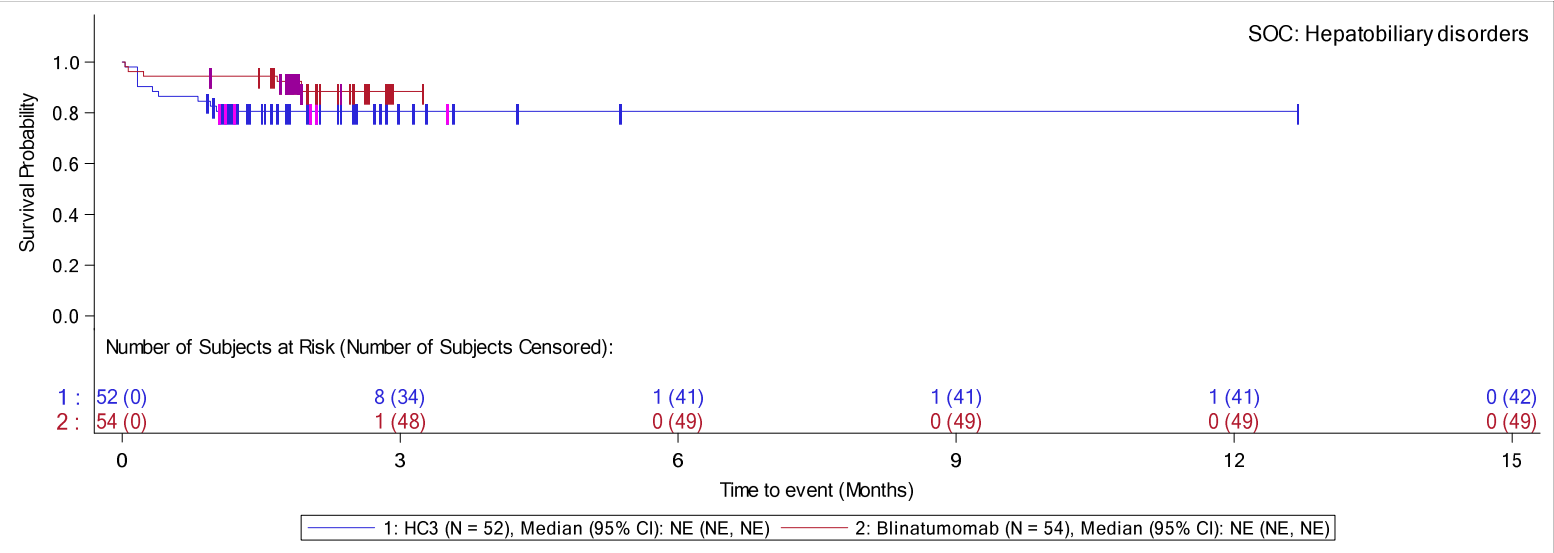
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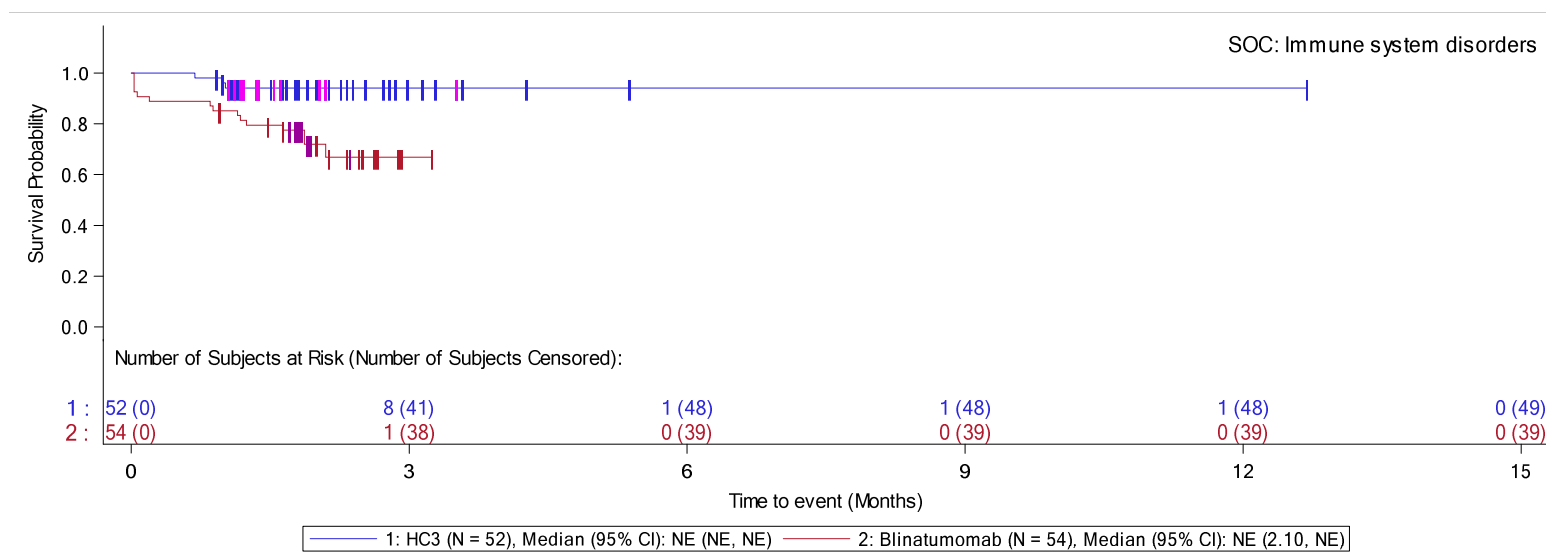
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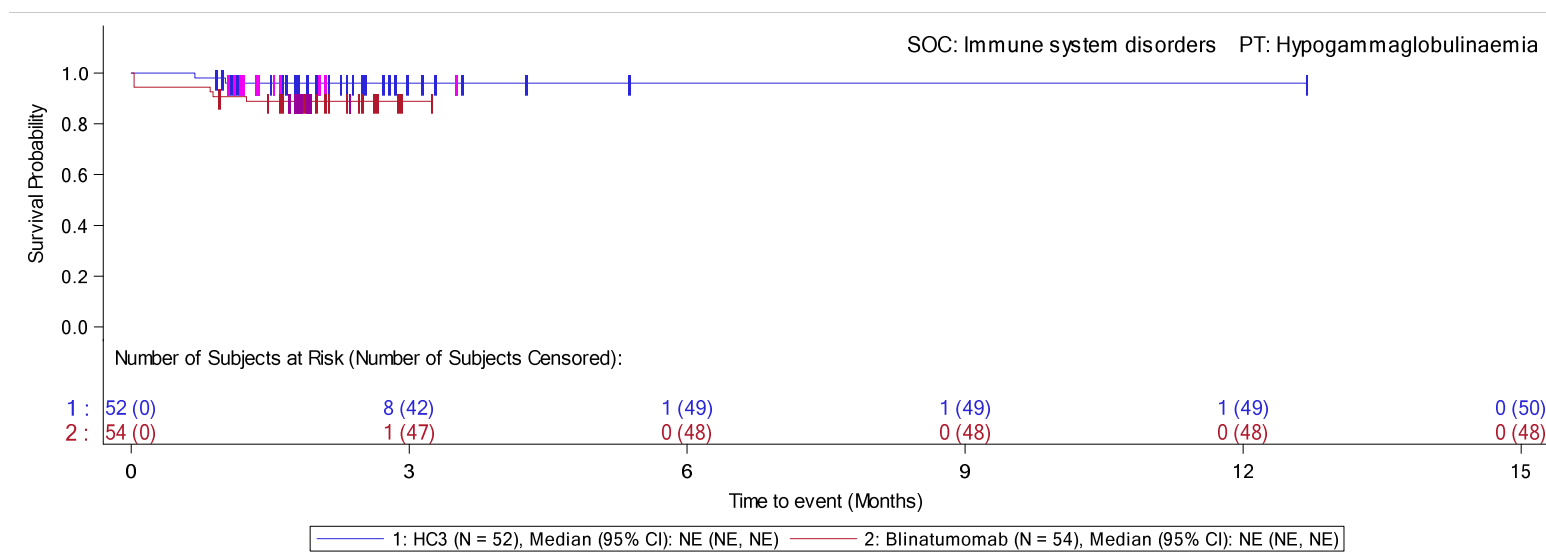
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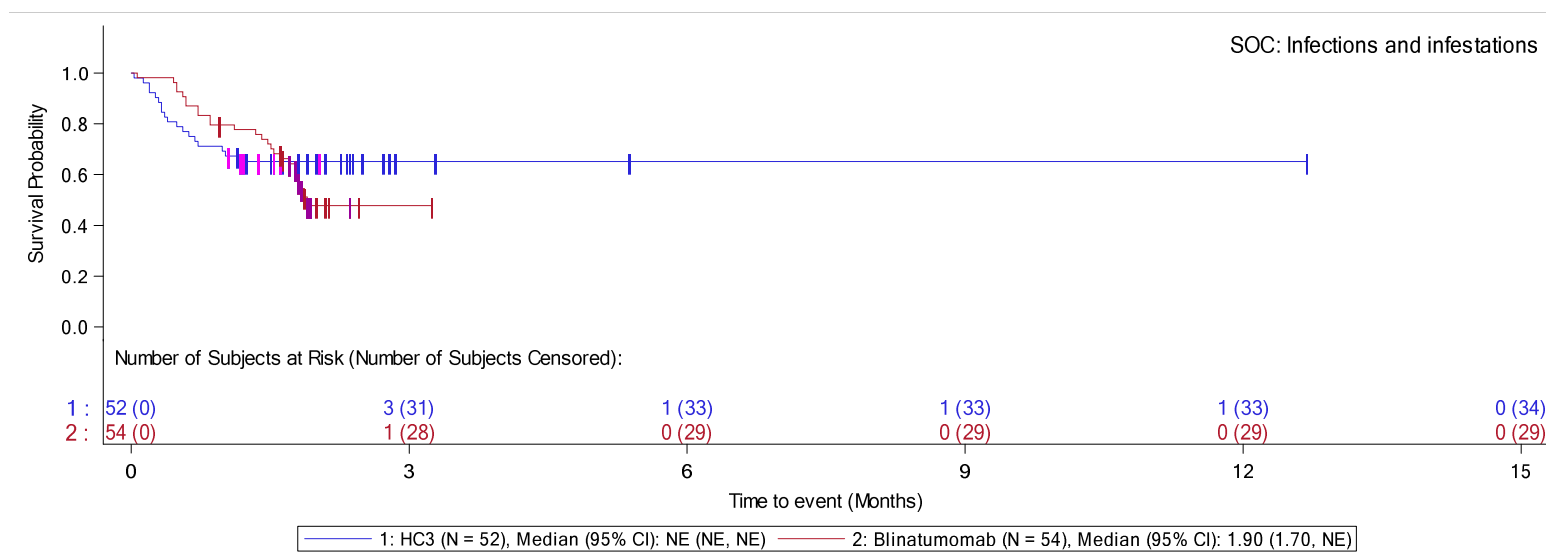
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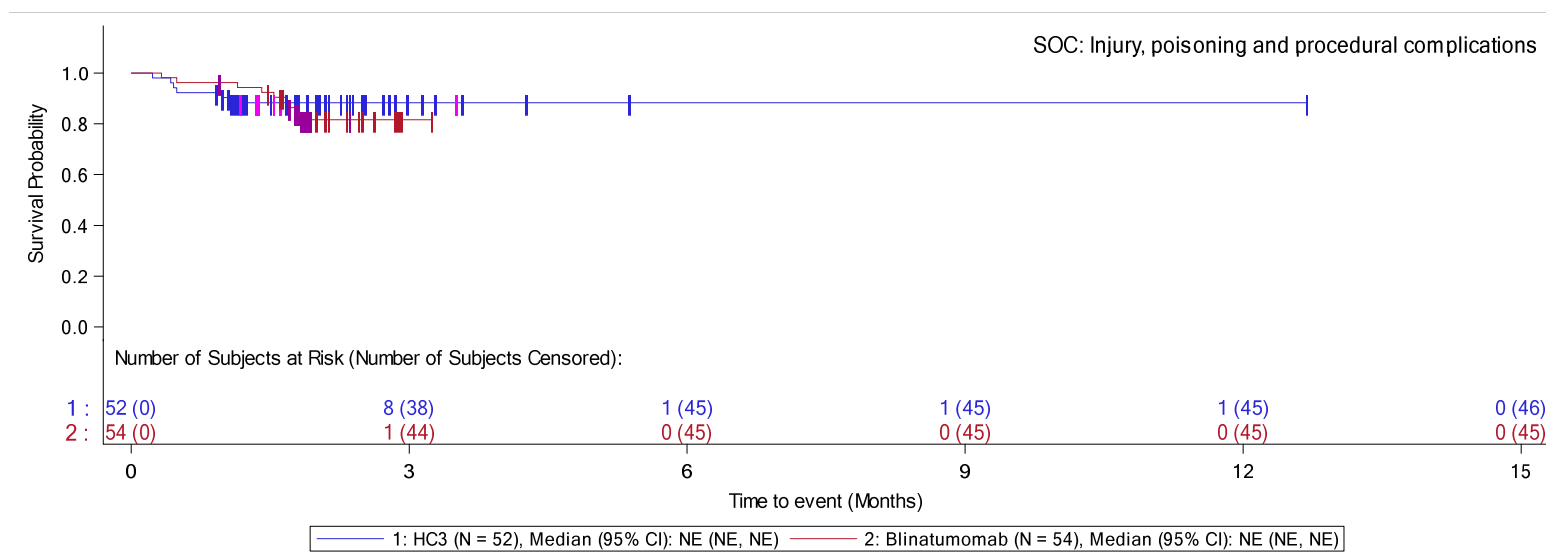
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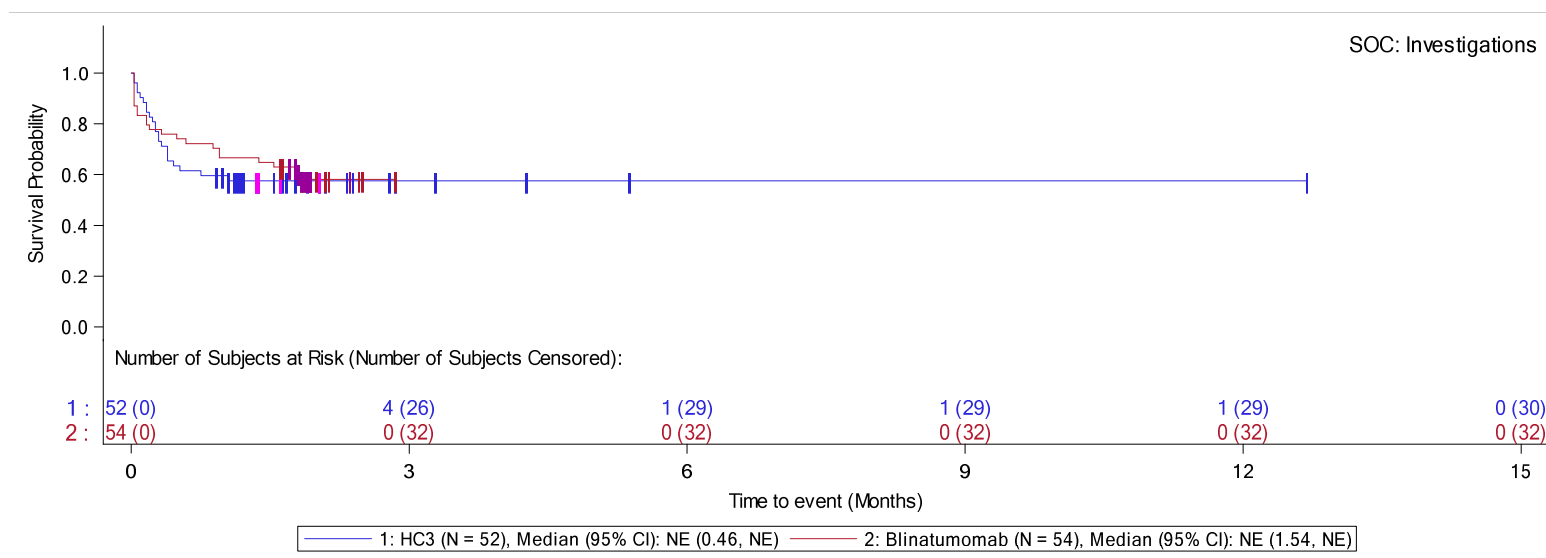
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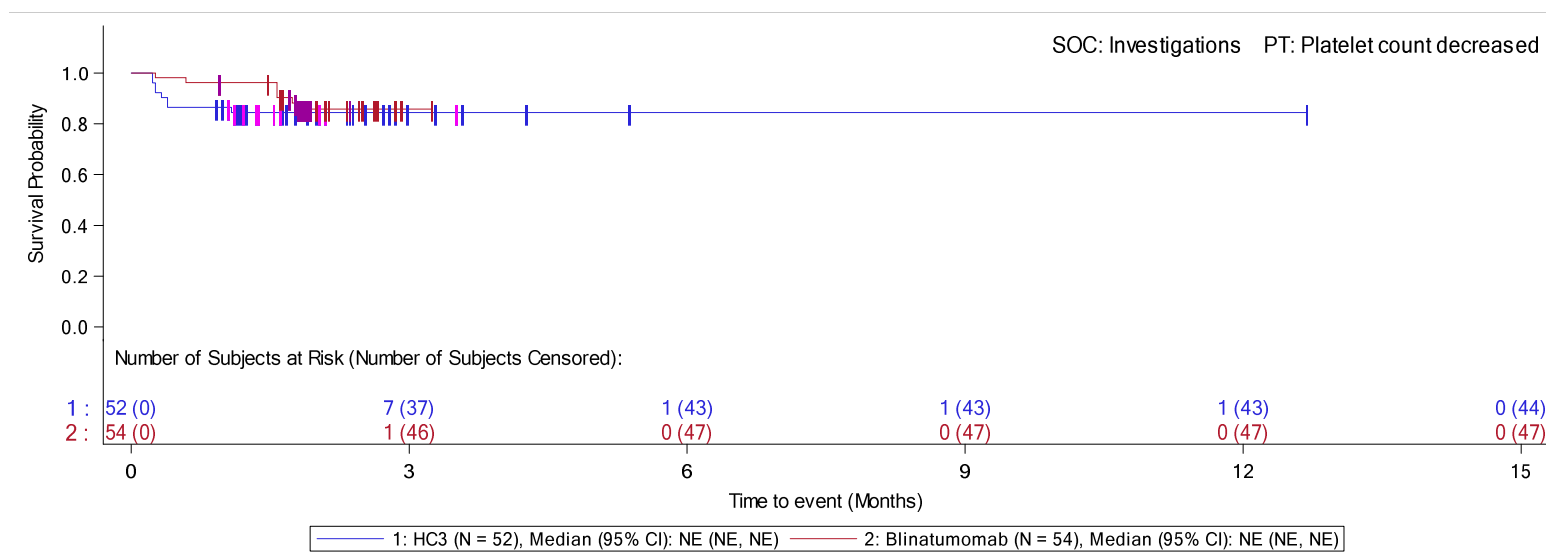
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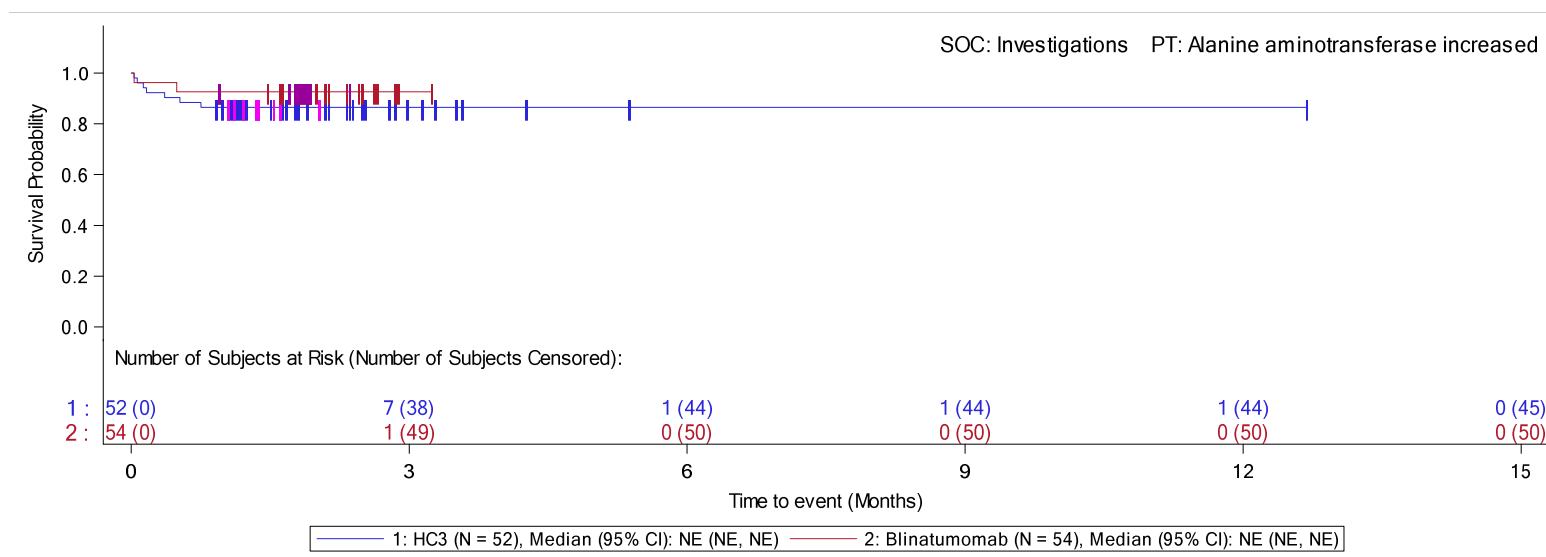
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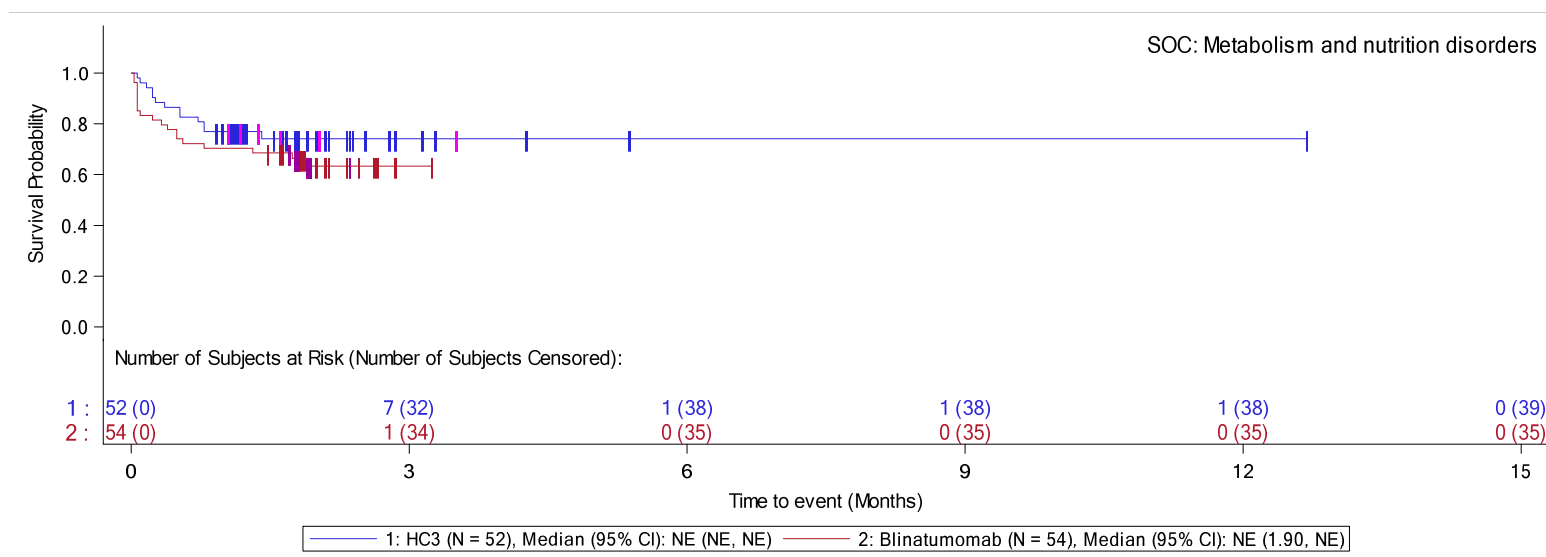
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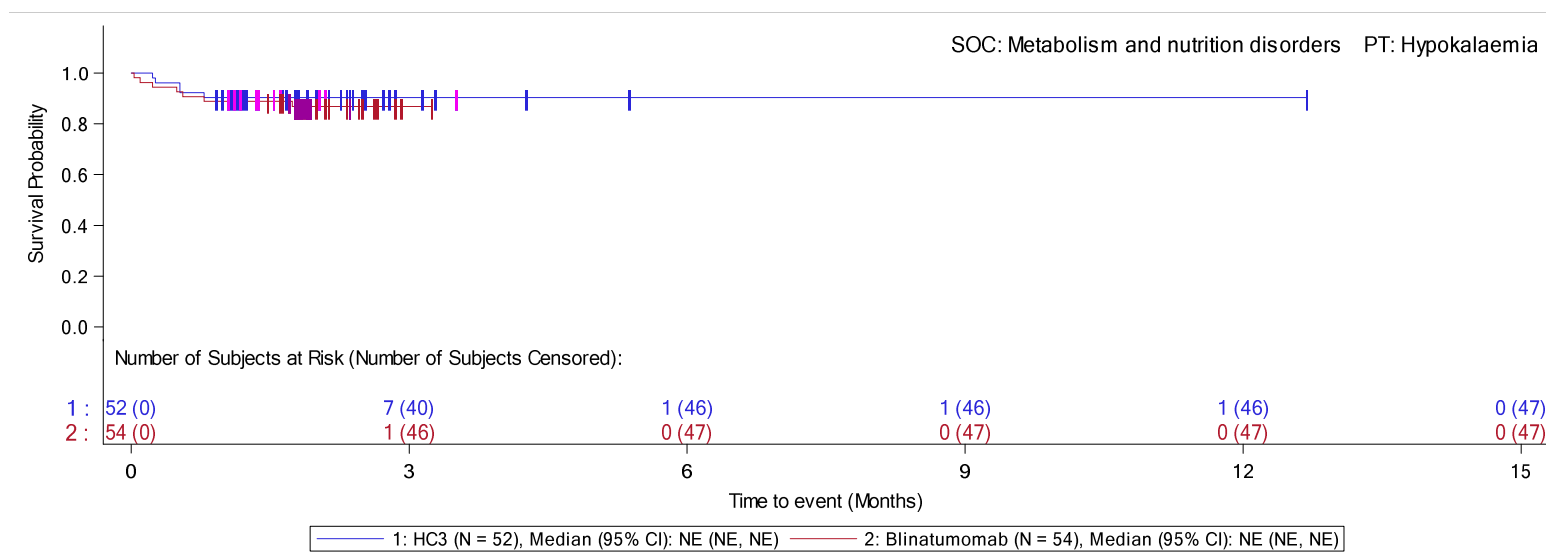
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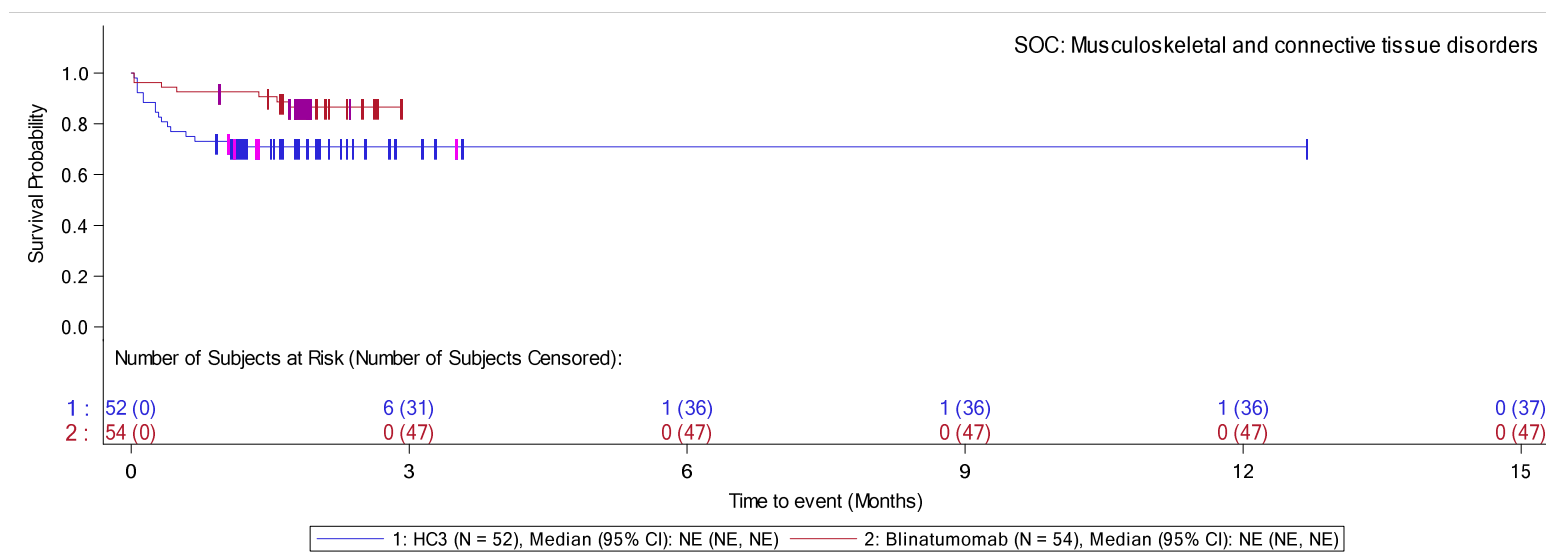
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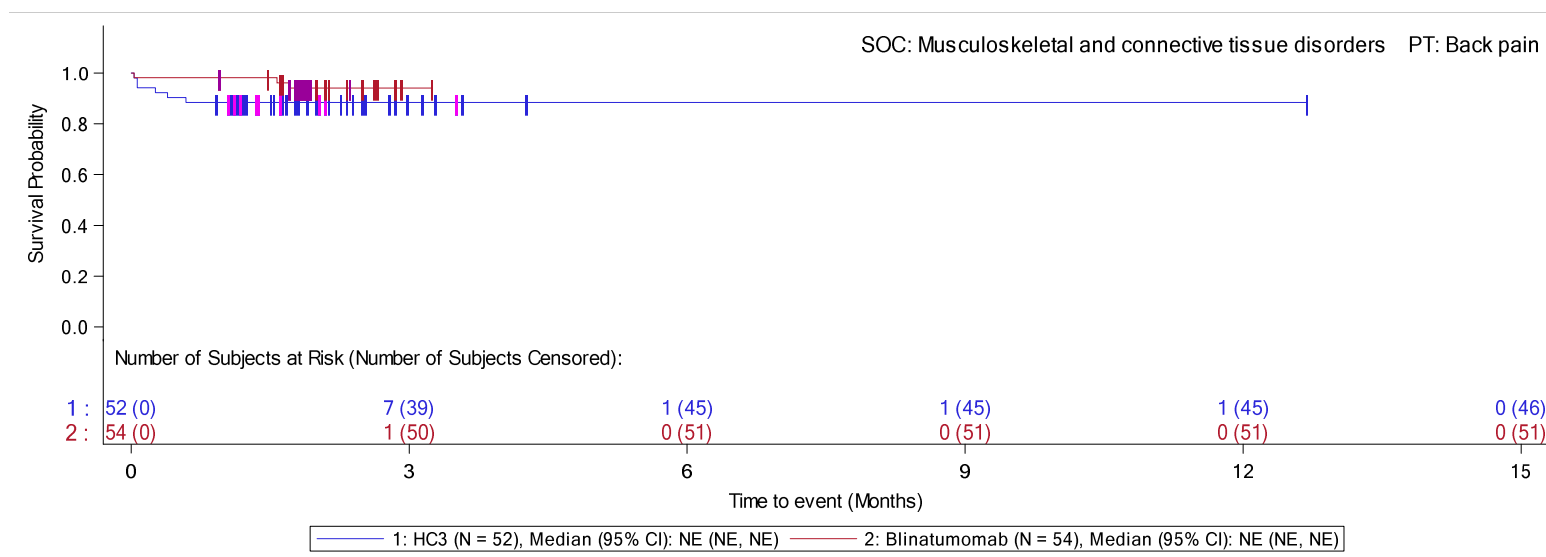
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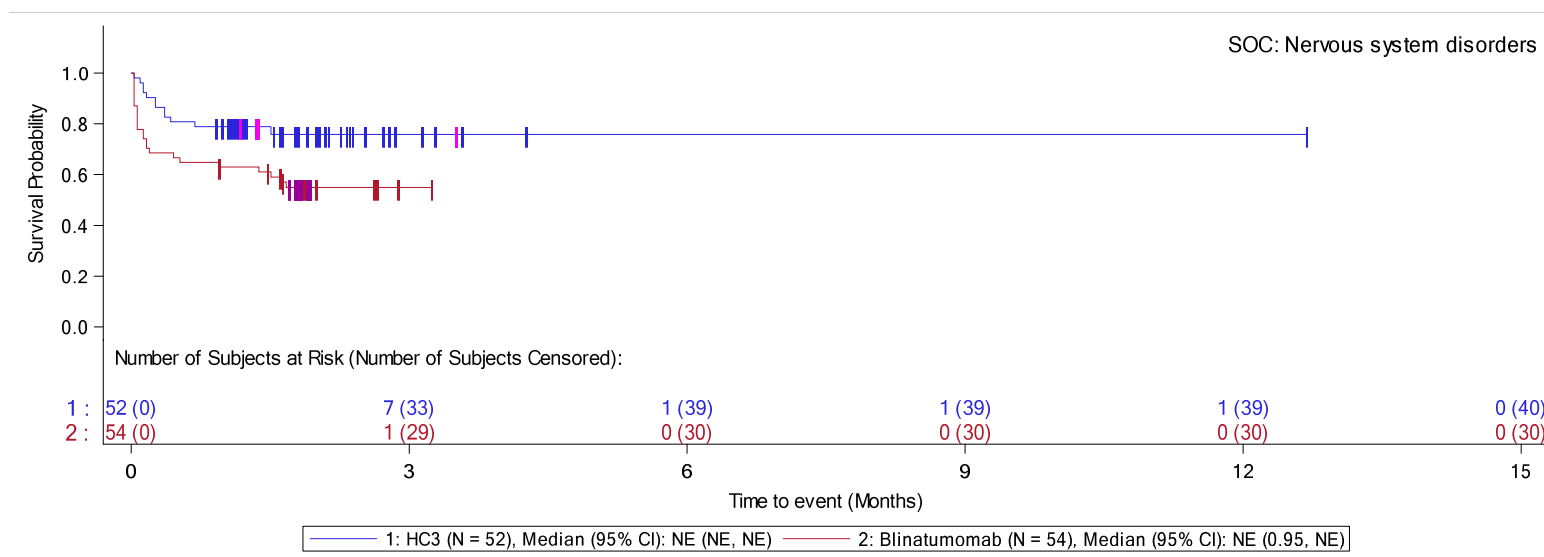
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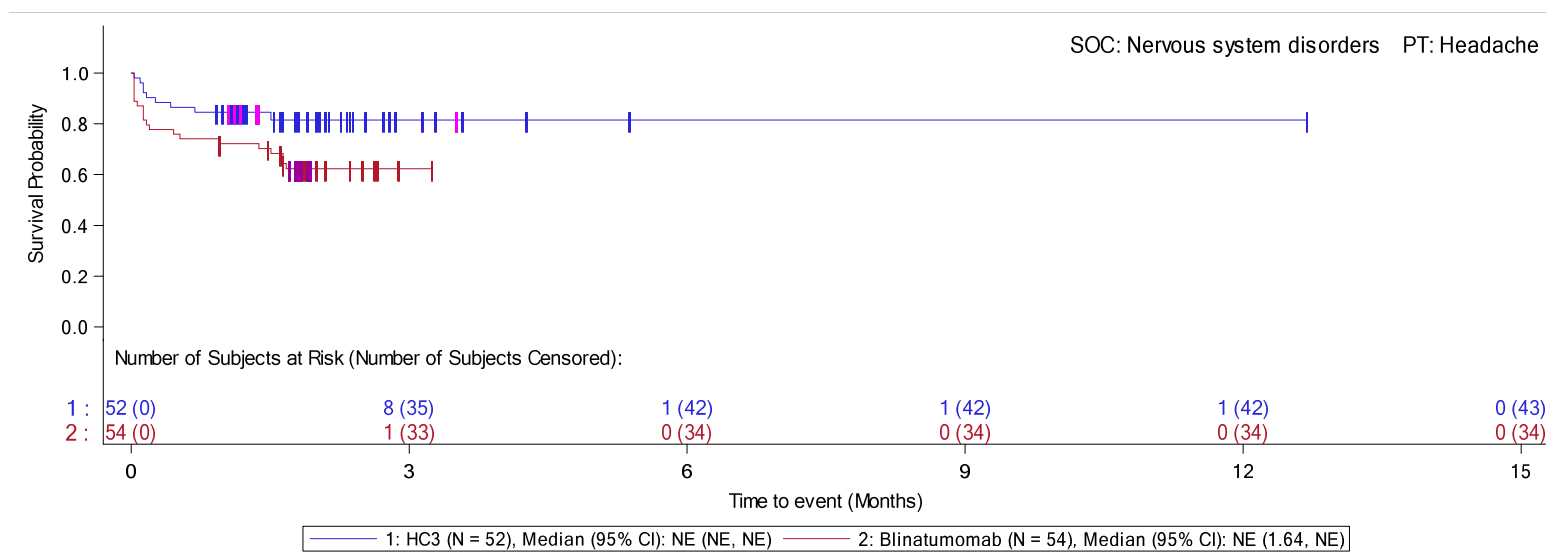
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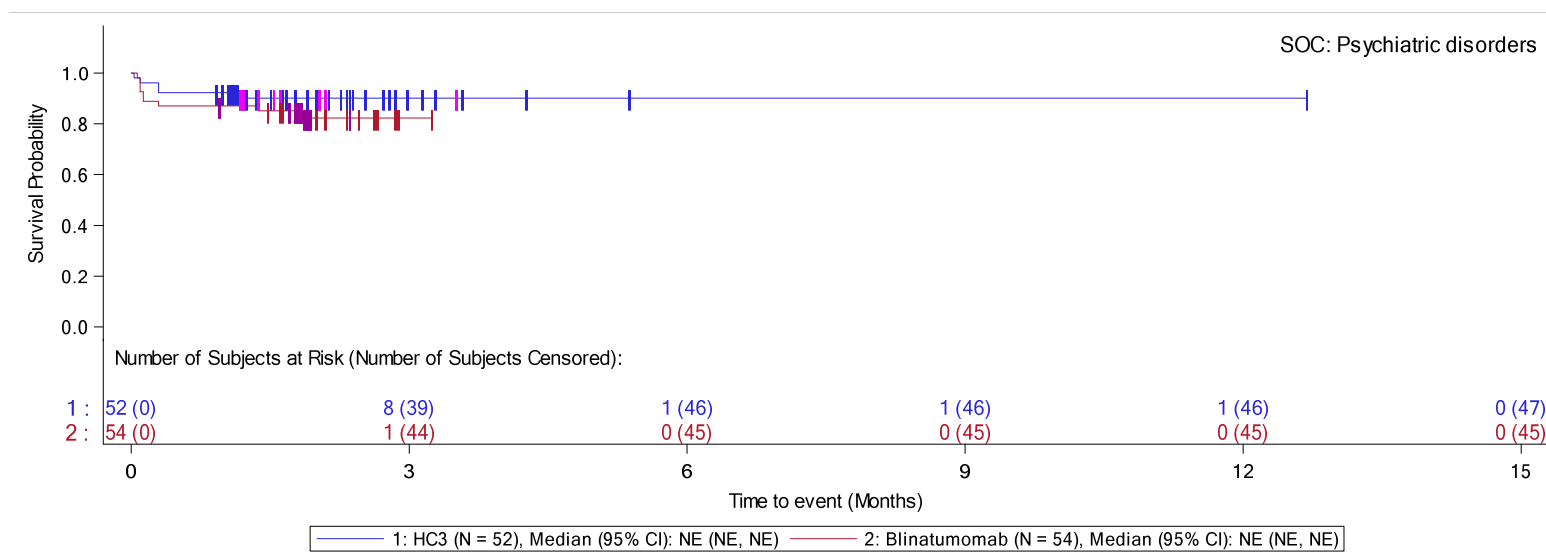
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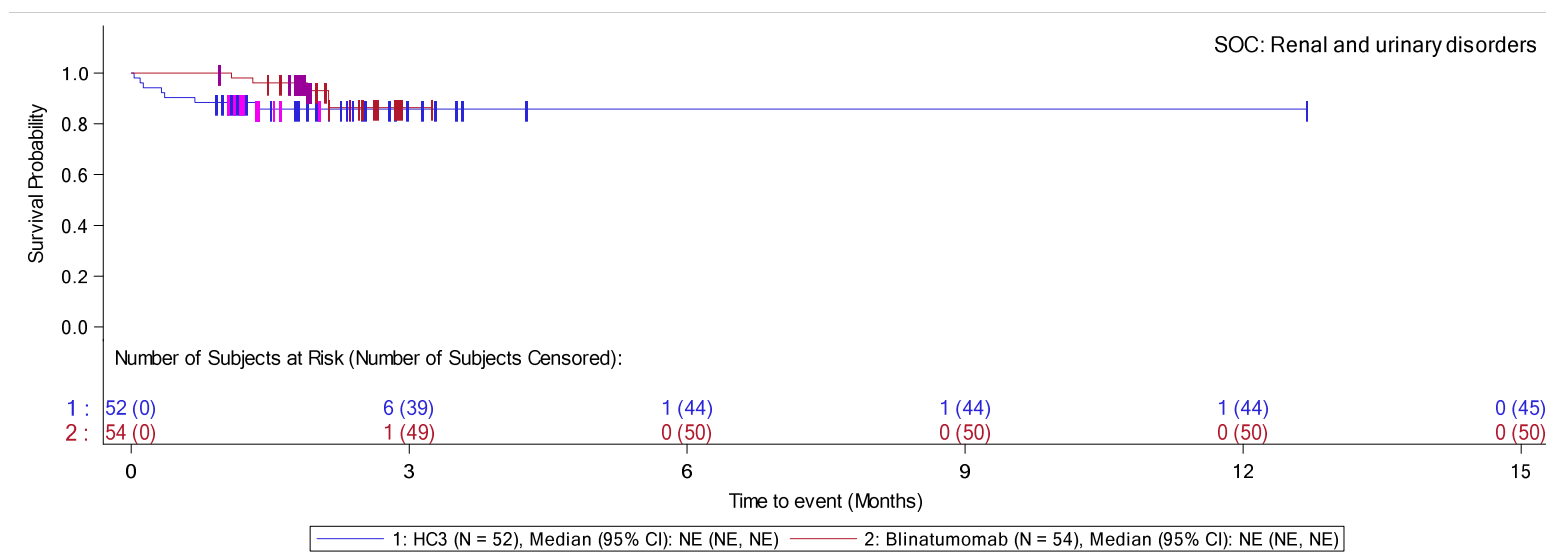
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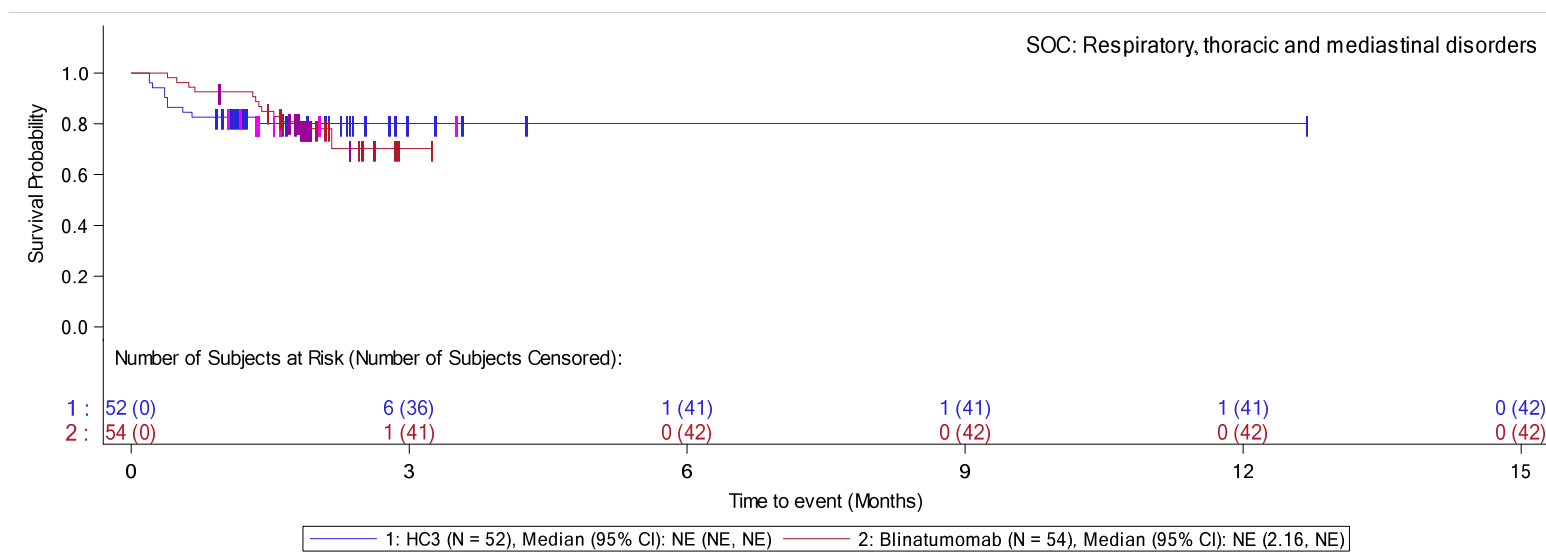
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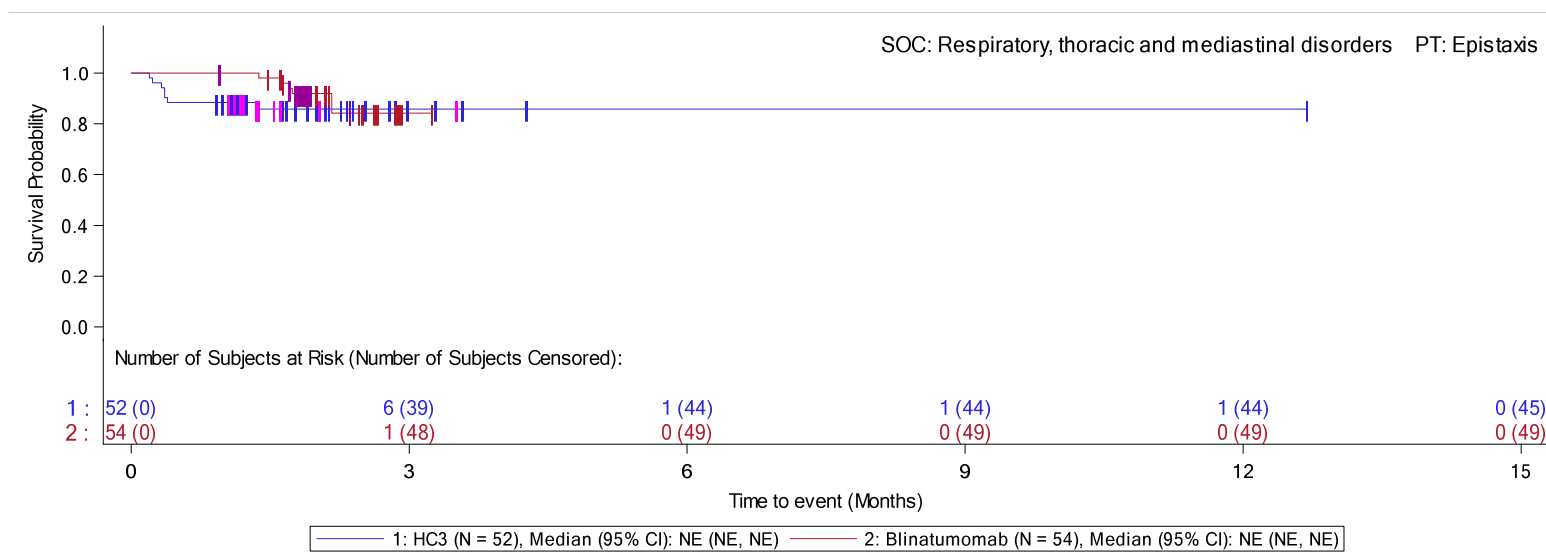
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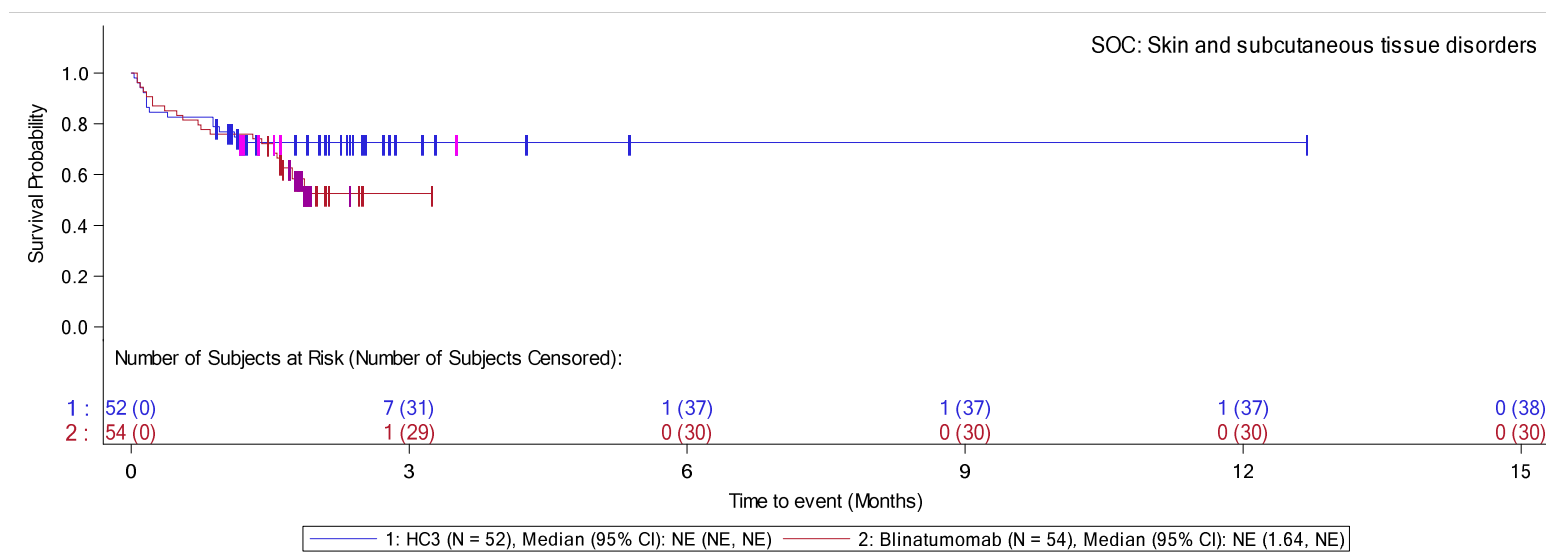
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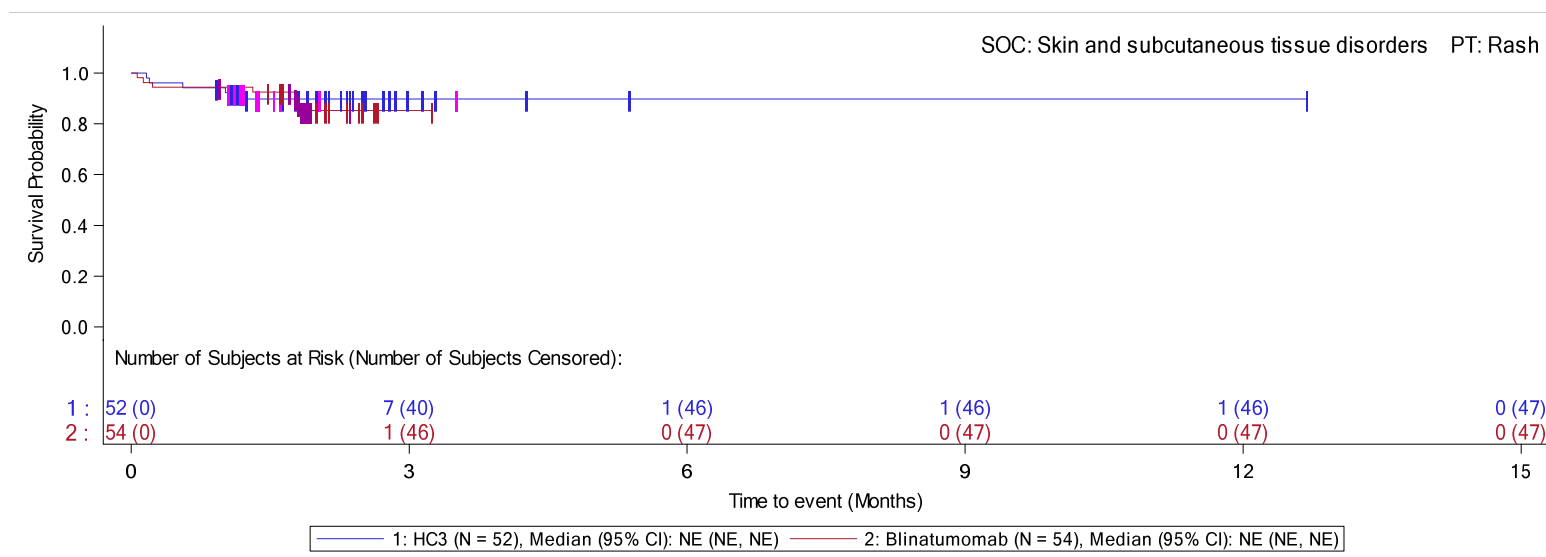
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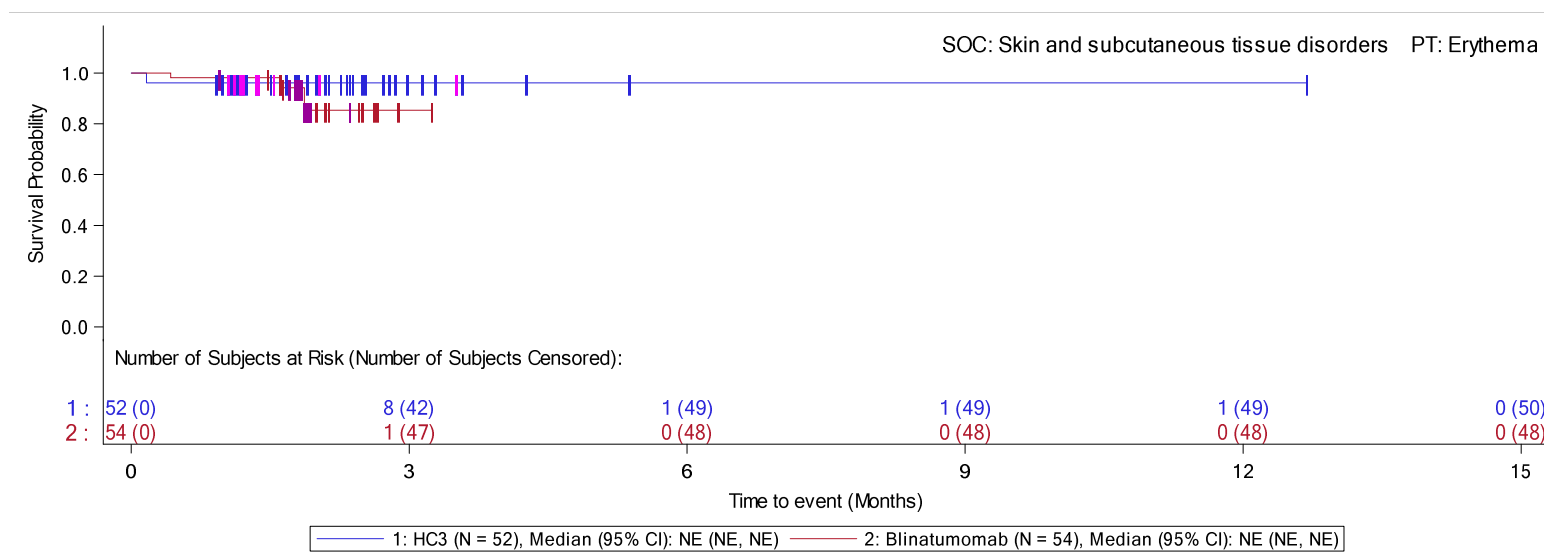
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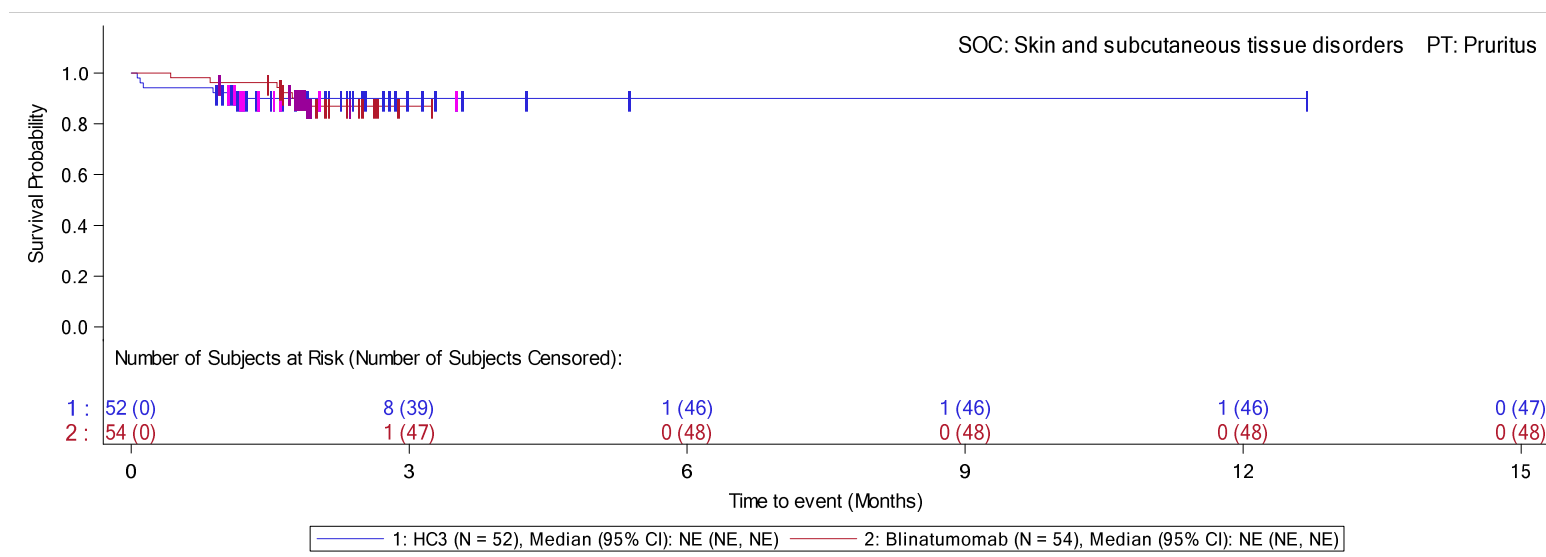
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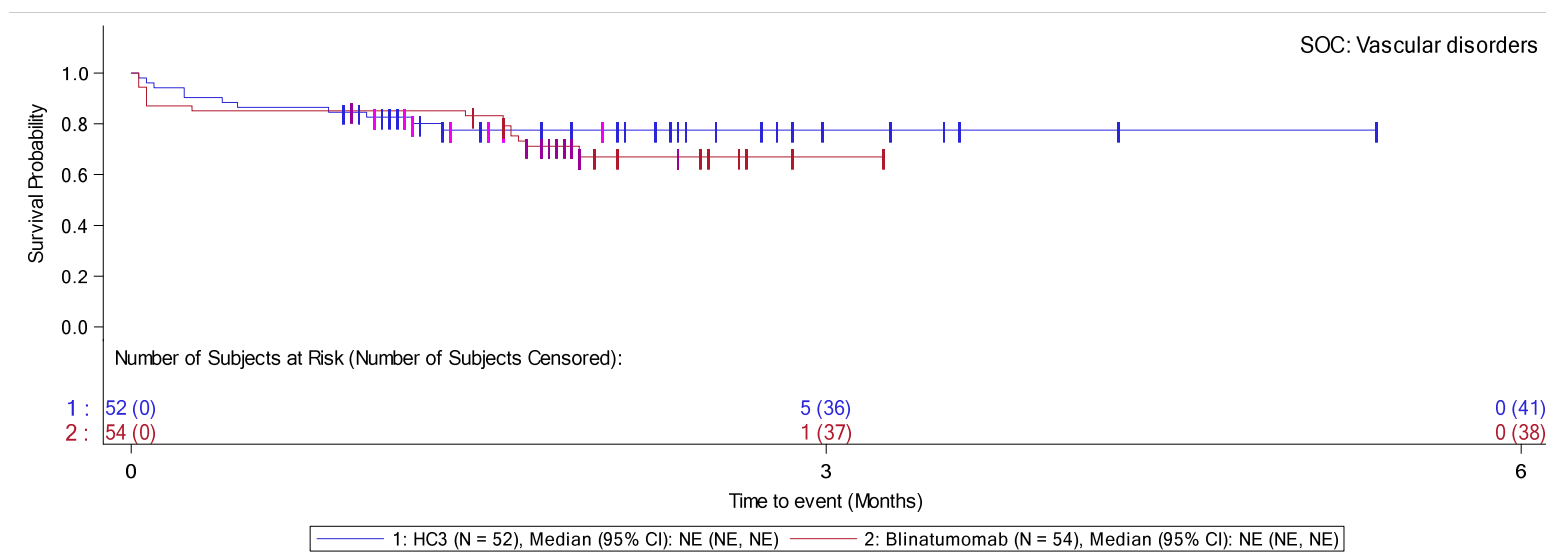
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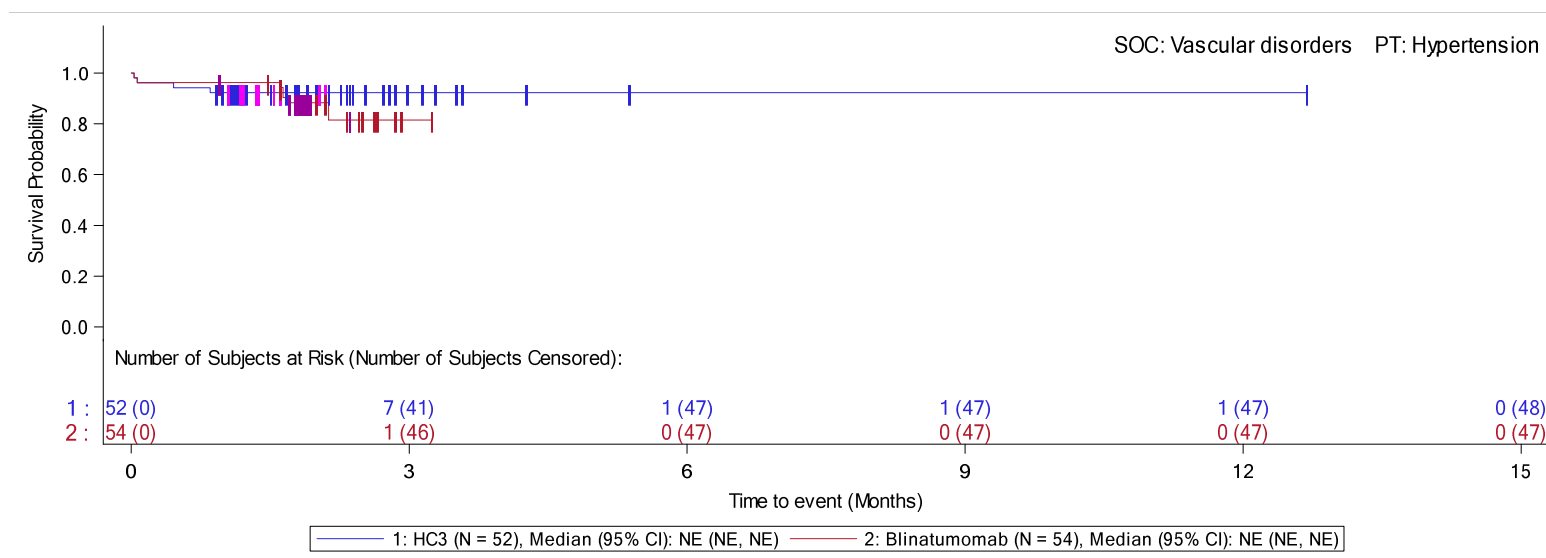
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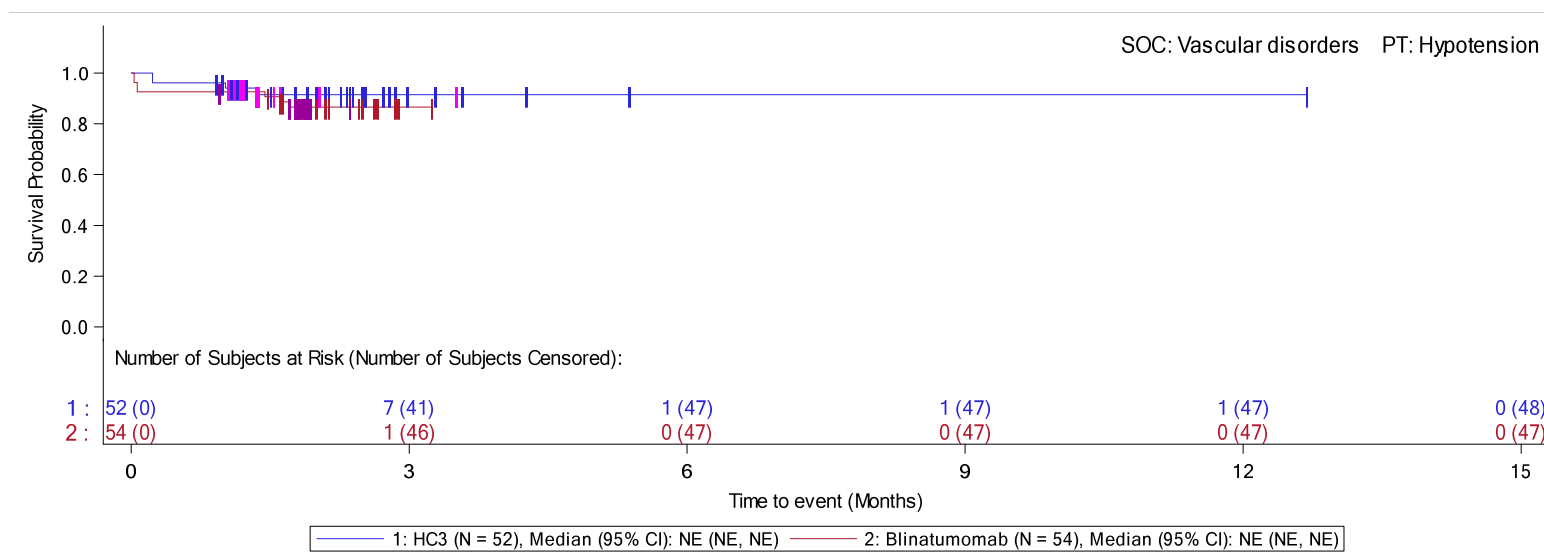
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Anhang 4-G2.7.6: Sicherheit: Häufige SUE nach SOC, PT

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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	13 (25.0)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-6.97
p-value			<0.0001
Stratified log-rank test ^c			
Normal score ^b			-6.86
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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.5	NE, NE	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-ser-teae-soc-pt-saf.sas

Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	9 (17.3)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-4.75
p-value			0.0014
Stratified log-rank test ^c			
Normal score ^b			-4.63
p-value			0.0019

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.5	NE, NE	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-1.54
p-value			0.0747
Stratified log-rank test ^c			
Normal score ^b			-1.52
p-value			0.0770

Page 5 of 12

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.5	NE, NE	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-ser-teae-soc-pt-saf.sas

Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	1 (1.9)	
Unstratified log-rank test			
Normal score ^b			-0.94
p-value			0.3431
Stratified log-rank test ^c			
Normal score ^b			-1.11
p-value			0.2665

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	2.0, 2.0	
Unstratified hazard ratio ^e			0.35
(95% CI)			(0.04, 3.39)
p-value			0.3646
Stratified hazard ratio ^{c,e}			0.30
(95% CI)			(0.03, 2.87)
p-value			0.2952

Page 8 of 12

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			-1.50
p-value			0.3376
Stratified log-rank test ^c			
Normal score ^b			-1.51
p-value			0.3326

Page 9 of 12

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.6, 1.8	
Unstratified hazard ratio ^e			0.54
(95% CI)			(0.15, 1.93)
p-value			0.3450
Stratified hazard ratio ^{c,e}			0.54
(95% CI)			(0.15, 1.92)
p-value			0.3400

Page 10 of 12

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-ser-teae-soc-pt-saf.sas

Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	5 (9.3)	
Unstratified log-rank test			
Normal score ^b			1.99
p-value			0.1013
Stratified log-rank test ^c			
Normal score ^b			1.83
p-value			0.1204

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:18) Source data: a215up.adsl, a215.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)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.7	0.1, 0.2	
Unstratified hazard ratio ^e			5.05
(95% CI)			(0.59, 43.25)
p-value			0.1392
Stratified hazard ratio ^{c,e}			4.82
(95% CI)			(0.56, 41.74)
p-value			0.1529

Page 12 of 12

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

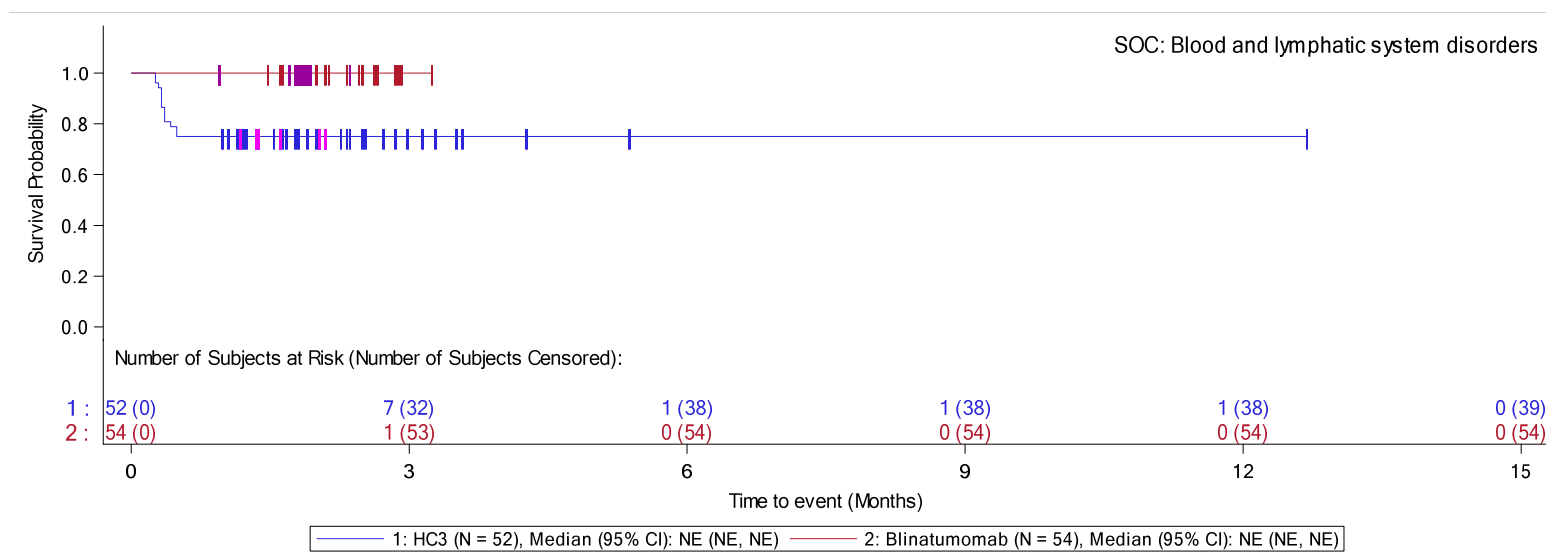
KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-ser-teae-soc-pt-saf.sas

Output: t14-06-001-013-tte-ser-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:18) Source data: a215up.adsl, a215.adae

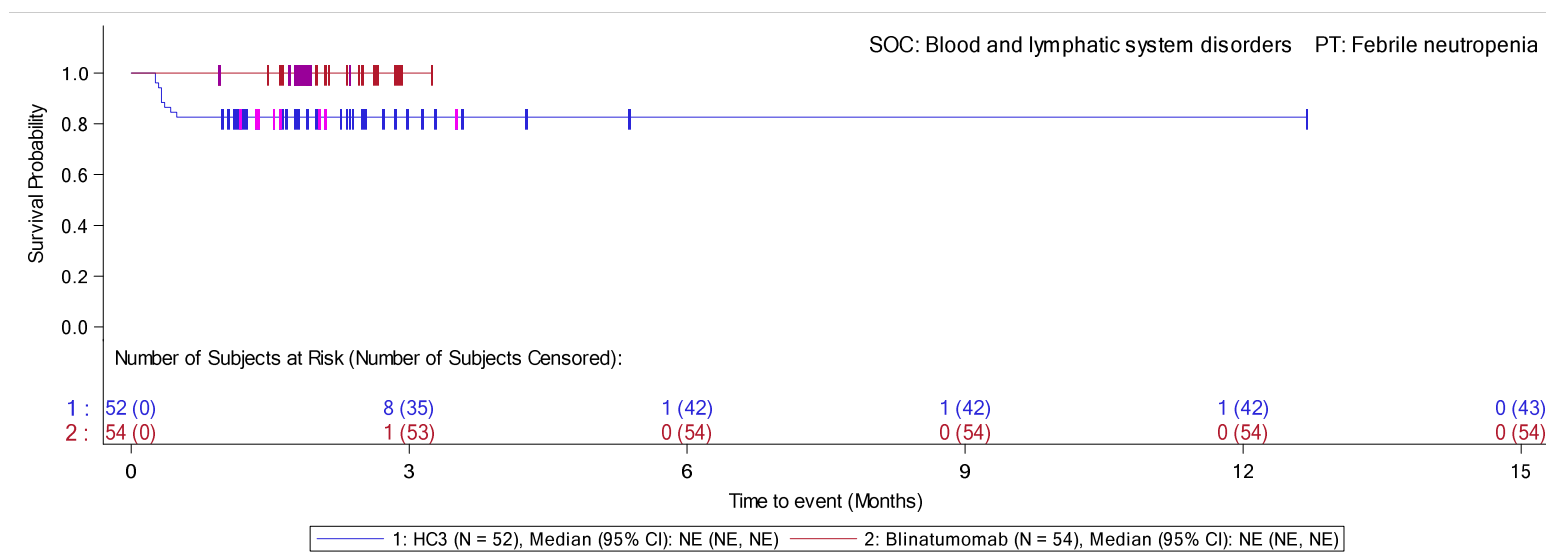
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:48) Source Data: a215up.adsl, outtab.t_saette_socpref

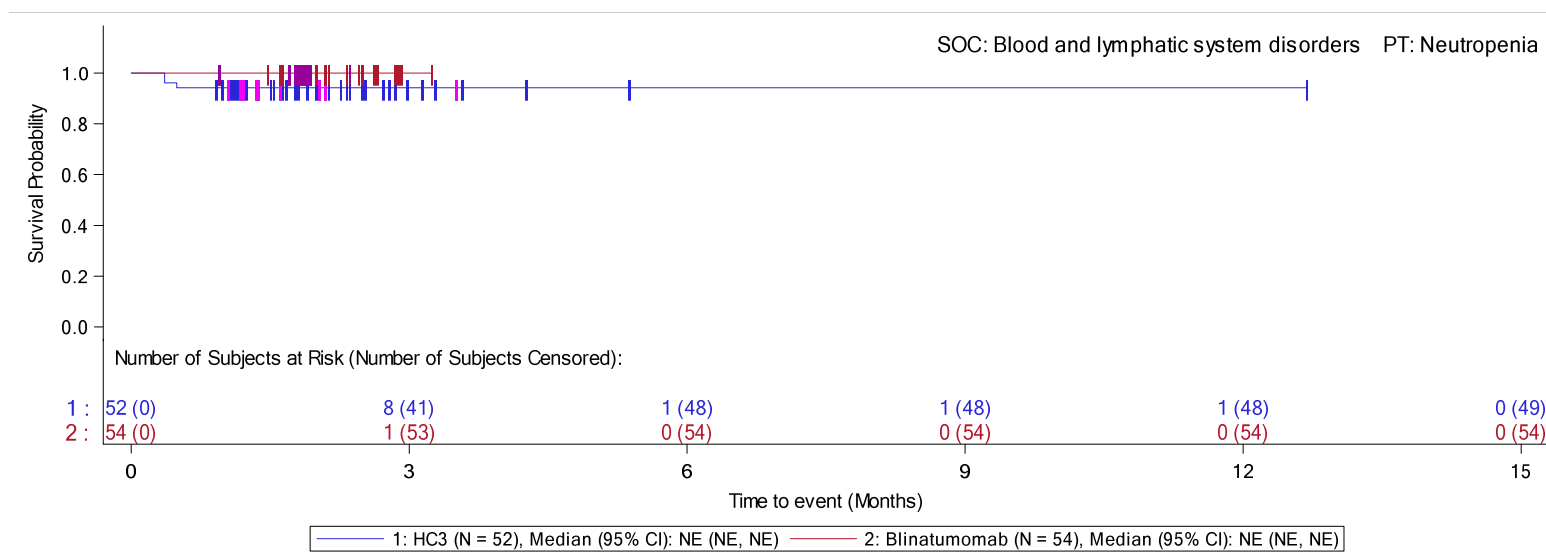
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:48) Source Data: a215up.adsl, outtab.t_saette_socpref

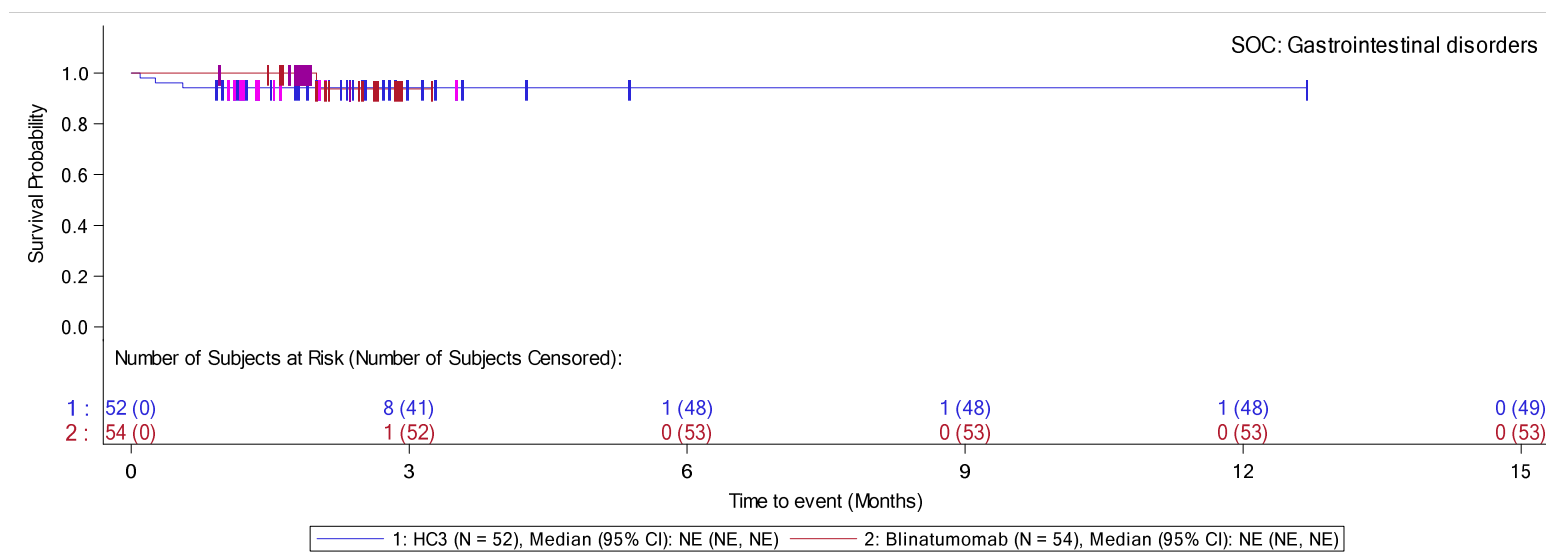
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:48) Source Data: a215up.adsl, outtab.t_saette_socpref

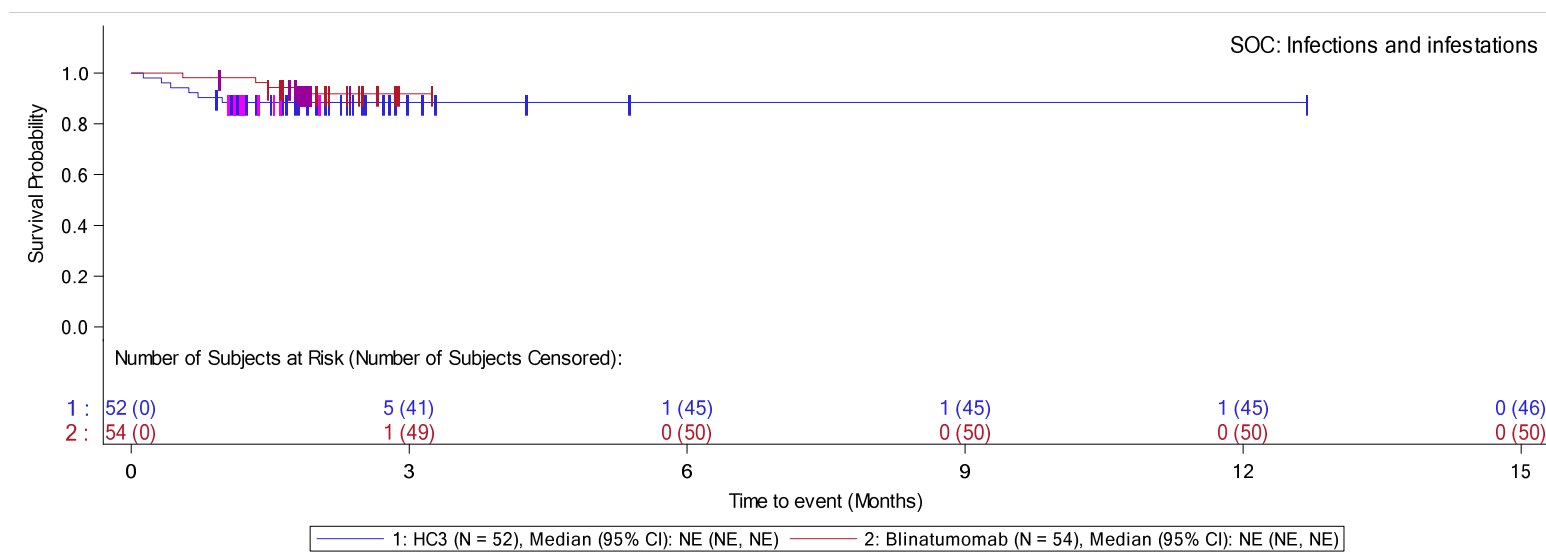
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:48) Source Data: a215up.adsl, outtab.t_saette_socpref

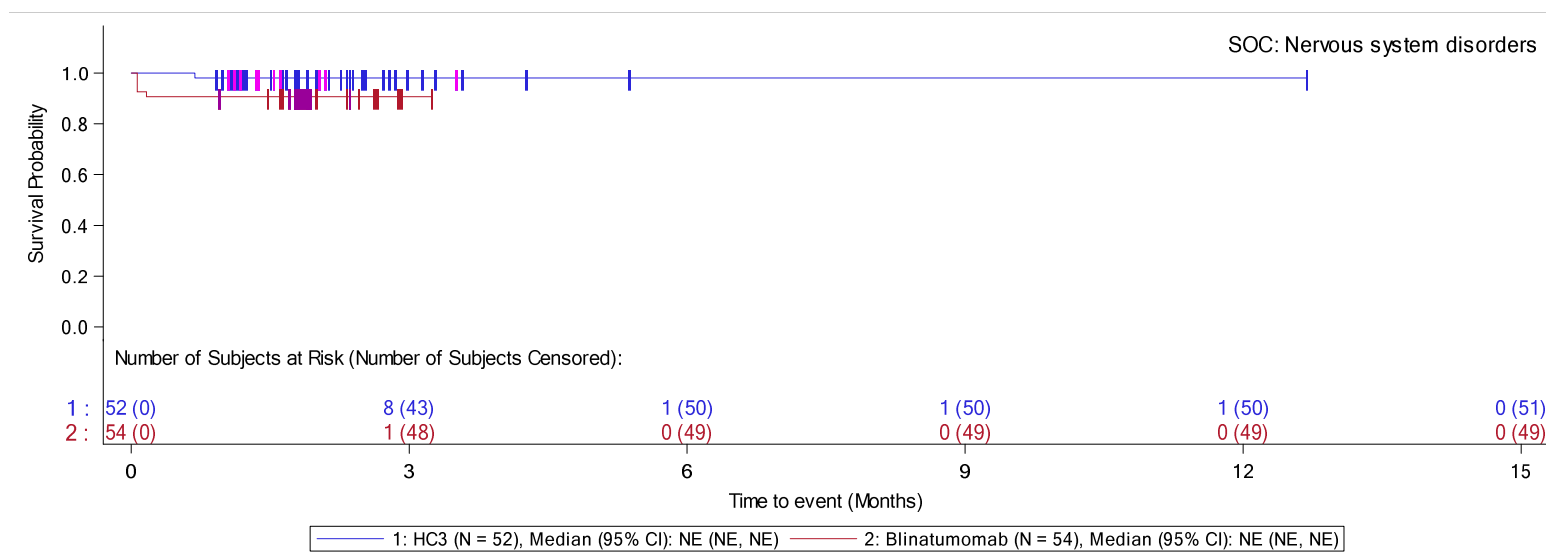
Figure 14-6.1.13. Kaplan-Meier plot for Time to First Onset of Serious Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:48) Source Data: a215up.adsl, outtab.t_saette_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)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:48) Source Data: a215up.adsl, outtab.t_saette_socpref

Anhang 4-G2.7.7: Sicherheit: Häufige schwere UE nach SOC, PT

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	38 (73.1)	15 (27.8)	
Unstratified log-rank test			
Normal score ^b			-16.85
p-value			<0.0001
Stratified log-rank test ^c			
Normal score ^b			-16.15
p-value			<0.0001

Page 1 of 54

N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	0.33	NE	
95% CI (median)	(0.26, 0.39)	(NE, NE)	
Q1, Q3	0.26, NE	1.64, NE	
Min, Max	0.0, 0.5	0.0, 1.7	
Unstratified hazard ratio ^e			0.23
(95% CI)			(0.13, 0.43)
p-value			<0.0001
Stratified hazard ratio ^{c,e}			0.24
(95% CI)			(0.13, 0.45)
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Anaemia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	22 (42.3)	8 (14.8)	
Unstratified log-rank test			
Normal score ^b			-9.39
p-value			0.0004
Stratified log-rank test ^c			
Normal score ^b			-9.39
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(0.43, NE)	(NE, NE)	
Q1, Q3	0.31, NE	NE, NE	
Min, Max	0.0, 0.9	0.1, 1.7	
Unstratified hazard ratio ^e			0.25
(95% CI)			(0.11, 0.57)
p-value			0.0010
Stratified hazard ratio ^{c,e}			0.23
(95% CI)			(0.10, 0.56)
p-value			0.0010

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Neutropenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	14 (26.9)	5 (9.3)	
Unstratified log-rank test			
Normal score ^b			-4.98
p-value			0.0208
Stratified log-rank test ^c			
Normal score ^b			-4.95
p-value			0.0213

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.48, NE	NE, NE	
Min, Max	0.2, 0.5	0.1, 1.6	
Unstratified hazard ratio ^e			0.32
(95% CI)			(0.11, 0.88)
p-value			0.0278
Stratified hazard ratio ^{c,e}			0.32
(95% CI)			(0.11, 0.88)
p-value			0.0283

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Thrombocytopenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	11 (21.2)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			-4.36
p-value			0.0219
Stratified log-rank test ^c			
Normal score ^b			-4.26
p-value			0.0258

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.1	0.1, 1.9	
Unstratified hazard ratio ^e			0.28
(95% CI)			(0.09, 0.89)
p-value			0.0310
Stratified hazard ratio ^{c,e}			0.29
(95% CI)			(0.09, 0.92)
p-value			0.0356

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Febrile neutropenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	13 (25.0)	2 (3.7)	
Unstratified log-rank test			
Normal score ^b			-6.32
p-value			0.0009
Stratified log-rank test ^c			
Normal score ^b			-6.09
p-value			0.0015

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	1.15, NE	NE, NE	
Min, Max	0.1, 1.1	1.4, 1.6	
Unstratified hazard ratio ^e			0.12
(95% CI)			(0.03, 0.54)
p-value			0.0055
Stratified hazard ratio ^{c,e}			0.13
(95% CI)			(0.03, 0.57)
p-value			0.0069

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Leukopenia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-1.54
p-value			0.0747
Stratified log-rank test ^c			
Normal score ^b			-1.56
p-value			0.0719

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.4	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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N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Congenital, familial and genetic disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	4 (7.7)	2 (3.7)	
Unstratified log-rank test			
Normal score ^b			-1.39
p-value			0.2495
Stratified log-rank test ^c			
Normal score ^b			-1.37
p-value			0.2535

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.4, 1.6	
Unstratified hazard ratio ^e			0.38
(95% CI)			(0.07, 2.09)
p-value			0.2664
Stratified hazard ratio ^{c,e}			0.38
(95% CI)			(0.07, 2.11)
p-value			0.2691

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Aplasia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	4 (7.7)	2 (3.7)	
Unstratified log-rank test			
Normal score ^b			-1.39
p-value			0.2495
Stratified log-rank test ^c			
Normal score ^b			-1.37
p-value			0.2535

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.4, 1.6	
Unstratified hazard ratio ^e			0.38
(95% CI)			(0.07, 2.09)
p-value			0.2664
Stratified hazard ratio ^{c,e}			0.38
(95% CI)			(0.07, 2.11)
p-value			0.2691

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Gastrointestinal disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	17 (32.7)	6 (11.1)	
Unstratified log-rank test			
Normal score ^b			-7.48
p-value			0.0012
Stratified log-rank test ^c			
Normal score ^b			-7.26
p-value			0.0018

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.33, NE	NE, NE	
Min, Max	0.1, 1.1	1.6, 2.0	
Unstratified hazard ratio ^e			0.24
(95% CI)			(0.09, 0.61)
p-value			0.0027
Stratified hazard ratio ^{c,e}			0.25
(95% CI)			(0.10, 0.63)
p-value			0.0036

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Stomatitis			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	16 (30.8)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			-7.72
p-value			0.0003
Stratified log-rank test ^c			
Normal score ^b			-7.64
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-sev-teae-soc-pt-saf.sas

Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.33, NE	NE, NE	
Min, Max	0.1, 1.1	1.7, 2.0	
Unstratified hazard ratio ^e			0.14
(95% CI)			(0.04, 0.48)
p-value			0.0018
Stratified hazard ratio ^{c,e}			0.14
(95% CI)			(0.04, 0.48)
p-value			0.0018

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: General disorders and administration site conditions			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	10 (18.5)	
Unstratified log-rank test			
Normal score ^b			3.85
p-value			0.0188
Stratified log-rank test ^c			
Normal score ^b			3.85
p-value			0.0189

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.9	
Unstratified hazard ratio ^e			7.97
(95% CI)			(1.02, 62.41)
p-value			0.0479
Stratified hazard ratio ^{c,e}			7.97
(95% CI)			(1.02, 62.44)
p-value			0.0481

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-sev-teae-soc-pt-saf.sas

Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Mucosal inflammation			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	7 (13.0)	
Unstratified log-rank test			
Normal score ^b			2.99
p-value			0.0218
Stratified log-rank test ^c			
Normal score ^b			3.05
p-value			0.0196

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.3, 1.9	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Pyrexia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			1.31
p-value			0.1255
Stratified log-rank test ^c			
Normal score ^b			1.32
p-value			0.1236

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-te-sev-teae-soc-pt-saf.sas

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.6	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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 Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Hepatobiliary disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	7 (13.5)	2 (3.7)	
Unstratified log-rank test			
Normal score ^b			-2.69
p-value			0.0708
Stratified log-rank test ^c			
Normal score ^b			-2.71
p-value			0.0694

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.2, 1.9	
Unstratified hazard ratio ^e			0.26
(95% CI)			(0.05, 1.25)
p-value			0.0920
Stratified hazard ratio ^{c,e}			0.26
(95% CI)			(0.05, 1.24)
p-value			0.0915

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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 Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Hepatotoxicity			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-1.54
p-value			0.0745
Stratified log-rank test ^c			
Normal score ^b			-1.57
p-value			0.0700

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.0	NE, NE	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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 Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Hypertransaminasaemia			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-1.54
p-value			0.0747
Stratified log-rank test ^c			
Normal score ^b			-1.56
p-value			0.0719

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.8	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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N = Number of subjects in the analysis set. n = Number of subjects with observed data.

KM = Kaplan-Meier. CI = Confidence interval. NE = Not estimable.

^a Events are first onset of treatment emergent adverse event.

^b A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Infections and infestations			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	6 (11.5)	11 (20.4)	
Unstratified log-rank test			
Normal score ^b			1.61
p-value			0.4290
Stratified log-rank test ^c			
Normal score ^b			1.34
p-value			0.5055

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(2.00, NE)	
Q1, Q3	NE, NE	2.00, NE	
Min, Max	0.1, 1.0	0.5, 2.0	
Unstratified hazard ratio ^e			1.50
(95% CI)			(0.55, 4.08)
p-value			0.4320
Stratified hazard ratio ^{c,e}			1.40
(95% CI)			(0.51, 3.84)
p-value			0.5074

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Investigations			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	15 (28.8)	12 (22.2)	
Unstratified log-rank test			
Normal score ^b			-2.52
p-value			0.3239
Stratified log-rank test ^c			
Normal score ^b			-2.50
p-value			0.3271

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
Time to event (KM) (months) ^d			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.46, NE	2.00, NE	
Min, Max	0.1, 1.1	0.0, 2.0	
Unstratified hazard ratio ^e			0.69
(95% CI)			(0.32, 1.48)
p-value			0.3354
Stratified hazard ratio ^{c,e}			0.68
(95% CI)			(0.32, 1.47)
p-value			0.3294

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Platelet count decreased			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	8 (15.4)	6 (11.1)	
Unstratified log-rank test			
Normal score ^b			-1.85
p-value			0.3124
Stratified log-rank test ^c			
Normal score ^b			-1.73
p-value			0.3443

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.1	0.3, 1.8	
Unstratified hazard ratio ^e			0.58
(95% CI)			(0.20, 1.69)
p-value			0.3174
Stratified hazard ratio ^{c,e}			0.60
(95% CI)			(0.21, 1.75)
p-value			0.3500

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Neutrophil count decreased			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	2 (3.8)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			0.98
p-value			0.4205
Stratified log-rank test ^c			
Normal score ^b			0.86
p-value			0.4770

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.0	
Unstratified hazard ratio ^e			2.01
(95% CI)			(0.37, 10.96)
p-value			0.4211
Stratified hazard ratio ^{c,e}			1.85
(95% CI)			(0.33, 10.26)
p-value			0.4801

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: White blood cell count decreased			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	1 (1.9)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			1.50
p-value			0.1795
Stratified log-rank test ^c			
Normal score ^b			1.47
p-value			0.1872

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.2	
Unstratified hazard ratio ^e			4.00
(95% CI)			(0.45, 35.81)
p-value			0.2148
Stratified hazard ratio ^{c,e}			3.92
(95% CI)			(0.44, 35.09)
p-value			0.2218

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Alanine aminotransferase increased			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	5 (9.6)	1 (1.9)	
Unstratified log-rank test			
Normal score ^b			-2.12
p-value			0.0830
Stratified log-rank test ^c			
Normal score ^b			-2.01
p-value			0.1006

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	0.5, 0.5	
Unstratified hazard ratio ^e			0.18
(95% CI)			(0.02, 1.58)
p-value			0.1228
Stratified hazard ratio ^{c,e}			0.20
(95% CI)			(0.02, 1.70)
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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Nervous system disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			1.36
p-value			0.1123
Stratified log-rank test ^c			
Normal score ^b			1.28
p-value			0.1240

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.8	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	1 (1.9)	
Unstratified log-rank test			
Normal score ^b			-1.17
p-value			0.2399
Stratified log-rank test ^c			
Normal score ^b			-1.04
p-value			0.2946

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.4	1.8, 1.8	
Unstratified hazard ratio ^e			0.28
(95% CI)			(0.03, 2.71)
p-value			0.2709
Stratified hazard ratio ^{c,e}			0.32
(95% CI)			(0.03, 3.07)
p-value			0.3203

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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 HC3 and therefore a longer survival time.^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).^d Months are calculated as days from treatment start date to event date, divided by 30.5.^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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 Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
PT: Epistaxis			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	3 (5.8)	0 (0.0)	
Unstratified log-rank test			
Normal score ^b			-1.54
p-value			0.0747
Stratified log-rank test ^c			
Normal score ^b			-1.45
p-value			0.0917

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 0.4	NE, NE	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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 Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Skin and subcutaneous tissue disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	0 (0.0)	3 (5.6)	
Unstratified log-rank test			
Normal score ^b			1.24
p-value			0.1466
Stratified log-rank test ^c			
Normal score ^b			1.27
p-value			0.1366

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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	1.5, 1.9	
Unstratified hazard ratio ^e (95% CI)			NE (NE, NE)
p-value			NE
Stratified hazard ratio ^{c,e} (95% CI)			NE (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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	Treatment Difference
SOC: Vascular disorders			
Subject status			
Number of subjects	52	54	
Events - n (%) ^a	2 (3.8)	4 (7.4)	
Unstratified log-rank test			
Normal score ^b			0.80
p-value			0.5087
Stratified log-rank test ^c			
Normal score ^b			0.79
p-value			0.5088

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

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Output: t14-06-001-014-tte-sev-teae-soc-pt-saf.rtf (Date generated: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Table 14-6.1.14. Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N = 52)	Blinatumomab (N = 54)	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, 1.2	0.1, 1.9	
Unstratified hazard ratio ^e			1.76
(95% CI)			(0.32, 9.71)
p-value			0.5142
Stratified hazard ratio ^{c,e}			1.78
(95% CI)			(0.32, 10.05)
p-value			0.5141

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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 HC3 and therefore a longer survival time.

^c Stratification factors are: age (1-9 years vs. other (<1 year and >9 years)), and marrow/MRD status (M1 with MRD level < 10⁻³ vs. M1 with MRD level ≥ 10⁻³ vs. M2).

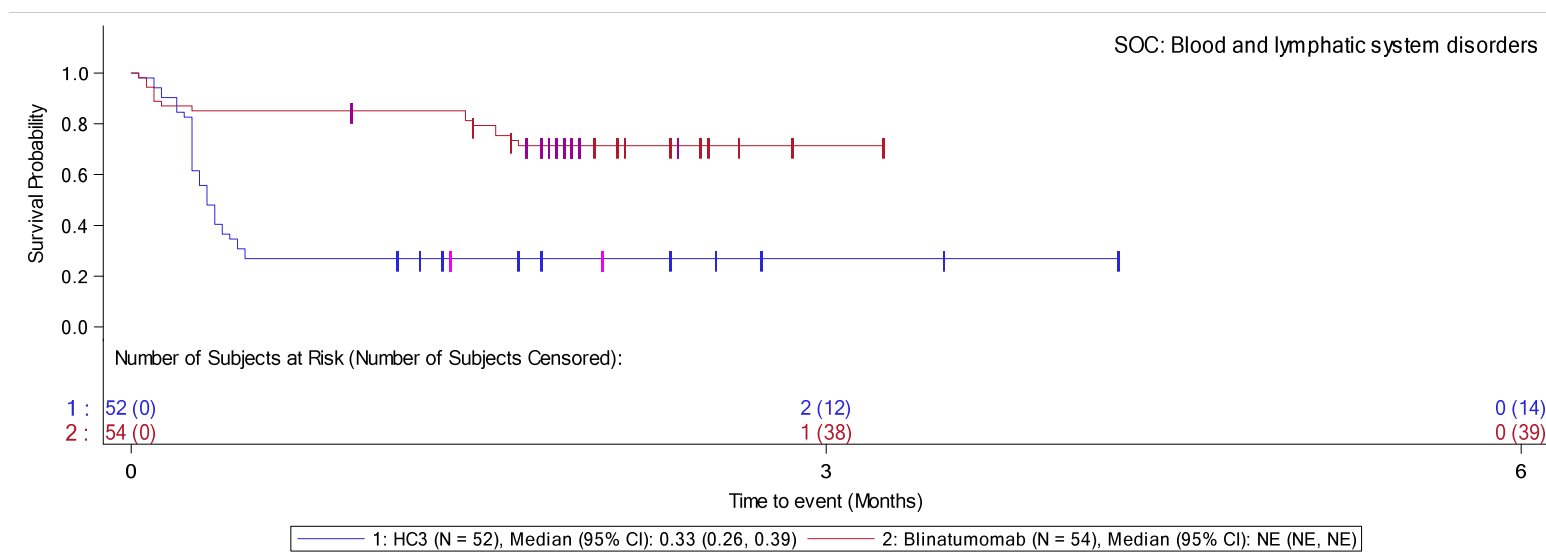
^d Months are calculated as days from treatment start date to event date, divided by 30.5.

^e The 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 HC3. Severity graded using CTCAE version 4.03.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 25JUL2025:05:14) Source data: a215up.adsl, a215.adae

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

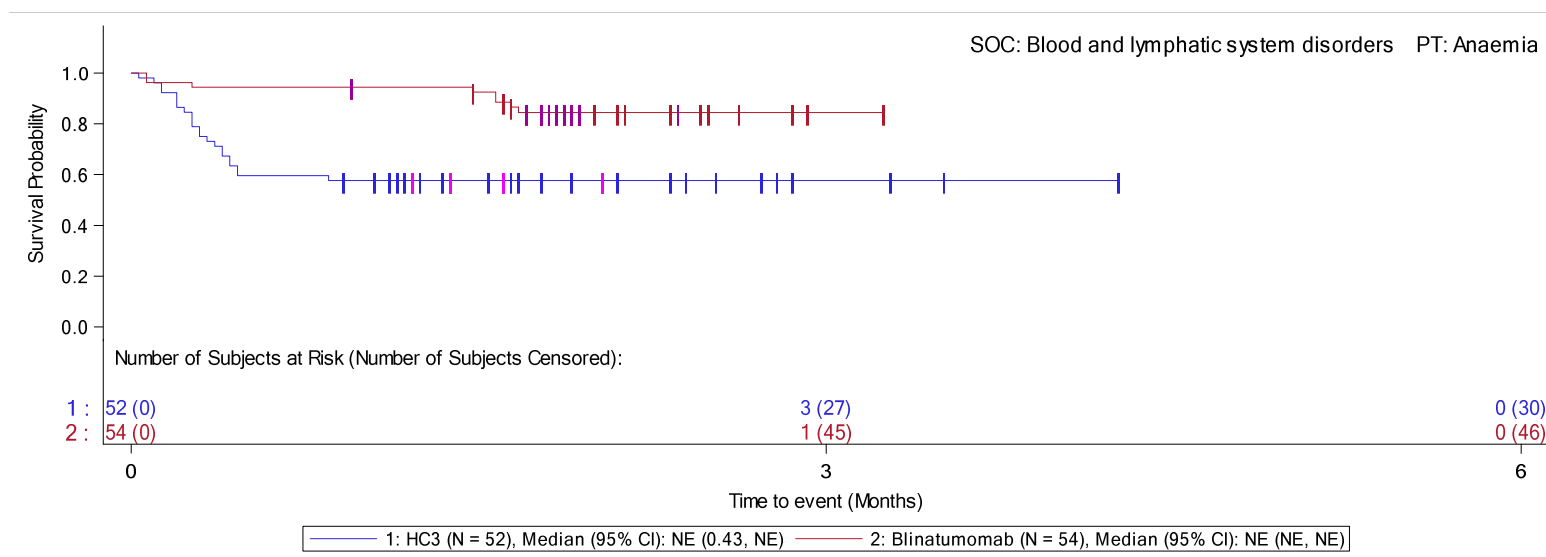


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas

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Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

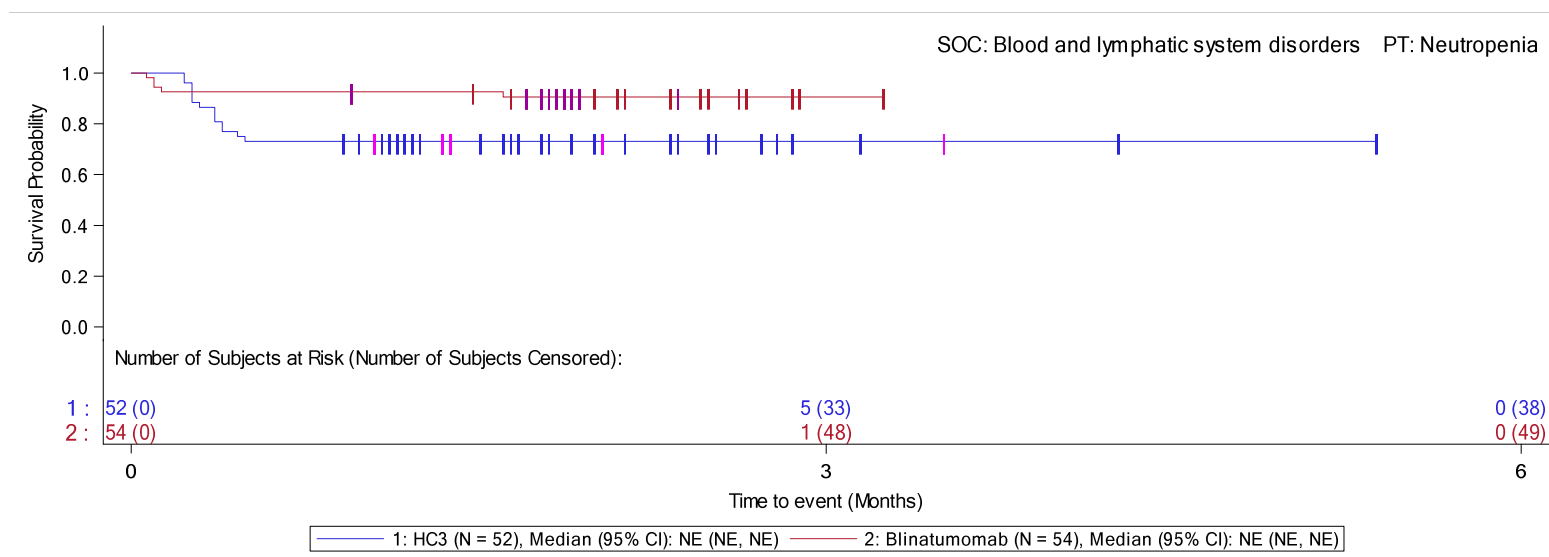


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Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

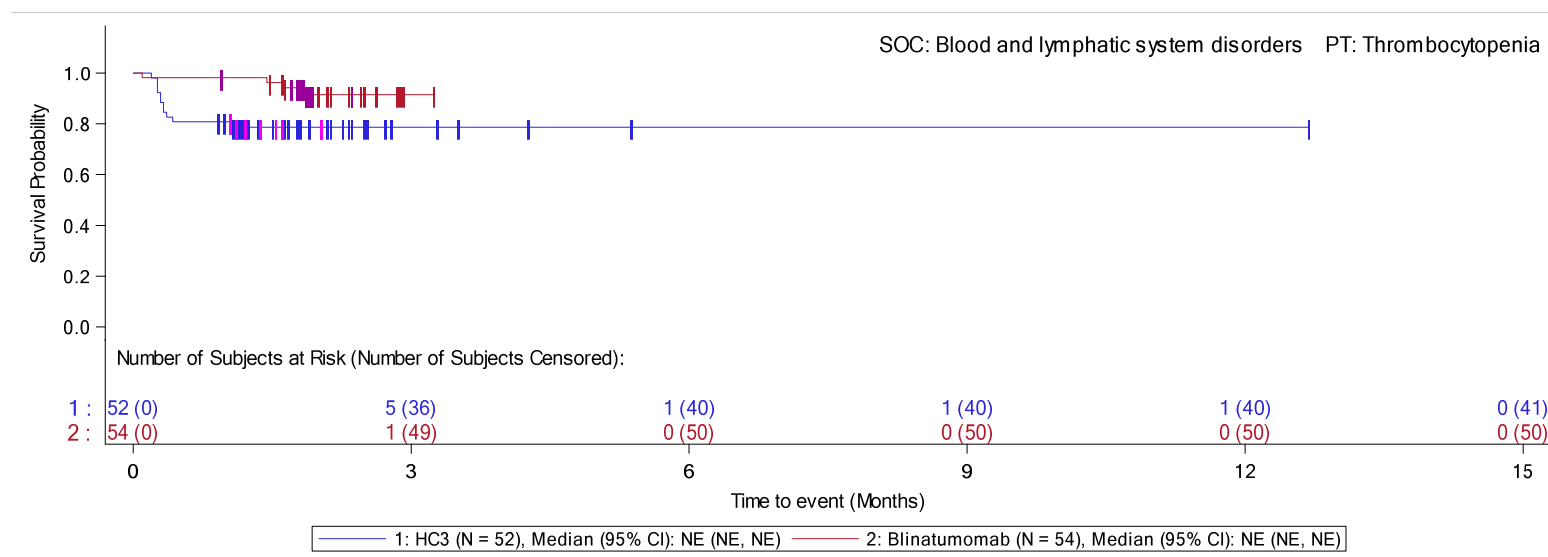


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas

Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

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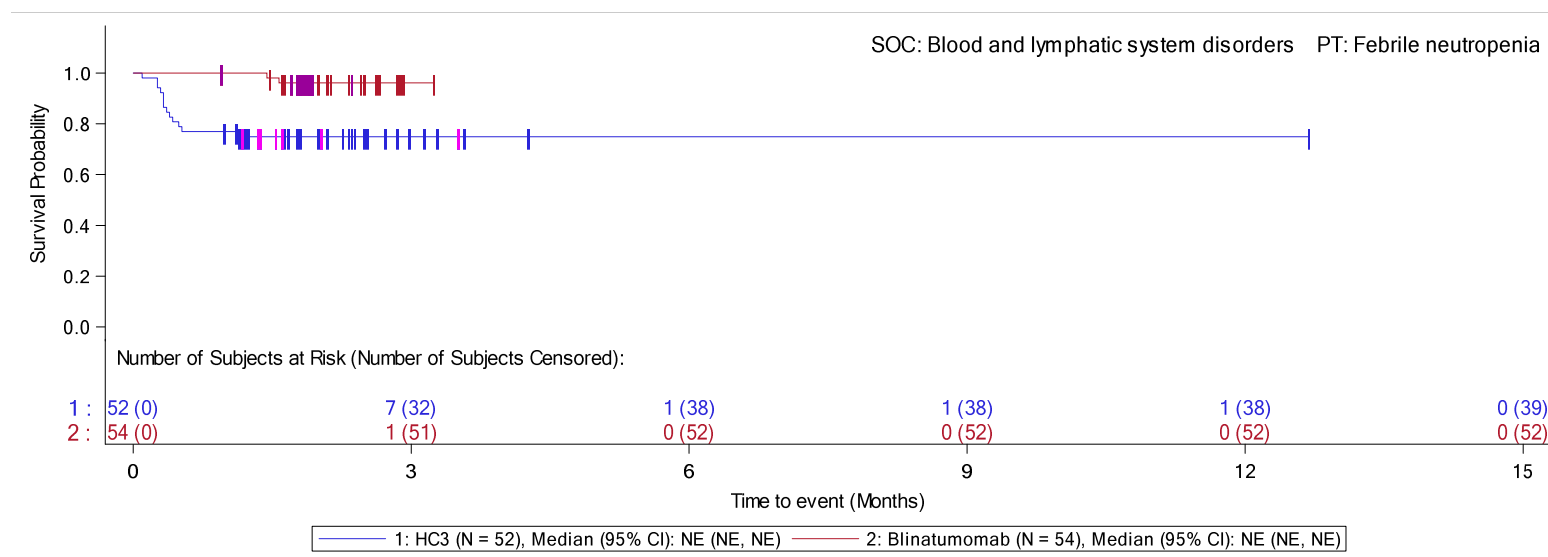


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

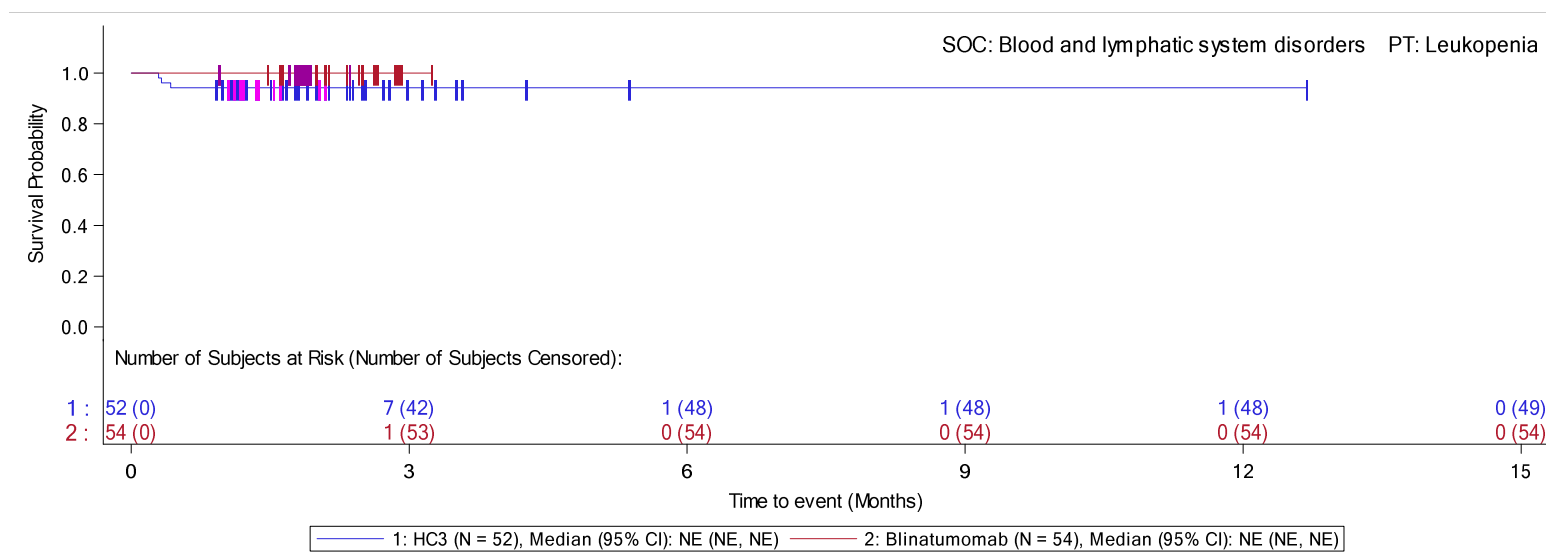


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

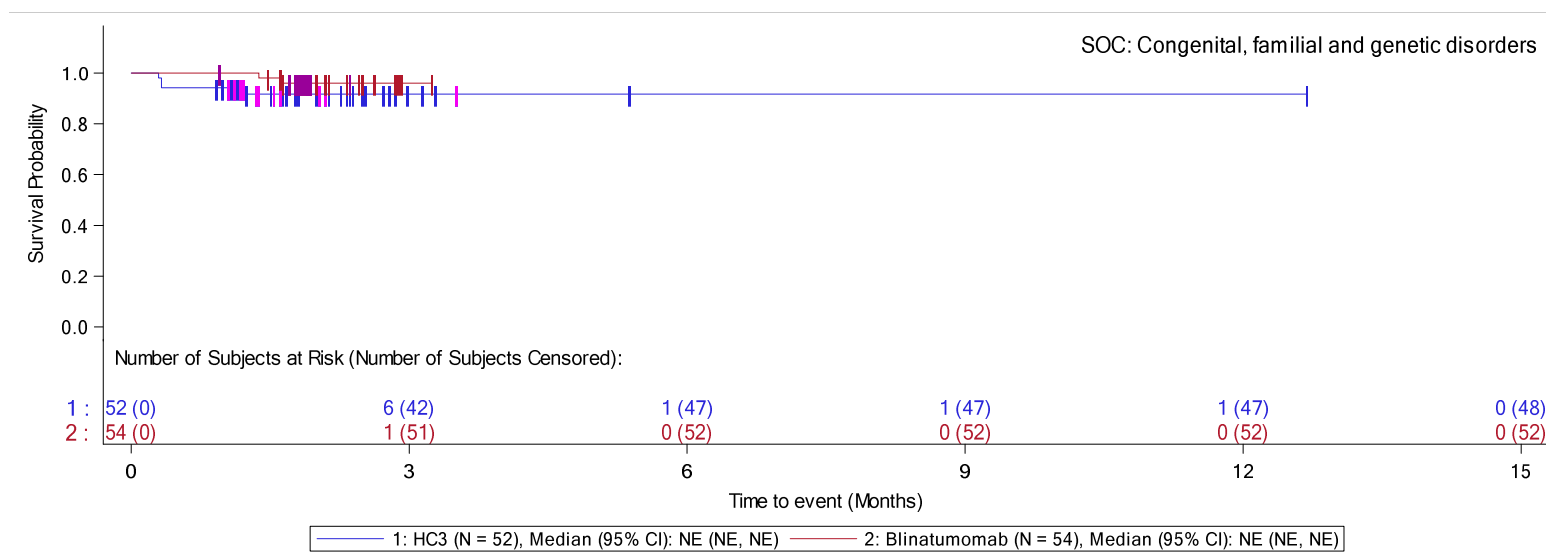


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Output: f14-06-001-014-km-sev-teae-soc-pt-saf.rtf (Date Generated: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

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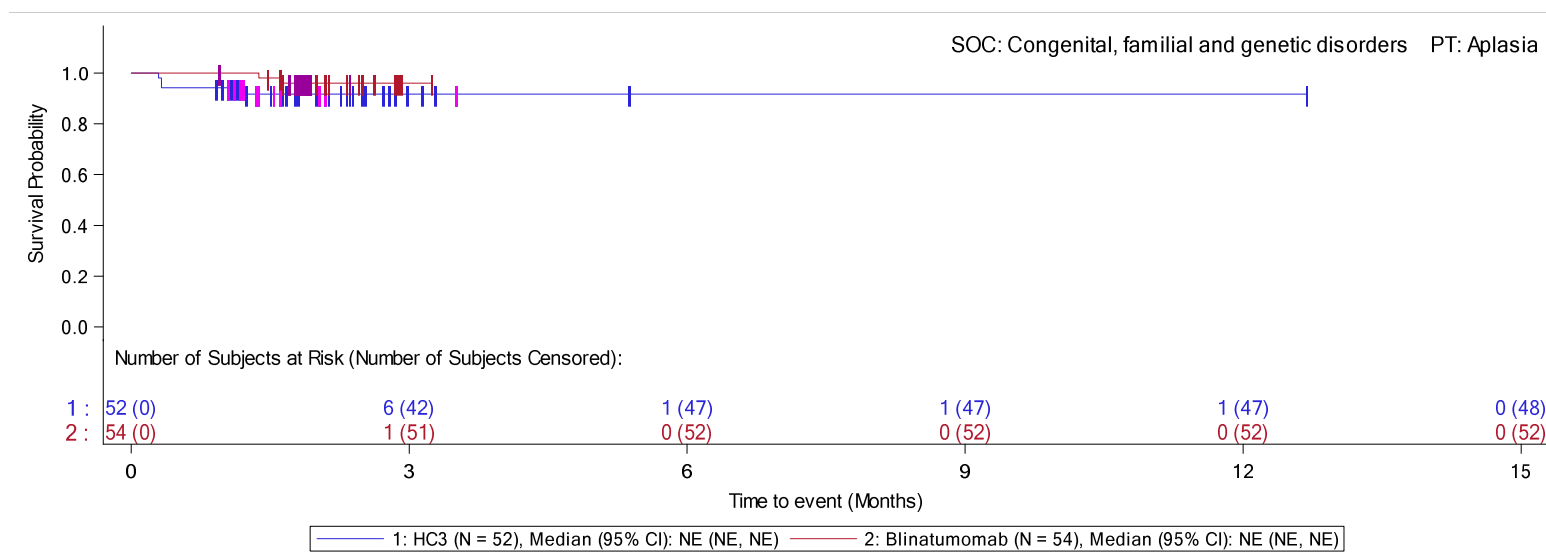


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

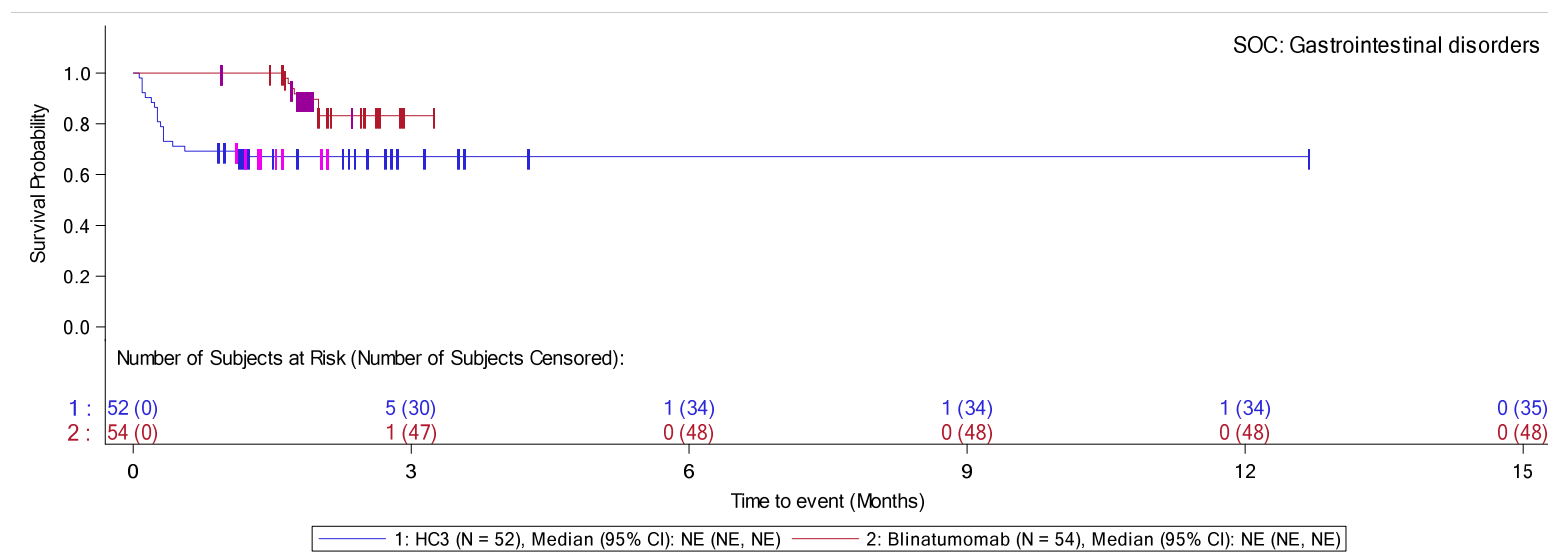


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

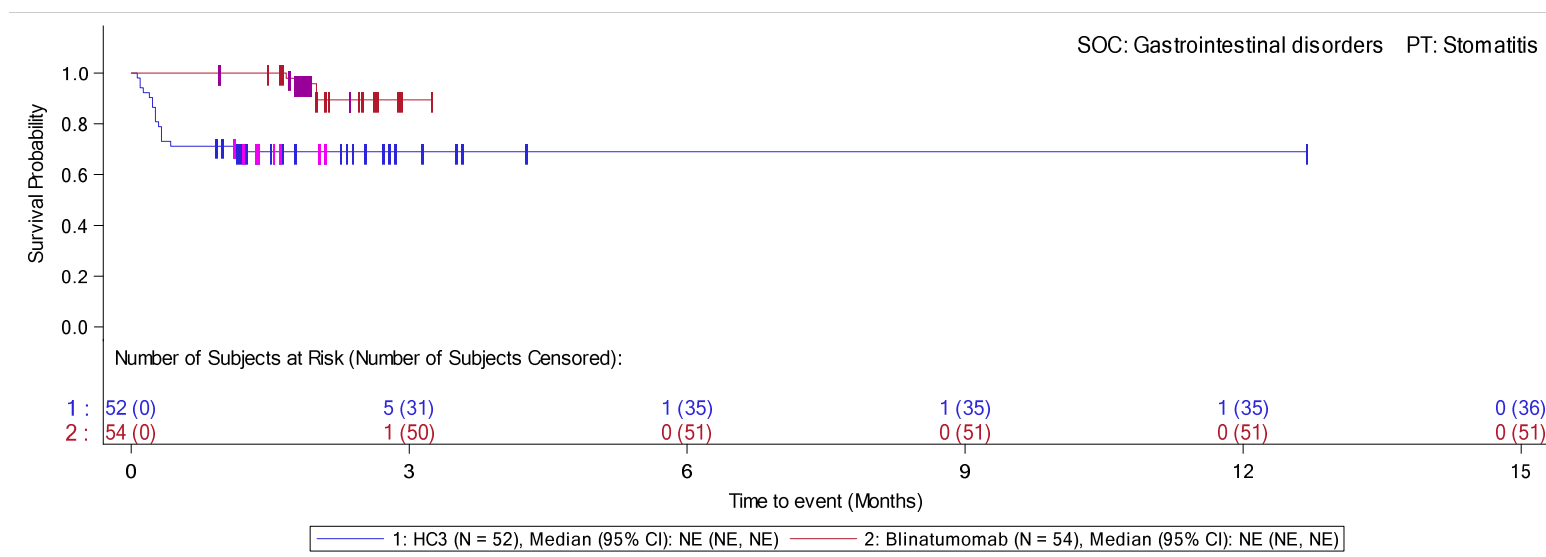


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

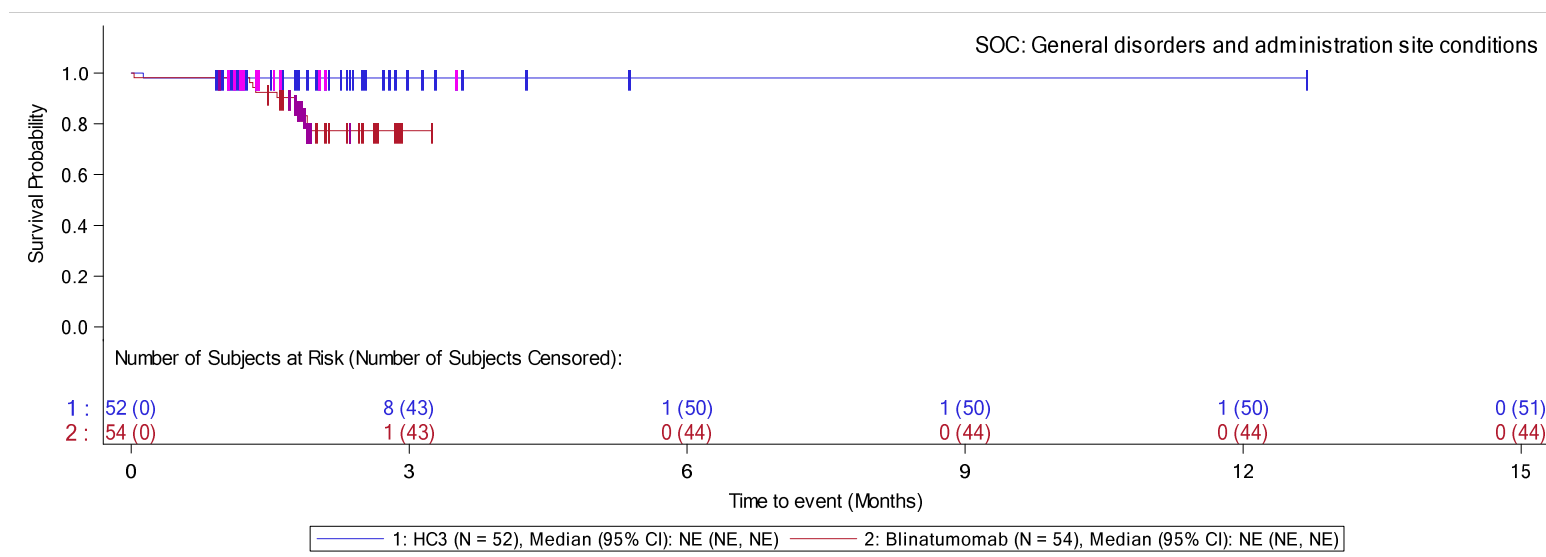


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sev-teae-soc-pt-saf.sas

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Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

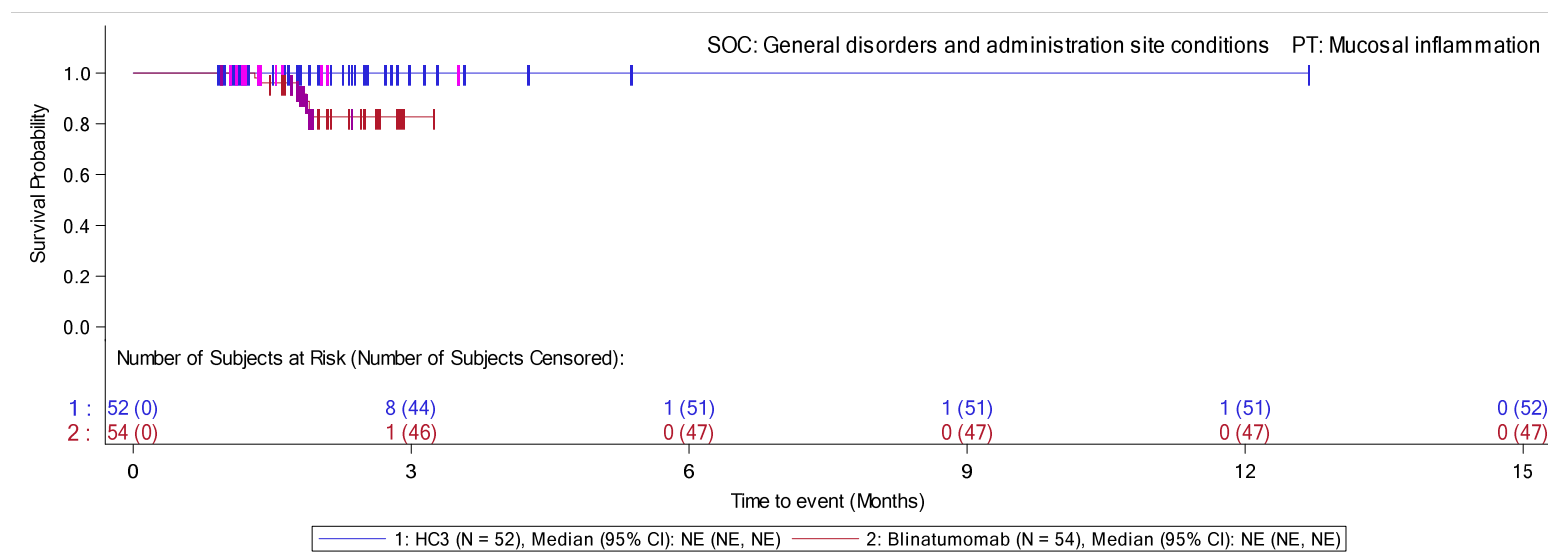


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 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

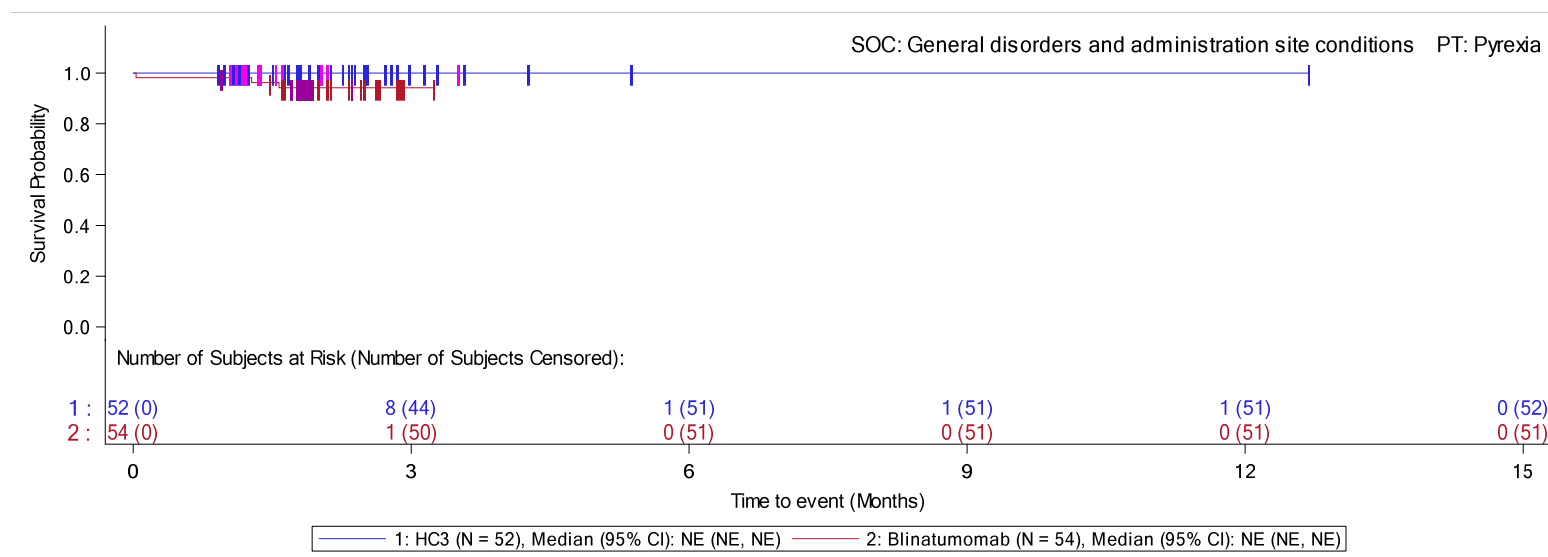


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

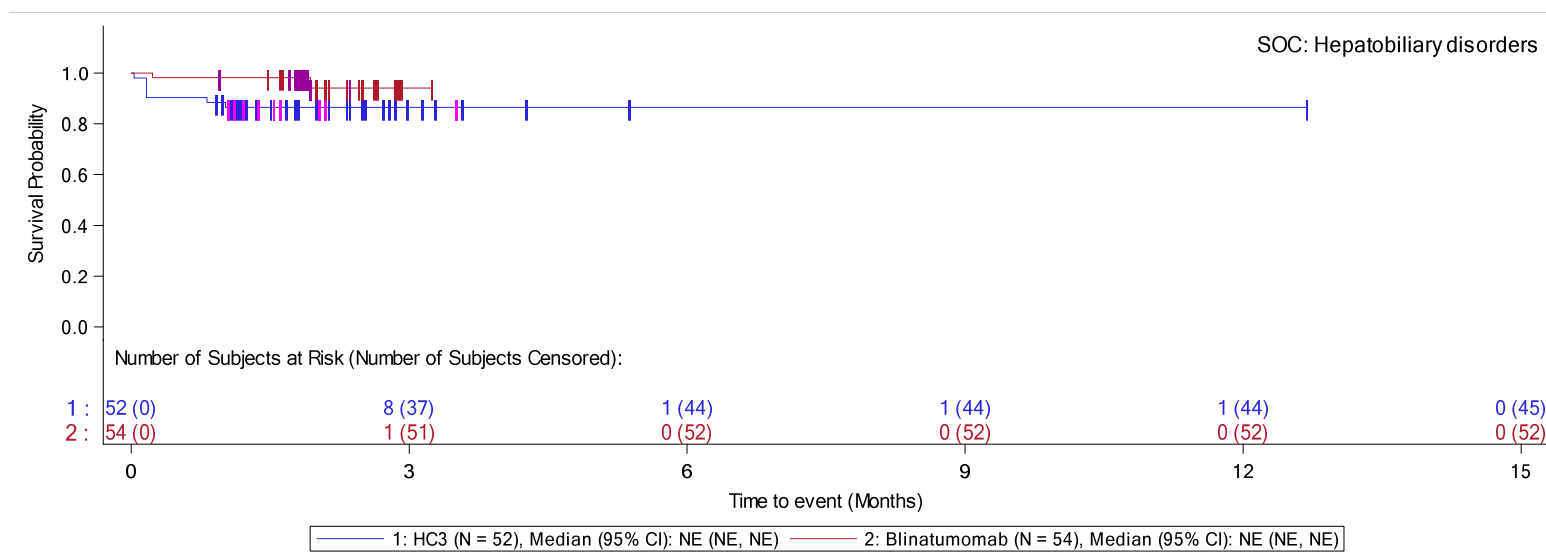


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

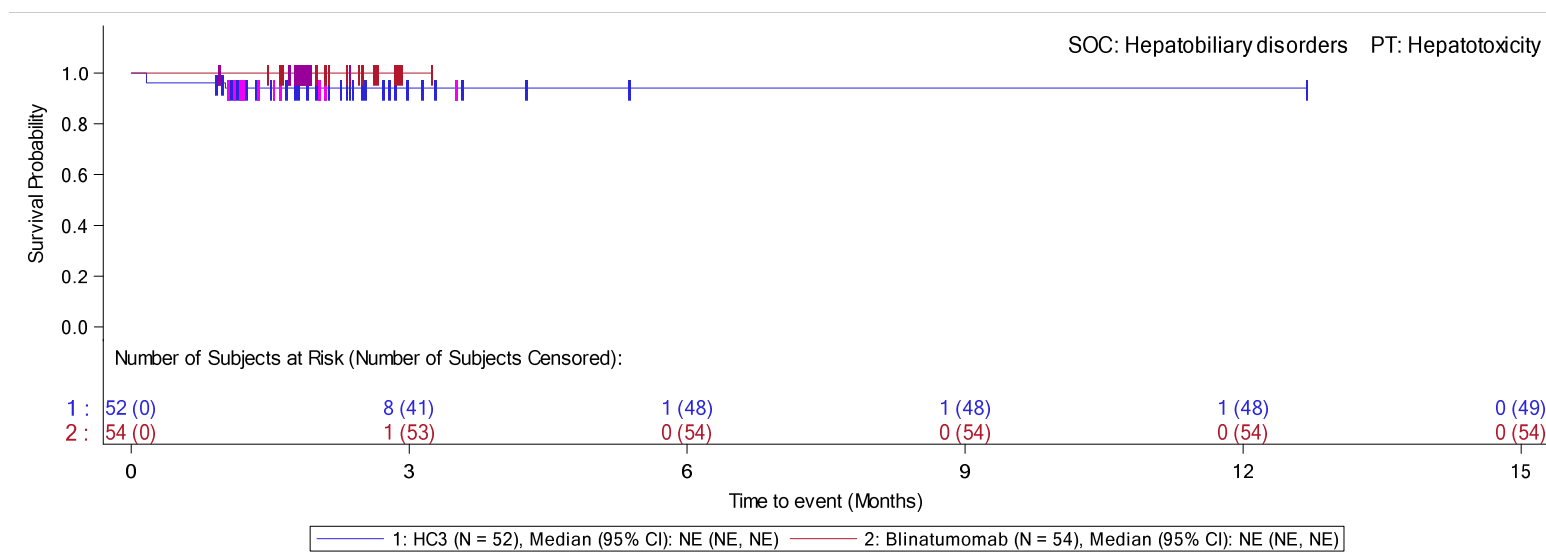


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

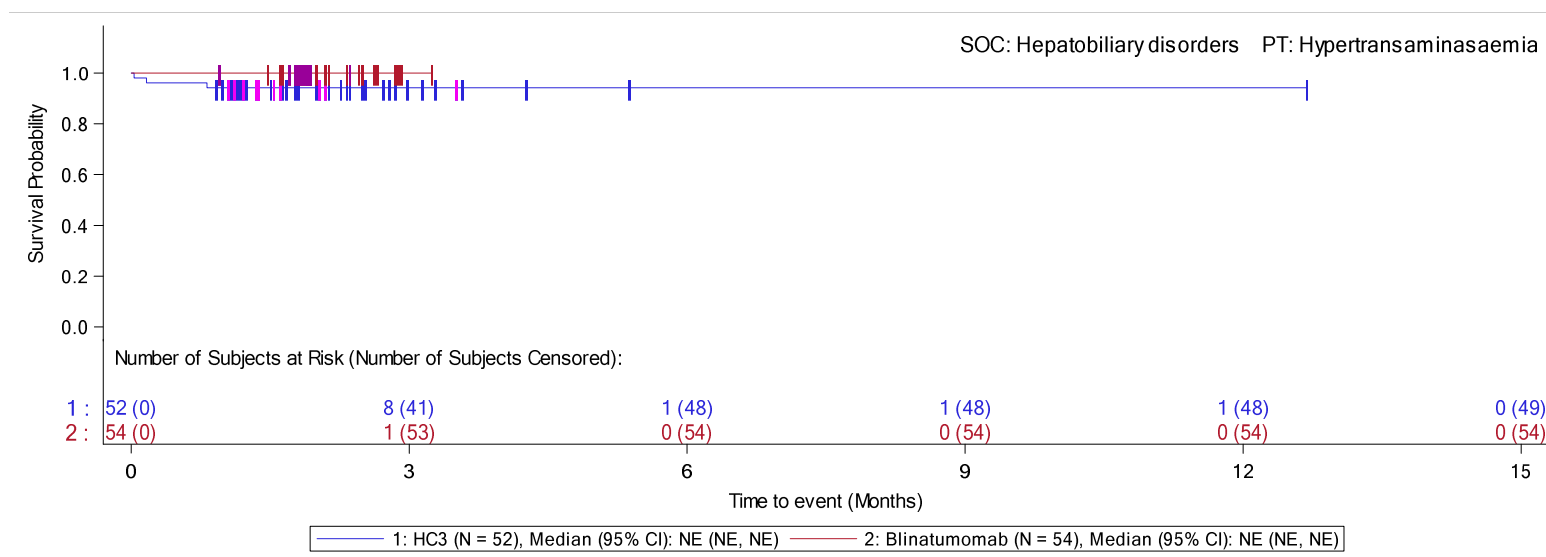


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

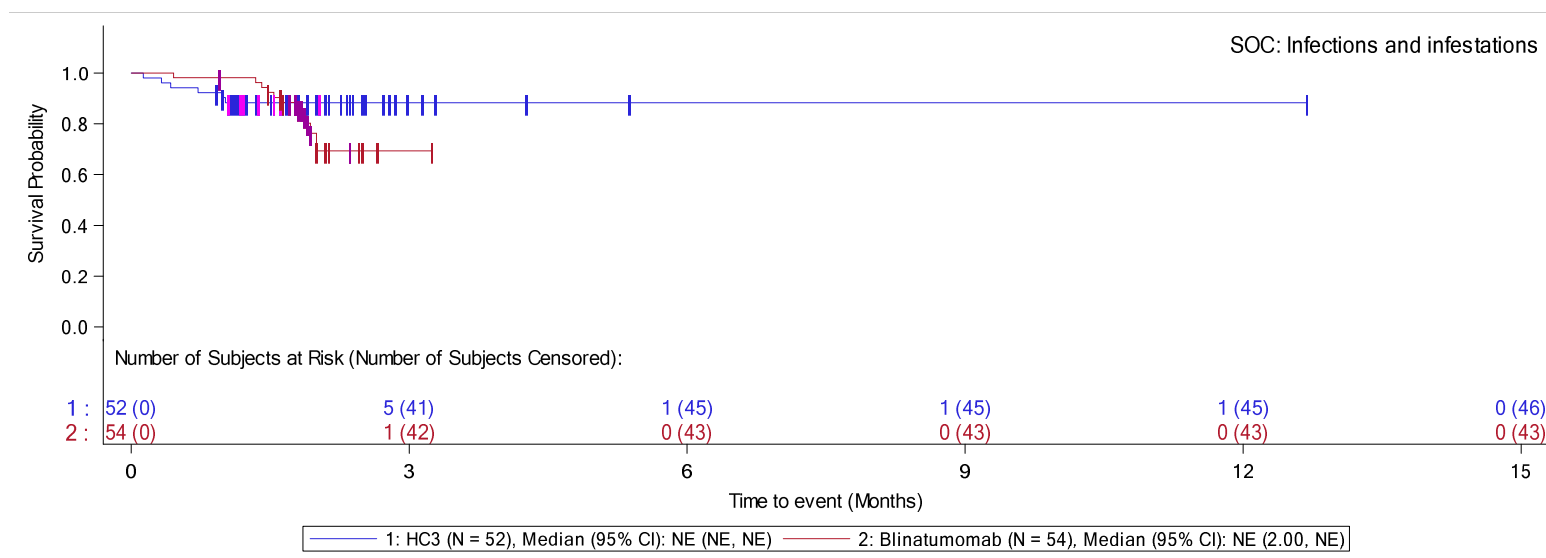


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

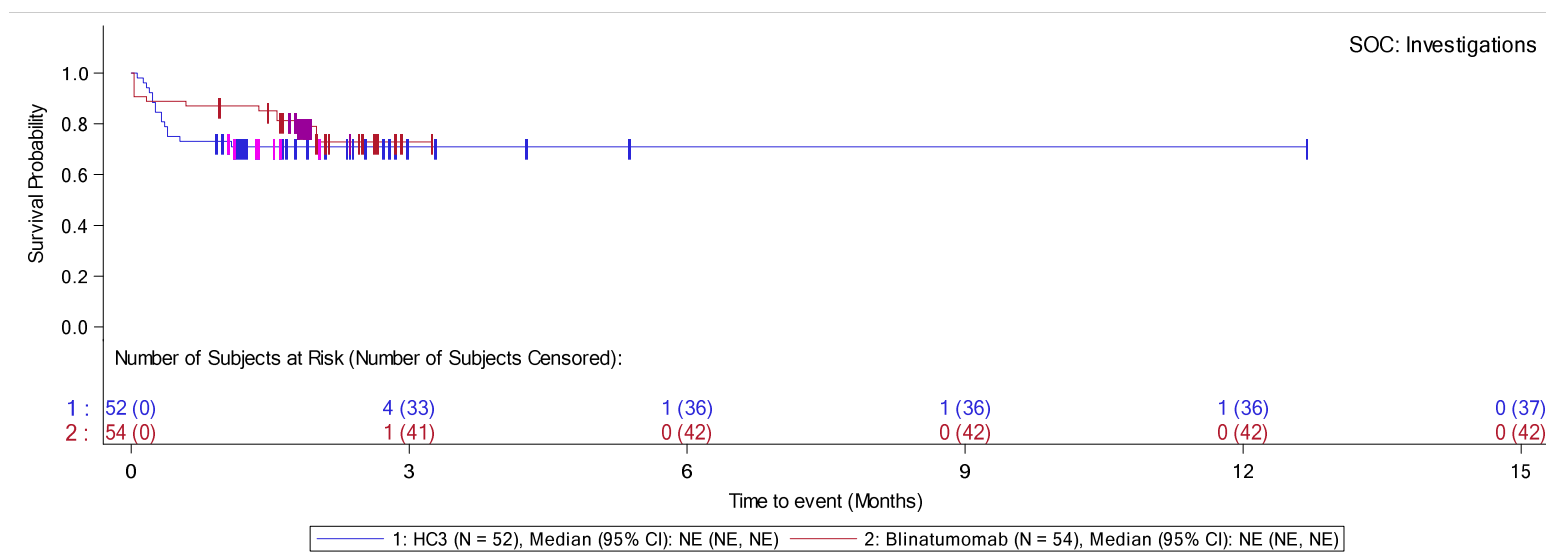


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

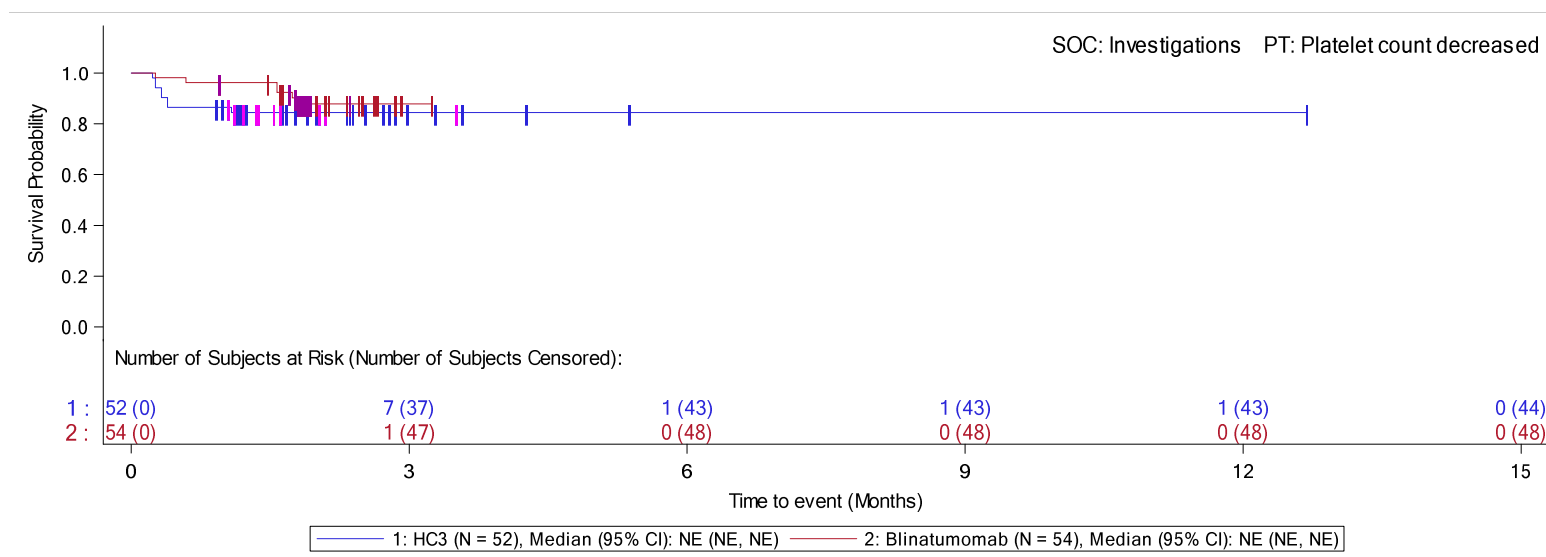


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

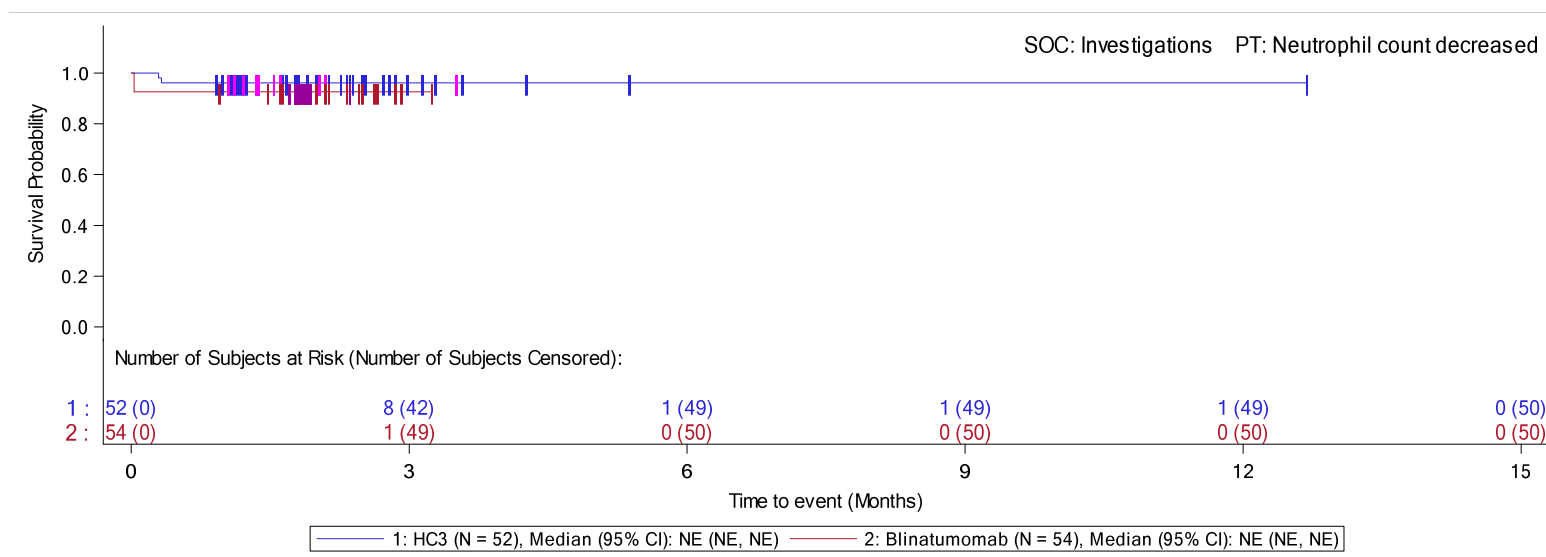


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

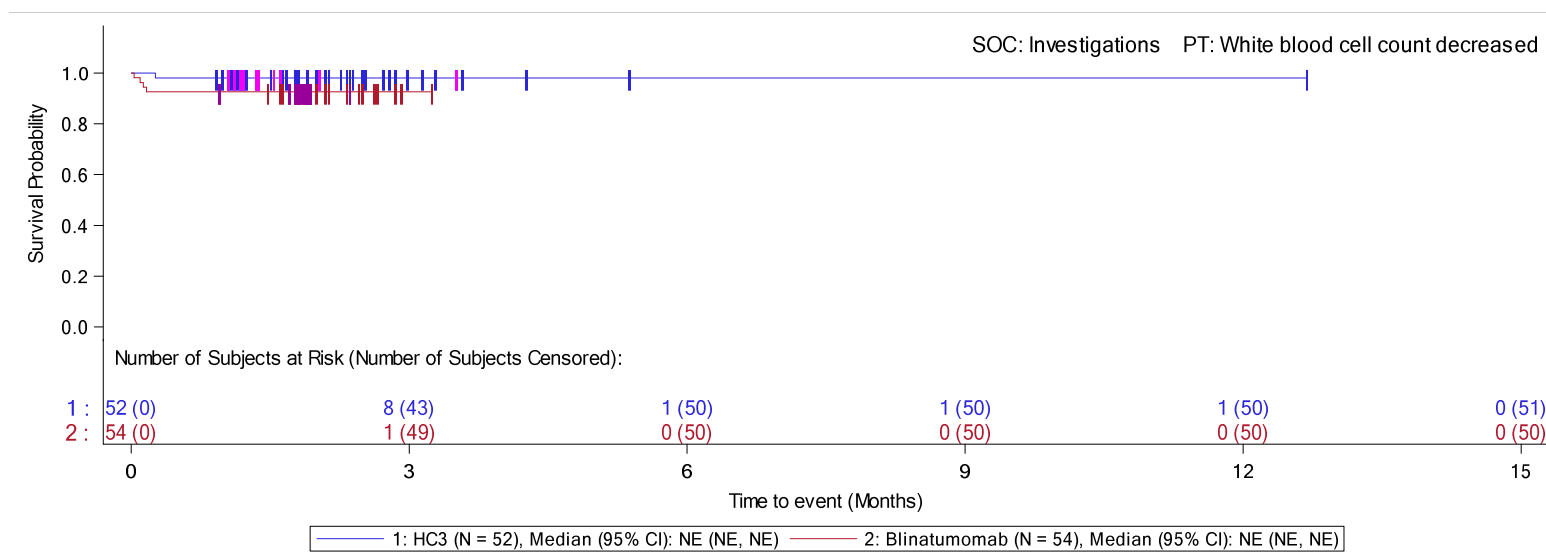


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

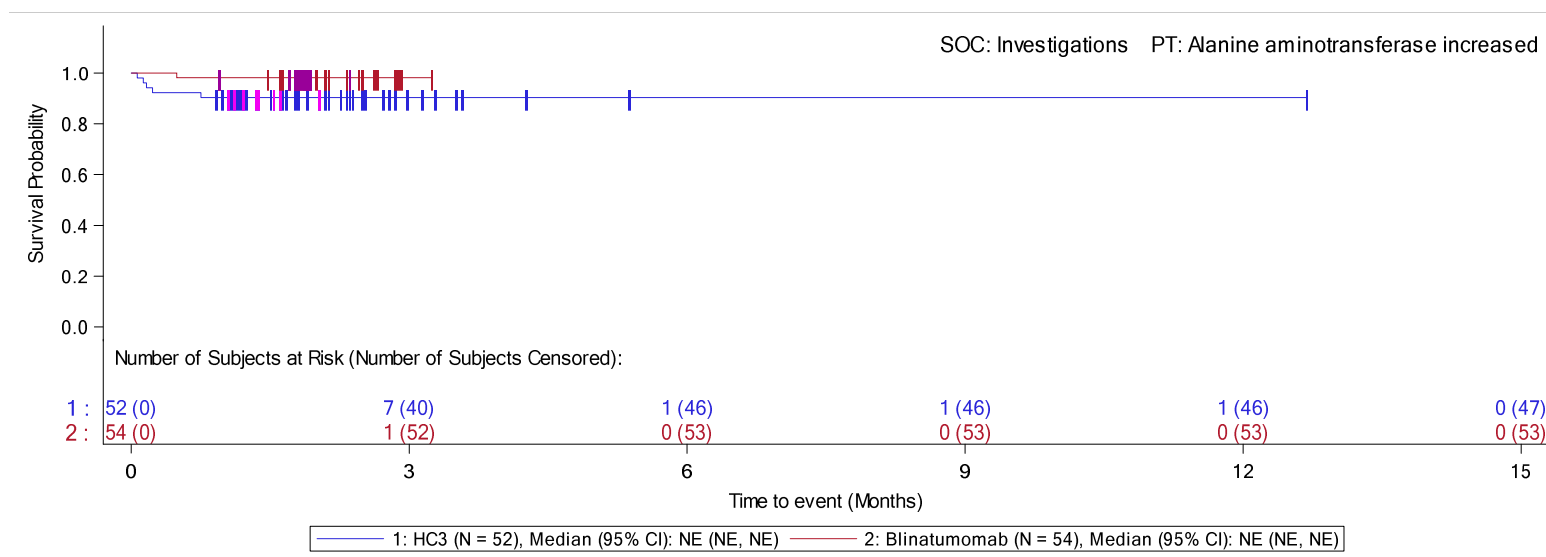


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

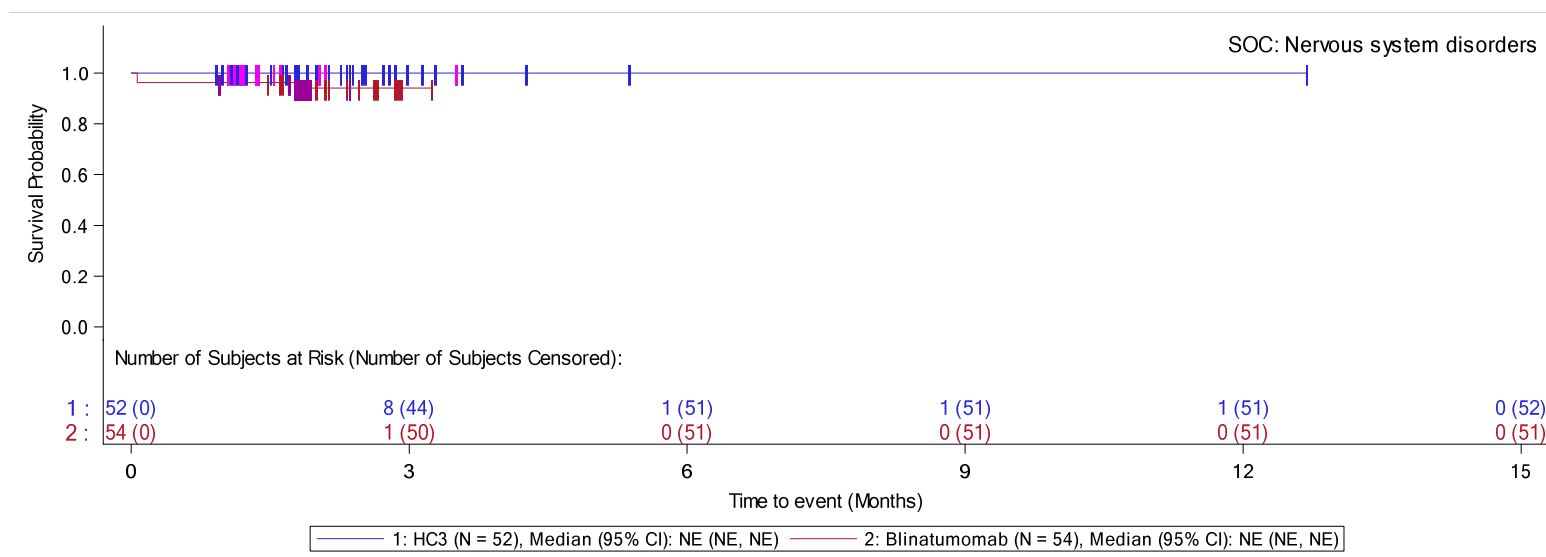


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

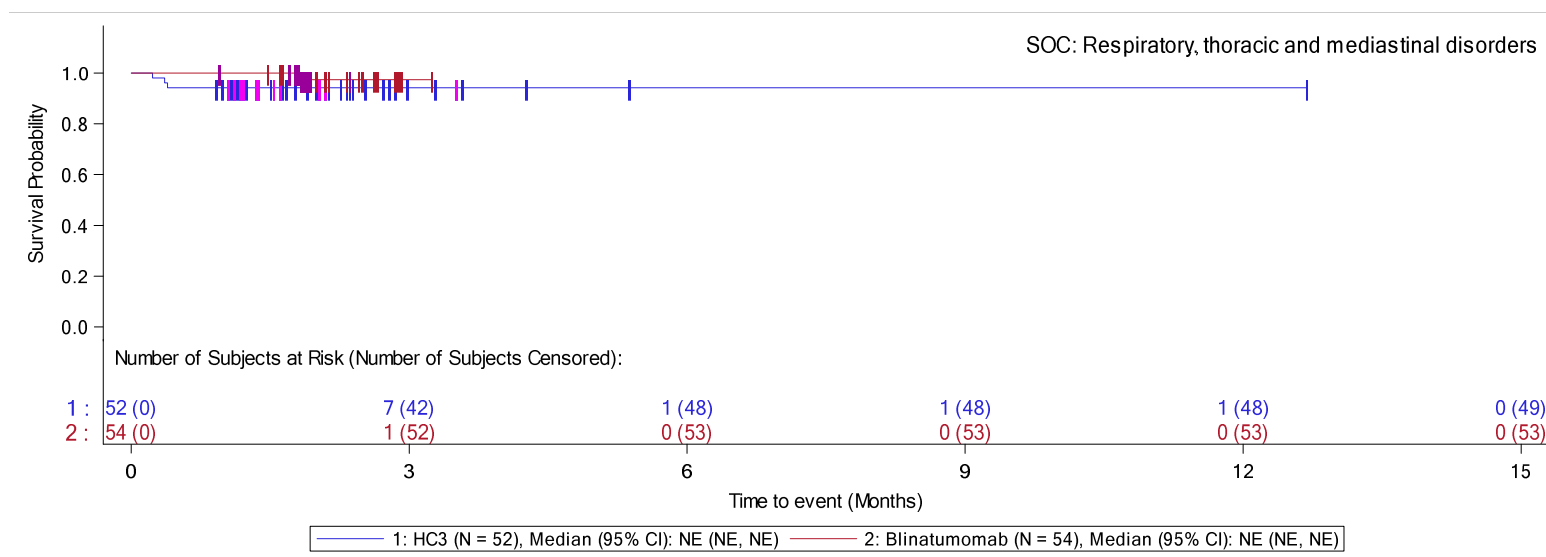


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

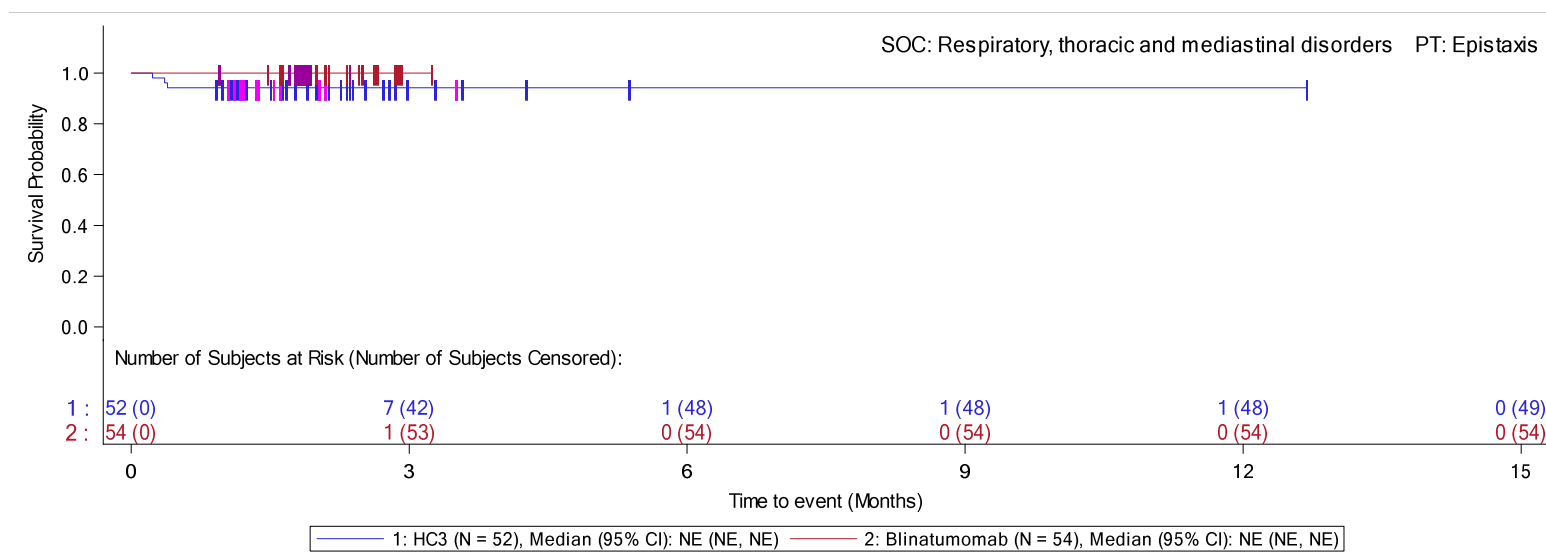


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

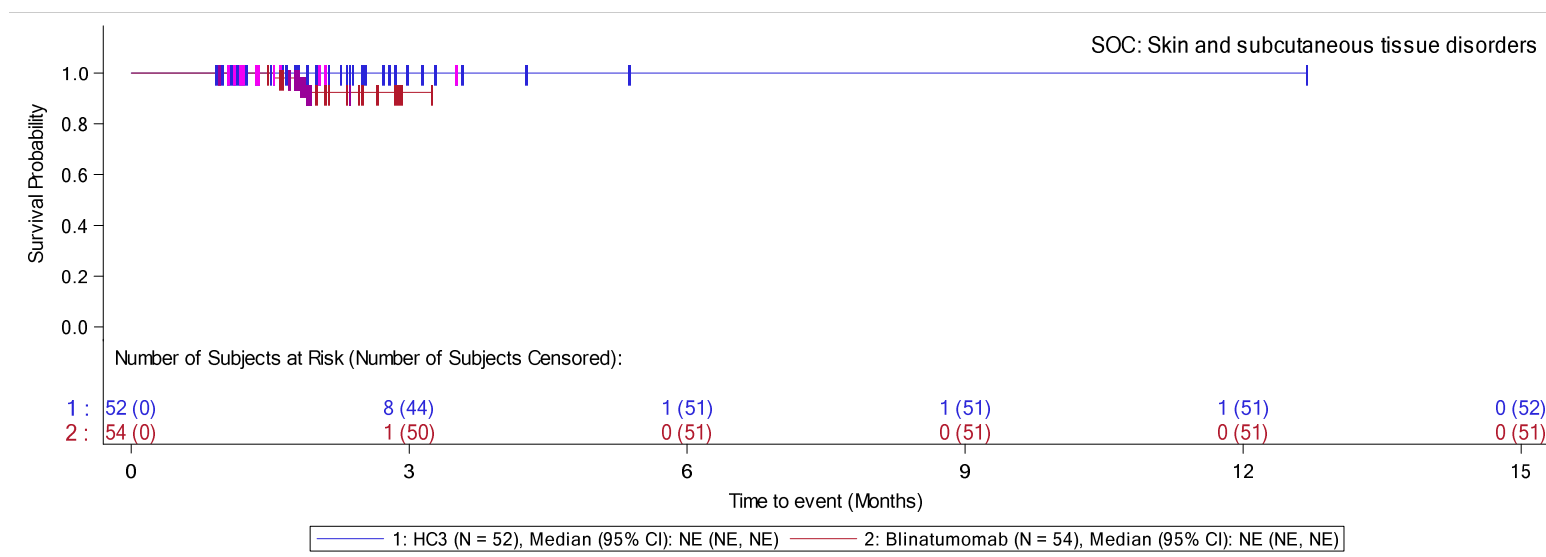


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

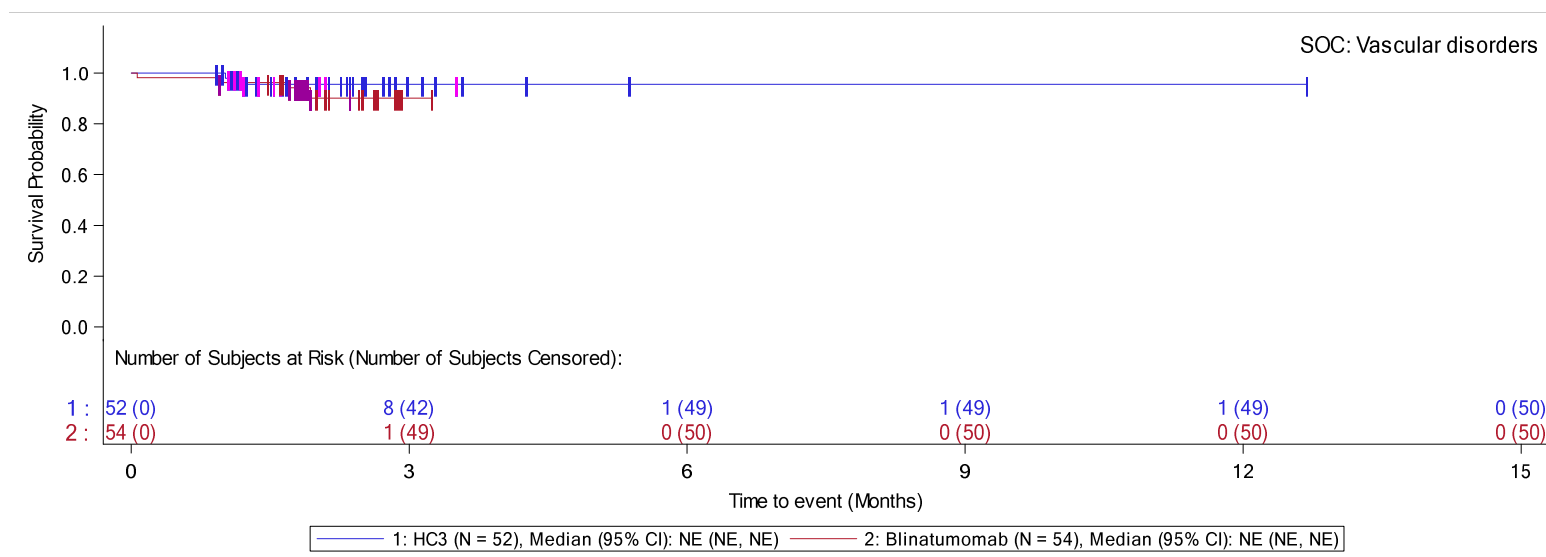


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Figure 14-6.1.14. Kaplan-Meier plot for Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 22:49) Source Data: a215up.adsl, outtab.t_aette_grade3_socpref

Anhang 4-G3: Subgruppenanalysen

Anhang 4-G3.1: Subgruppenanalysen zum Gesamtüberleben

**Table 14-4.2.1. Overall Survival by Subgroup
(Full Analysis Set)**

	HC3 (N = 57)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.5383
1-9 years	20/41 (48.8)	25.2 (12.5, NE)	7/39 (17.9)	NE (NE, NE)	0.29 (0.12, 0.70)	0.0032	
Other	8/16 (50.0)	52.7 (15.7, NE)	4/15 (26.7)	NE (10.6, NE)	0.43 (0.13, 1.42)	0.1525	
Sex							0.3110
Male	12/23 (52.2)	19.0 (10.2, NE)	5/30 (16.7)	NE (NE, NE)	0.22 (0.08, 0.63)	0.0020	
Female	16/34 (47.1)	52.7 (18.6, NE)	6/24 (25.0)	NE (NE, NE)	0.46 (0.18, 1.18)	0.0963	
Region							-
Europe	26/55 (47.3)	-	9/49 (18.4)	-	-	-	
Rest of world	2/2 (100.0)	-	2/5 (40.0)	-	-	-	

Page 1 of 3

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Overall Survival (OS) time is calculated from time of randomization until death due to any cause.

Months are calculated as days from randomization date to event date, divided by 30.5.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-os-fas.sas

Output: t14-04-002-001-subgrp-os-fas.rtf (Date generated: 29MAY2025:09:11) Source data: a215up.adsl, a215up.adbase, a215up.adtteff

**Table 14-4.2.1. Overall Survival by Subgroup
(Full Analysis Set)**

	HC3 (N = 57)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.5443
M1 with MRD level < 10 ⁻³	18/36 (50.0)	52.7 (17.5, NE)	8/35 (22.9)	NE (NE, NE)	0.37 (0.16, 0.86)	0.0154	
M1 with MRD level ≥ 10 ⁻³ or M2	10/21 (47.6)	19.3 (8.0, NE)	3/19 (15.8)	NE (NE, NE)	0.25 (0.07, 0.91)	0.0228	
Race							0.2323
Caucasian	21/46 (45.7)	52.7 (17.5, NE)	9/50 (18.0)	NE (NE, NE)	0.30 (0.14, 0.67)	0.0016	
Others	7/11 (63.6)	22.2 (4.5, NE)	2/4 (50.0)	NE (3.3, NE)	0.91 (0.19, 4.38)	0.9026	
Time from 1 st diagnosis to relapse							0.1214
< 18 months	12/22 (54.5)	21.7 (7.2, NE)	2/19 (10.5)	NE (NE, NE)	0.13 (0.03, 0.58)	0.0016	
≥ 18 months	16/35 (45.7)	52.7 (17.5, NE)	9/35 (25.7)	NE (NE, NE)	0.49 (0.22, 1.12)	0.0834	

Page 2 of 3

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Overall Survival (OS) time is calculated from time of randomization until death due to any cause.

Months are calculated as days from randomization date to event date, divided by 30.5.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-os-fas.sas

Output: t14-04-002-001-subgrp-os-fas.rtf (Date generated: 29MAY2025:09:11) Source data: a215up.adsl, a215up.adbase, a215up.adtteff

**Table 14-4.2.1. Overall Survival by Subgroup
(Full Analysis Set)**

	HC3 (N = 57)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.6457
<10 ⁻⁴	14/31 (45.2)	56.5 (18.6, NE)	5/28 (17.9)	NE (NE, NE)	0.37 (0.13, 1.03)	0.0465	
≥10 ⁻⁴	14/25 (56.0)	19.5 (10.2, NE)	6/26 (23.1)	NE (NE, NE)	0.28 (0.11, 0.74)	0.0059	
Extramedullary Disease at relapse							0.4915
Yes	7/15 (46.7)	56.5 (7.2, NE)	3/10 (30.0)	NE (3.9, NE)	0.52 (0.13, 2.02)	0.3373	
No	21/42 (50.0)	25.2 (17.5, NE)	8/44 (18.2)	NE (NE, NE)	0.28 (0.12, 0.64)	0.0012	

Page 3 of 3

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Overall Survival (OS) time is calculated from time of randomization until death due to any cause.

Months are calculated as days from randomization date to event date, divided by 30.5.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-os-fas.sas

Output: t14-04-002-001-subgrp-os-fas.rtf (Date generated: 29MAY2025:09:11) Source data: a215up.adsl, a215up.adbase, a215up.adtteff

Anhang 4-G3.2: Subgruppenanalysen zum Ereignisfreien Überleben

**Table 14-4.2.2. Event Free Survival by Subgroup
(Full Analysis Set)**

	HC3 (N = 57)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.4368
1-9 years	28/41 (68.3)	7.4 (4.5, 12.7)	14/39 (35.9)	NE (24.8, NE)	0.34 (0.18, 0.64)	0.0005	
Other	9/16 (56.3)	8.1 (1.9, NE)	7/15 (46.7)	50.5 (5.3, NE)	0.49 (0.18, 1.33)	0.1539	
Sex							0.0791
Male	16/23 (69.6)	5.8 (1.3, 9.2)	10/30 (33.3)	NE (24.4, NE)	0.23 (0.10, 0.52)	0.0001	
Female	21/34 (61.8)	9.5 (6.4, 28.6)	11/24 (45.8)	NE (6.8, NE)	0.57 (0.27, 1.18)	0.1244	
Region							-
Europe	35/55 (63.6)	-	18/49 (36.7)	-	-	-	
Rest of world	2/2 (100.0)	-	3/5 (60.0)	-	-	-	

Page 1 of 3

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Event Free Survival (EFS) is calculated from the time of randomization until the date relapse or M2 marrow after having achieved a CR, failure to achieve a CR at the end of treatment, second malignancy, or death due to any cause, whichever occurs first.

Months are calculated as days from randomization date to event date, divided by 30.5.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-efs-fas.sas

Output: t14-04-002-002-subgrp-efs-fas.rtf (Date generated: 29MAY2025:09:11) Source data: a215up.adsl, a215up.adbase, a215up.adtteeff

**Table 14-4.2.2. Event Free Survival by Subgroup
(Full Analysis Set)**

	HC3 (N = 57)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.3697
M1 with MRD level < 10 ⁻³	23/36 (63.9)	8.8 (5.8, 22.0)	14/35 (40.0)	NE (12.0, NE)	0.45 (0.23, 0.88)	0.0162	
M1 with MRD level ≥ 10 ⁻³ or M2	14/21 (66.7)	4.5 (1.1, 9.2)	7/19 (36.8)	NE (5.6, NE)	0.27 (0.11, 0.69)	0.0035	
Race							0.4198
Caucasian	29/46 (63.0)	8.1 (5.8, 15.4)	18/50 (36.0)	NE (24.8, NE)	0.37 (0.21, 0.67)	0.0007	
Others	8/11 (72.7)	5.7 (1.0, 18.6)	3/4 (75.0)	25.8 (3.3, NE)	0.66 (0.17, 2.52)	0.5430	
Time from 1 st diagnosis to relapse							0.2391
< 18 months	17/22 (77.3)	4.5 (1.6, 9.2)	8/19 (42.1)	NE (6.8, NE)	0.26 (0.11, 0.61)	0.0009	
≥ 18 months	20/35 (57.1)	9.5 (6.4, NE)	13/35 (37.1)	NE (12.0, NE)	0.47 (0.24, 0.96)	0.0331	

Page 2 of 3

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Event Free Survival (EFS) is calculated from the time of randomization until the date relapse or M2 marrow after having achieved a CR, failure to achieve a CR at the end of treatment, second malignancy, or death due to any cause, whichever occurs first.

Months are calculated as days from randomization date to event date, divided by 30.5.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-efs-fas.sas

Output: t14-04-002-002-subgrp-efs-fas.rtf (Date generated: 29MAY2025:09:11) Source data: a215up.adsl, a215up.adbase, a215up.adtteff

**Table 14-4.2.2. Event Free Survival by Subgroup
(Full Analysis Set)**

	HC3 (N = 57)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.4657
<10 ⁻⁴	20/31 (64.5)	9.5 (5.8, 28.6)	10/28 (35.7)	NE (12.0, NE)	0.43 (0.20, 0.93)	0.0263	
≥10 ⁻⁴	17/25 (68.0)	5.8 (1.1, 9.2)	11/26 (42.3)	NE (8.4, NE)	0.32 (0.15, 0.69)	0.0023	
Extramedullary Disease at relapse							0.4890
Yes	10/15 (66.7)	4.5 (1.9, 28.6)	6/10 (60.0)	11.3 (3.9, NE)	0.51 (0.19, 1.42)	0.1911	
No	27/42 (64.3)	8.1 (5.8, 15.4)	15/44 (34.1)	NE (45.2, NE)	0.34 (0.18, 0.65)	0.0006	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Event Free Survival (EFS) is calculated from the time of randomization until the date relapse or M2 marrow after having achieved a CR, failure to achieve a CR at the end of treatment, second malignancy, or death due to any cause, whichever occurs first.

Months are calculated as days from randomization date to event date, divided by 30.5.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-04-002-002-subgrp-efs-fas.rtf (Date generated: 29MAY2025:09:11) Source data: a215up.adsl, a215up.adbase, a215up.adtteff

Anhang 4-G3.3: Subgruppenanalysen zur Remission der minimalen Resterkrankung

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Age group				0.4777
1-9 years	41	39		
Number of subjects assessed	36	34		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	18 (50.0)	33 (97.1)	47.1	
Unstratified odds ratio ^a (95% CI) p-value			33.00 (4.07, 267.86) 0.0011	
Unstratified risk ratio ^a (95% CI) p-value			1.94 (1.39, 2.71) <0.0001	
Absolute risk reduction (95% CI) p-value			0.47 (0.30, 0.64) <0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-
pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data:
a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Other	16	15		
Number of subjects assessed	12	13		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	8 (66.7)	13 (100.0)	33.3	
Unstratified odds ratio ^a			14.29	
(95% CI)			(0.68, 300.20)	
p-value			0.0869	
Unstratified risk ratio ^a			1.47	
(95% CI)			(0.98, 2.22)	
p-value			0.0621	
Absolute risk reduction			0.31	
(95% CI)			(0.03, 0.59)	
p-value			0.0276	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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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Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Sex				0.5483
Male	23	30		
Number of subjects assessed	18	26		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	7 (38.9)	25 (96.2)	57.3	
Unstratified odds ratio ^a			39.29	
(95% CI)			(4.30, 358.85)	
p-value			0.0011	
Unstratified risk ratio ^a			2.47	
(95% CI)			(1.38, 4.43)	
p-value			0.0024	
Absolute risk reduction			0.57	
(95% CI)			(0.34, 0.81)	
p-value			<0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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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pcr-fas.sas

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Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Female	34	24		
Number of subjects assessed	30	21		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	19 (63.3)	21 (100.0)	36.7	
Unstratified odds ratio ^a			25.36	
(95% CI)			(1.40, 459.47)	
p-value			0.0287	
Unstratified risk ratio ^a			1.55	
(95% CI)			(1.18, 2.05)	
p-value			0.0019	
Absolute risk reduction			0.35	
(95% CI)			(0.17, 0.53)	
p-value			0.0002	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Region				-
Europe	55	49		
Number of subjects assessed	47	46		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	25 (53.2)	45 (97.8)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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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a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Rest of world	2	5		
Number of subjects assessed	1	1		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	1 (100.0)	1 (100.0)	-	
Unstratified odds ratio ^a			-	
(95% CI)			-	
p-value			-	
Unstratified risk ratio ^a			-	
(95% CI)			-	
p-value			-	
Absolute risk reduction			-	
(95% CI)			-	
p-value			-	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Marrow/MRD Status at baseline				0.5295
M1 with MRD level $< 10^{-3}$	36	35		
Number of subjects assessed	31	30		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	20 (64.5)	29 (96.7)	32.2	
Unstratified odds ratio ^a (95% CI) p-value			15.95 (1.91, 133.53) 0.0106	
Unstratified risk ratio ^a (95% CI) p-value			1.50 (1.14, 1.96) 0.0033	
Absolute risk reduction (95% CI) p-value			0.32 (0.14, 0.50) 0.0005	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
M1 with MRD level $\geq 10^{-3}$ or M2	21	19		
Number of subjects assessed	17	17		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	6 (35.3)	17 (100.0)	64.7	
Unstratified odds ratio ^a			61.92	
(95% CI)			(3.17, 1208.18)	
p-value			0.0065	
Unstratified risk ratio ^a			2.69	
(95% CI)			(1.45, 5.00)	
p-value			0.0017	
Absolute risk reduction			0.61	
(95% CI)			(0.38, 0.85)	
p-value			<0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval.

Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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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Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Race				0.0614
Caucasian	46	50		
Number of subjects assessed	38	45		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	20 (52.6)	44 (97.8)	45.1	
Unstratified odds ratio ^a			39.60	
(95% CI)			(4.94, 317.55)	
p-value			0.0005	
Unstratified risk ratio ^a			1.86	
(95% CI)			(1.37, 2.52)	
p-value			<0.0001	
Absolute risk reduction			0.45	
(95% CI)			(0.29, 0.62)	
p-value			<0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

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One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

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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a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Others	11	4		
Number of subjects assessed	10	2		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	6 (60.0)	2 (100.0)	40.0	
Unstratified odds ratio ^a			3.46	
(95% CI)			(0.13, 90.67)	
p-value			0.4561	
Unstratified risk ratio ^a			1.41	
(95% CI)			(0.70, 2.86)	
p-value			0.3396	
Absolute risk reduction			0.24	
(95% CI)			(-0.27, 0.75)	
p-value			0.3535	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

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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 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Time from 1st diagnosis to relapse				0.6451
< 18 months	22	19		
Number of subjects assessed	20	17		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	11 (55.0)	17 (100.0)	45.0	
Unstratified odds ratio ^a			28.91	
(95% CI)			(1.53, 546.64)	
p-value			0.0249	
Unstratified risk ratio ^a			1.78	
(95% CI)			(1.19, 2.64)	
p-value			0.0045	
Absolute risk reduction			0.42	
(95% CI)			(0.20, 0.65)	
p-value			0.0002	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

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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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
≥ 18 months	35	35		
Number of subjects assessed	28	30		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	15 (53.6)	29 (96.7)	43.1	
Unstratified odds ratio ^a			25.13	
(95% CI)			(2.99, 210.93)	
p-value			0.0030	
Unstratified risk ratio ^a			1.80	
(95% CI)			(1.27, 2.56)	
p-value			0.0010	
Absolute risk reduction			0.43	
(95% CI)			(0.24, 0.63)	
p-value			<0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
MRD before treatment start				0.1140
$<10^{-4}$	31	28		
Number of subjects assessed	26	21		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	22 (84.6)	21 (100.0)	15.4	
Unstratified odds ratio ^a			8.60	
(95% CI)			(0.44, 169.42)	
p-value			0.1571	
Unstratified risk ratio ^a			1.17	
(95% CI)			(0.98, 1.40)	
p-value			0.0833	
Absolute risk reduction			0.14	
(95% CI)			(-0.01, 0.30)	
p-value			0.0665	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
$\geq 10^{-4}$	25	26		
Number of subjects assessed	22	26		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	4 (18.2)	25 (96.2)	78.0	
Unstratified odds ratio ^a (95% CI) p-value			112.50 (11.58, 1092.76) <0.0001	
Unstratified risk ratio ^a (95% CI) p-value			5.29 (2.17, 12.87) 0.0002	
Absolute risk reduction (95% CI) p-value			0.78 (0.60, 0.96) <0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
Extramedullary Disease at relapse				0.5972
Yes	15	10		
Number of subjects assessed	14	9		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	10 (71.4)	9 (100.0)	28.6	
Unstratified odds ratio ^a			8.14	
(95% CI)			(0.39, 172.05)	
p-value			0.1779	
Unstratified risk ratio ^a			1.36	
(95% CI)			(0.95, 1.95)	
p-value			0.0969	
Absolute risk reduction			0.25	
(95% CI)			(-0.02, 0.52)	
p-value			0.0679	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Table 14-4.2.4. Subgroup Analysis - MRD level $<10^{-4}$ Reduction by PCR (Full Analysis Set)

	HC3 (N = 57)	Blinatumomab (N = 54)	Treatment Difference	Interaction p-value ^b
No	42	44		
Number of subjects assessed	34	38		
Number of subjects with MRD level $<10^{-4}$ reduction - n (%)	16 (47.1)	37 (97.4)	50.3	
Unstratified odds ratio ^a			41.62	
(95% CI)			(5.11, 339.00)	
p-value			0.0005	
Unstratified risk ratio ^a			2.07	
(95% CI)			(1.44, 2.97)	
p-value			<0.0001	
Absolute risk reduction			0.50	
(95% CI)			(0.33, 0.68)	
p-value			<0.0001	

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N = Number of subjects in the analysis set and treatment arm. n = Number of subjects with observed data. MRD = Minimal residual disease. PCR = Polymerase chain reaction. CI = Confidence interval. Percentages calculated by using number of subjects assessed as denominator.

MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product.

Subjects who are part of full analysis set and are missing end of treatment (Cycle 1 Day 29) assessment for respective MRD assessment methods are considered not to have achieved a response.

One subject baseline minimal residual disease status is inevaluable, hence the subject did not considered in MRD before treatment start subgroup.

^a The odds ratio obtained from a logistic regression models with logit link and risk ratio obtained from generalized binomial models with log link. An odds ratio or risk ratio <1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.

^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.

In cases with zero events, the table presents OR, RR, and ARR, including 95% confidence intervals and p-values, with zero-cell correction.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-mrd-pcr-fas.sas

Output: t14-04-002-004-subgrp-mrd-pcr-fas.rtf (Date generated: 29MAY2025:01:10) Source data: a215up.adsl, a215up.adbase, a215up.adrs

Anhang 4-G3.4: Subgruppenanalysen zu Sicherheitsrelevanten Endpunkten

Anhang 4-G3.4.1: Subgruppenanalysen zu Gesamtraten UE

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.3685
1-9 years	36/38 (94.7)	0.1 (0.1, 0.2)	39/39 (100.0)	0.03 (0.03, 0.1)	2.60 (1.61, 4.17)	0.0001	
Other	14/14 (100.0)	0.1 (0.03, 0.2)	15/15 (100.0)	0.03 (NE, NE)	1.39 (0.64, 3.01)	0.6235	
Sex							0.5367
Male	20/20 (100.0)	0.2 (0.1, 0.3)	30/30 (100.0)	0.03 (0.03, 0.1)	1.87 (1.03, 3.40)	0.0843	
Female	30/32 (93.8)	0.1 (0.1, 0.2)	24/24 (100.0)	0.03 (NE, NE)	2.66 (1.50, 4.69)	0.0009	
Region							-
Europe	49/50 (98.0)	-	49/49 (100.0)	-	-	-	
Rest of world	1/2 (50.0)	-	5/5 (100.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-saf.sas

Output: t14-06-001-001-subgrp-ae-saf.rtf (Date generated: 13JUN2025:06:37) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.7888
M1 with MRD level < 10 ⁻³	32/33 (97.0)	0.1 (0.1, 0.2)	35/35 (100.0)	0.03 (0.03, 0.1)	2.08 (1.26, 3.43)	0.0091	
M1 with MRD level ≥ 10 ⁻³ or M2	18/19 (94.7)	0.1 (0.03, 0.2)	19/19 (100.0)	0.03 (NE, NE)	2.22 (1.13, 4.37)	0.0259	
Race							0.4491
Caucasian	40/42 (95.2)	0.1 (0.1, 0.2)	50/50 (100.0)	0.03 (NE, NE)	2.12 (1.38, 3.26)	0.0014	
Others	10/10 (100.0)	0.2 (0.03, 0.2)	4/4 (100.0)	0.03 (0.03, NE)	4.29 (1.03, 17.94)	0.0359	
Time from 1 st diagnosis to relapse							0.1133
< 18 months	20/21 (95.2)	0.1 (0.1, 0.2)	19/19 (100.0)	0.03 (0.03, 0.1)	4.39 (2.05, 9.40)	<0.0001	
≥ 18 months	30/31 (96.8)	0.1 (0.1, 0.2)	35/35 (100.0)	0.03 (NE, NE)	1.72 (1.03, 2.87)	0.0628	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-saf.sas

Output: t14-06-001-001-subgrp-ae-saf.rtf (Date generated: 13JUN2025:06:37) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.0866
<10 ⁻⁴	29/29 (100.0)	0.1 (0.1, 0.2)	28/28 (100.0)	0.03 (0.03, 0.1)	1.52 (0.88, 2.62)	0.2173	
≥10 ⁻⁴	21/23 (91.3)	0.1 (0.1, 0.2)	26/26 (100.0)	0.03 (NE, NE)	3.36 (1.79, 6.30)	0.0002	
Extramedullary Disease at relapse							0.5910
Yes	14/14 (100.0)	0.1 (0.03, 0.2)	10/10 (100.0)	0.03 (0.03, 0.1)	1.74 (0.73, 4.19)	0.2113	
No	36/38 (94.7)	0.1 (0.1, 0.2)	44/44 (100.0)	0.03 (NE, NE)	2.29 (1.45, 3.62)	0.0007	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-saf.sas

Output: t14-06-001-001-subgrp-ae-saf.rtf (Date generated: 13JUN2025:06:37) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.0968
1-9 years	20/38 (52.6)	1.1 (0.4, NE)	10/39 (25.6)	NE (NE, NE)	0.36 (0.17, 0.77)	0.0062	
Other	4/14 (28.6)	NE (0.4, NE)	5/15 (33.3)	NE (0.1, NE)	1.44 (0.39, 5.38)	0.6596	
Sex							0.8280
Male	12/20 (60.0)	1.0 (0.4, NE)	10/30 (33.3)	NE (1.3, NE)	0.53 (0.23, 1.24)	0.1181	
Female	12/32 (37.5)	NE (0.5, NE)	5/24 (20.8)	NE (1.9, NE)	0.42 (0.15, 1.21)	0.1009	
Region							-
Europe	23/50 (46.0)	-	12/49 (24.5)	-	-	-	
Rest of world	1/2 (50.0)	-	3/5 (60.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-ser-saf.sas

Output: t14-06-001-002-subgrp-ae-ser-saf.rtf (Date generated: 13JUN2025:06:37) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.4371
M1 with MRD level < 10 ⁻³	13/33 (39.4)	NE (0.6, NE)	10/35 (28.6)	NE (1.9, NE)	0.63 (0.28, 1.45)	0.2689	
M1 with MRD level ≥ 10 ⁻³ or M2	11/19 (57.9)	1.0 (0.3, NE)	5/19 (26.3)	NE (1.3, NE)	0.38 (0.13, 1.10)	0.0649	
Race							0.0590
Caucasian	19/42 (45.2)	NE (0.6, NE)	12/50 (24.0)	NE (NE, NE)	0.44 (0.21, 0.92)	0.0238	
Others	5/10 (50.0)	NE (0.3, NE)	3/4 (75.0)	1.0 (0.1, NE)	2.18 (0.52, 9.18)	0.2976	
Time from 1 st diagnosis to relapse							0.1828
< 18 months	8/21 (38.1)	NE (0.4, NE)	2/19 (10.5)	NE (NE, NE)	0.21 (0.04, 0.99)	0.0295	
≥ 18 months	16/31 (51.6)	1.2 (0.5, NE)	13/35 (37.1)	NE (1.8, NE)	0.67 (0.32, 1.40)	0.2685	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-ser-saf.sas

Output: t14-06-001-002-subgrp-ae-ser-saf.rtf (Date generated: 13JUN2025:06:37) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.1129
<10 ⁻⁴	13/29 (44.8)	NE (0.4, NE)	11/28 (39.3)	NE (1.8, NE)	0.82 (0.37, 1.85)	0.6123	
≥10 ⁻⁴	11/23 (47.8)	NE (0.4, NE)	4/26 (15.4)	NE (NE, NE)	0.27 (0.08, 0.84)	0.0159	
Extramedullary Disease at relapse							0.3089
Yes	7/14 (50.0)	NE (0.3, NE)	2/10 (20.0)	NE (1.8, NE)	0.26 (0.05, 1.25)	0.0719	
No	17/38 (44.7)	NE (0.6, NE)	13/44 (29.5)	NE (NE, NE)	0.62 (0.30, 1.27)	0.1770	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-ser-saf.sas

Output: t14-06-001-002-subgrp-ae-ser-saf.rtf (Date generated: 13JUN2025:06:37) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.1.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.9418
1-9 years	31/38 (81.6)	0.3 (0.2, 0.4)	24/39 (61.5)	1.6 (0.9, NE)	0.40 (0.23, 0.70)	0.0010	
Other	12/14 (85.7)	0.3 (0.1, 0.4)	9/15 (60.0)	1.7 (0.1, NE)	0.44 (0.18, 1.08)	0.0693	
Sex							0.1460
Male	18/20 (90.0)	0.2 (0.1, 0.3)	17/30 (56.7)	1.7 (1.3, NE)	0.26 (0.13, 0.55)	0.0002	
Female	25/32 (78.1)	0.3 (0.2, 0.5)	16/24 (66.7)	1.7 (0.5, 1.9)	0.55 (0.29, 1.05)	0.0670	
Region							-
Europe	42/50 (84.0)	-	28/49 (57.1)	-	-	-	
Rest of world	1/2 (50.0)	-	5/5 (100.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-grd3-saf.sas

Output: t14-06-001-003-subgrp-ae-grd3-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.1.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.6486
M1 with MRD level < 10 ⁻³	26/33 (78.8)	0.3 (0.2, 0.4)	21/35 (60.0)	1.7 (1.3, NE)	0.41 (0.22, 0.75)	0.0029	
M1 with MRD level ≥ 10 ⁻³ or M2	17/19 (89.5)	0.2 (0.1, 0.3)	12/19 (63.2)	1.6 (0.1, NE)	0.40 (0.18, 0.86)	0.0160	
Race							0.7842
Caucasian	35/42 (83.3)	0.3 (0.2, 0.3)	31/50 (62.0)	1.7 (1.3, 1.9)	0.38 (0.23, 0.63)	0.0001	
Others	8/10 (80.0)	0.2 (0.1, 0.4)	2/4 (50.0)	NE (0.03, NE)	0.72 (0.15, 3.46)	0.6533	
Time from 1 st diagnosis to relapse							0.7239
< 18 months	16/21 (76.2)	0.3 (0.1, 0.4)	11/19 (57.9)	1.6 (0.9, NE)	0.42 (0.19, 0.93)	0.0304	
≥ 18 months	27/31 (87.1)	0.3 (0.2, 0.3)	22/35 (62.9)	1.7 (0.6, 1.9)	0.38 (0.21, 0.71)	0.0015	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-grd3-saf.sas

Output: t14-06-001-003-subgrp-ae-grd3-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.1.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.5518
<10 ⁻⁴	25/29 (86.2)	0.3 (0.2, 0.3)	18/28 (64.3)	1.7 (1.3, 1.9)	0.31 (0.17, 0.59)	0.0002	
≥10 ⁻⁴	18/23 (78.3)	0.3 (0.2, 0.4)	15/26 (57.7)	1.7 (0.1, NE)	0.57 (0.28, 1.16)	0.1125	
Extramedullary Disease at relapse							0.6494
Yes	11/14 (78.6)	0.2 (0.1, 0.5)	5/10 (50.0)	1.9 (0.03, NE)	0.38 (0.13, 1.12)	0.0785	
No	32/38 (84.2)	0.3 (0.2, 0.4)	28/44 (63.6)	1.7 (1.3, 1.9)	0.39 (0.23, 0.68)	0.0006	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-grd3-saf.sas

Output: t14-06-001-003-subgrp-ae-grd3-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.9989
1-9 years	0/38 (0.0)	-	0/39 (0.0)	-	-	-	
Other	0/14 (0.0)	-	2/15 (13.3)	-	-	-	
Sex							0.9990
Male	0/20 (0.0)	-	2/30 (6.7)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-trtdis-saf.sas

Output: t14-06-001-004-subgrp-ae-trtdis-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.9989
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	2/35 (5.7)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9998
Caucasian	0/42 (0.0)	-	1/50 (2.0)	-	-	-	
Others	0/10 (0.0)	-	1/4 (25.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9989
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	2/35 (5.7)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-trtdis-saf.sas

Output: t14-06-001-004-subgrp-ae-trtdis-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

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

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9991
<10 ⁻⁴	0/29 (0.0)	-	2/28 (7.1)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9990
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	2/44 (4.5)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-trtdis-saf.sas

Output: t14-06-001-004-subgrp-ae-trtdis-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.3685
1-9 years	36/38 (94.7)	0.1 (0.1, 0.2)	39/39 (100.0)	0.03 (0.03, 0.1)	2.60 (1.61, 4.17)	0.0001	
Other	14/14 (100.0)	0.1 (0.03, 0.2)	15/15 (100.0)	0.03 (NE, NE)	1.39 (0.64, 3.01)	0.6235	
Sex							0.5367
Male	20/20 (100.0)	0.2 (0.1, 0.3)	30/30 (100.0)	0.03 (0.03, 0.1)	1.87 (1.03, 3.40)	0.0843	
Female	30/32 (93.8)	0.1 (0.1, 0.2)	24/24 (100.0)	0.03 (NE, NE)	2.66 (1.50, 4.69)	0.0009	
Region							-
Europe	49/50 (98.0)	-	49/49 (100.0)	-	-	-	
Rest of world	1/2 (50.0)	-	5/5 (100.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-epd-saf.sas

Output: t14-06-013-001-subgrp-ae-epd-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.7888
M1 with MRD level < 10 ⁻³	32/33 (97.0)	0.1 (0.1, 0.2)	35/35 (100.0)	0.03 (0.03, 0.1)	2.08 (1.26, 3.43)	0.0091	
M1 with MRD level ≥ 10 ⁻³ or M2	18/19 (94.7)	0.1 (0.03, 0.2)	19/19 (100.0)	0.03 (NE, NE)	2.22 (1.13, 4.37)	0.0259	
Race							0.4491
Caucasian	40/42 (95.2)	0.1 (0.1, 0.2)	50/50 (100.0)	0.03 (NE, NE)	2.12 (1.38, 3.26)	0.0014	
Others	10/10 (100.0)	0.2 (0.03, 0.2)	4/4 (100.0)	0.03 (0.03, NE)	4.29 (1.03, 17.94)	0.0359	
Time from 1 st diagnosis to relapse							0.1133
< 18 months	20/21 (95.2)	0.1 (0.1, 0.2)	19/19 (100.0)	0.03 (0.03, 0.1)	4.39 (2.05, 9.40)	<0.0001	
≥ 18 months	30/31 (96.8)	0.1 (0.1, 0.2)	35/35 (100.0)	0.03 (NE, NE)	1.72 (1.03, 2.87)	0.0628	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-epd-saf.sas

Output: t14-06-013-001-subgrp-ae-epd-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.0866
<10 ⁻⁴	29/29 (100.0)	0.1 (0.1, 0.2)	28/28 (100.0)	0.03 (0.03, 0.1)	1.52 (0.88, 2.62)	0.2173	
≥10 ⁻⁴	21/23 (91.3)	0.1 (0.1, 0.2)	26/26 (100.0)	0.03 (NE, NE)	3.36 (1.79, 6.30)	0.0002	
Extramedullary Disease at relapse							0.5910
Yes	14/14 (100.0)	0.1 (0.03, 0.2)	10/10 (100.0)	0.03 (0.03, 0.1)	1.74 (0.73, 4.19)	0.2113	
No	36/38 (94.7)	0.1 (0.1, 0.2)	44/44 (100.0)	0.03 (NE, NE)	2.29 (1.45, 3.62)	0.0007	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-epd-saf.sas

Output: t14-06-013-001-subgrp-ae-epd-saf.rtf (Date generated: 13JUN2025:06:38) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.2. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.9418
1-9 years	31/38 (81.6)	0.3 (0.2, 0.4)	24/39 (61.5)	1.6 (0.9, NE)	0.40 (0.23, 0.70)	0.0010	
Other	12/14 (85.7)	0.3 (0.1, 0.4)	9/15 (60.0)	1.7 (0.1, NE)	0.44 (0.18, 1.08)	0.0693	
Sex							0.1460
Male	18/20 (90.0)	0.2 (0.1, 0.3)	17/30 (56.7)	1.7 (1.3, NE)	0.26 (0.13, 0.55)	0.0002	
Female	25/32 (78.1)	0.3 (0.2, 0.5)	16/24 (66.7)	1.7 (0.5, 1.9)	0.55 (0.29, 1.05)	0.0670	
Region							-
Europe	42/50 (84.0)	-	28/49 (57.1)	-	-	-	
Rest of world	1/2 (50.0)	-	5/5 (100.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-grd3-epd-saf.sas

Output: t14-06-013-002-subgrp-ae-grd3-epd-saf.rtf (Date generated: 13JUN2025:06:39) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.2. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.6486
M1 with MRD level < 10 ⁻³	26/33 (78.8)	0.3 (0.2, 0.4)	21/35 (60.0)	1.7 (1.3, NE)	0.41 (0.22, 0.75)	0.0029	
M1 with MRD level ≥ 10 ⁻³ or M2	17/19 (89.5)	0.2 (0.1, 0.3)	12/19 (63.2)	1.6 (0.1, NE)	0.40 (0.18, 0.86)	0.0160	
Race							0.7842
Caucasian	35/42 (83.3)	0.3 (0.2, 0.3)	31/50 (62.0)	1.7 (1.3, 1.9)	0.38 (0.23, 0.63)	0.0001	
Others	8/10 (80.0)	0.2 (0.1, 0.4)	2/4 (50.0)	NE (0.03, NE)	0.72 (0.15, 3.46)	0.6533	
Time from 1 st diagnosis to relapse							0.7239
< 18 months	16/21 (76.2)	0.3 (0.1, 0.4)	11/19 (57.9)	1.6 (0.9, NE)	0.42 (0.19, 0.93)	0.0304	
≥ 18 months	27/31 (87.1)	0.3 (0.2, 0.3)	22/35 (62.9)	1.7 (0.6, 1.9)	0.38 (0.21, 0.71)	0.0015	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-grd3-epd-saf.sas

Output: t14-06-013-002-subgrp-ae-grd3-epd-saf.rtf (Date generated: 13JUN2025:06:39) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.2. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.5518
<10 ⁻⁴	25/29 (86.2)	0.3 (0.2, 0.3)	18/28 (64.3)	1.7 (1.3, 1.9)	0.31 (0.17, 0.59)	0.0002	
≥10 ⁻⁴	18/23 (78.3)	0.3 (0.2, 0.4)	15/26 (57.7)	1.7 (0.1, NE)	0.57 (0.28, 1.16)	0.1125	
Extramedullary Disease at relapse							0.6494
Yes	11/14 (78.6)	0.2 (0.1, 0.5)	5/10 (50.0)	1.9 (0.03, NE)	0.38 (0.13, 1.12)	0.0785	
No	32/38 (84.2)	0.3 (0.2, 0.4)	28/44 (63.6)	1.7 (1.3, 1.9)	0.39 (0.23, 0.68)	0.0006	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-grd3-epd-saf.sas

Output: t14-06-013-002-subgrp-ae-grd3-epd-saf.rtf (Date generated: 13JUN2025:06:39) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.3. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.1151
1-9 years	19/38 (50.0)	1.2 (0.4, NE)	10/39 (25.6)	NE (NE, NE)	0.38 (0.18, 0.83)	0.0117	
Other	4/14 (28.6)	NE (0.4, NE)	5/15 (33.3)	NE (0.1, NE)	1.44 (0.39, 5.38)	0.6596	
Sex							0.7206
Male	11/20 (55.0)	1.1 (0.4, NE)	10/30 (33.3)	NE (1.3, NE)	0.60 (0.25, 1.41)	0.2079	
Female	12/32 (37.5)	NE (0.5, NE)	5/24 (20.8)	NE (1.9, NE)	0.42 (0.15, 1.21)	0.1009	
Region							-
Europe	22/50 (44.0)	-	12/49 (24.5)	-	-	-	
Rest of world	1/2 (50.0)	-	3/5 (60.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-ser-epd-saf.sas

Output: t14-06-013-003-subgrp-ae-ser-epd-saf.rtf (Date generated: 13JUN2025:06:39) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.3. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.3728
M1 with MRD level < 10 ⁻³	12/33 (36.4)	NE (0.6, NE)	10/35 (28.6)	NE (1.9, NE)	0.69 (0.30, 1.61)	0.3834	
M1 with MRD level ≥ 10 ⁻³ or M2	11/19 (57.9)	1.0 (0.3, NE)	5/19 (26.3)	NE (1.3, NE)	0.38 (0.13, 1.10)	0.0649	
Race							0.0689
Caucasian	18/42 (42.9)	NE (0.6, NE)	12/50 (24.0)	NE (NE, NE)	0.47 (0.23, 0.99)	0.0404	
Others	5/10 (50.0)	NE (0.3, NE)	3/4 (75.0)	1.0 (0.1, NE)	2.18 (0.52, 9.18)	0.2976	
Time from 1 st diagnosis to relapse							0.1589
< 18 months	8/21 (38.1)	NE (0.4, NE)	2/19 (10.5)	NE (NE, NE)	0.21 (0.04, 0.99)	0.0295	
≥ 18 months	15/31 (48.4)	NE (0.5, NE)	13/35 (37.1)	NE (1.8, NE)	0.72 (0.34, 1.53)	0.3778	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-ser-epd-saf.sas

Output: t14-06-013-003-subgrp-ae-ser-epd-saf.rtf (Date generated: 13JUN2025:06:39) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.3. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.1517
<10 ⁻⁴	13/29 (44.8)	NE (0.4, NE)	11/28 (39.3)	NE (1.8, NE)	0.82 (0.37, 1.85)	0.6123	
≥10 ⁻⁴	10/23 (43.5)	NE (0.4, NE)	4/26 (15.4)	NE (NE, NE)	0.30 (0.09, 0.97)	0.0329	
Extramedullary Disease at relapse							0.2779
Yes	7/14 (50.0)	NE (0.3, NE)	2/10 (20.0)	NE (1.8, NE)	0.26 (0.05, 1.25)	0.0719	
No	16/38 (42.1)	NE (0.6, NE)	13/44 (29.5)	NE (NE, NE)	0.66 (0.32, 1.38)	0.2570	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-ser-epd-saf.sas

Output: t14-06-013-003-subgrp-ae-ser-epd-saf.rtf (Date generated: 13JUN2025:06:39) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Age group							0.9989
1-9 years	0/38 (0.0)	-	0/39 (0.0)	-	-	-	
Other	0/14 (0.0)	-	2/15 (13.3)	-	-	-	
Sex							0.9990
Male	0/20 (0.0)	-	2/30 (6.7)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-trtdisc-epd-saf.sas

Output: t14-06-013-004-subgrp-ae-trtdisc-epd-saf.rtf (Date generated: 04DEC2025:22:50) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Marrow/MRD Status at baseline							0.9989
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	2/35 (5.7)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9998
Caucasian	0/42 (0.0)	-	1/50 (2.0)	-	-	-	
Others	0/10 (0.0)	-	1/4 (25.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9989
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	2/35 (5.7)	-	-	-	

Page 2 of 3

N = Number of subjects in the analysis set. CI = Confidence interval.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-trtdisc-epd-saf.sas

Output: t14-06-013-004-subgrp-ae-trtdisc-epd-saf.rtf (Date generated: 04DEC2025:22:50) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Table 14-6.13.4. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events Leading to Discontinuation of Study Treatment Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9991
<10 ⁻⁴	0/29 (0.0)	-	2/28 (7.1)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9990
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	2/44 (4.5)	-	-	-	

Page 3 of 3

N = Number of subjects in the analysis set. CI = Confidence interval.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-subgrp-ae-trtdisc-epd-saf.sas

Output: t14-06-013-004-subgrp-ae-trtdisc-epd-saf.rtf (Date generated: 04DEC2025:22:50) Source data: a215up.adsl, adam.adtteae, a215up.adbase

Anhang 4-G3.4.2: Subgruppenanalysen zu UE von besonderem Interesse

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Capillary leak syndrome (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2658	
Age group							0.9993
1-9 years	1/38 (2.6)	-	0/39 (0.0)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	1/20 (5.0)	-	0/30 (0.0)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

Page 1 of 33

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	0/49 (0.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9995
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	0/19 (0.0)	-	-	-	
Race							0.9995
Caucasian	1/42 (2.4)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

Page 2 of 33

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9994
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	1/31 (3.2)	-	0/35 (0.0)	-	-	-	
MRD before treatment start							0.9993
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9994
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	1/38 (2.6)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Cytokine release syndrome (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	2/54 (3.7)	NE (NE, NE)	1.98 (0.18, 21.79)	0.5709	
Age group							0.9962
1-9 years	0/38 (0.0)	-	2/39 (5.1)	-	-	-	
Other	1/14 (7.1)	-	0/15 (0.0)	-	-	-	
Sex							>0.9999
Male	0/20 (0.0)	-	0/30 (0.0)	-	-	-	
Female	1/32 (3.1)	-	2/24 (8.3)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	2/49 (4.1)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							>0.9999
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	2/19 (10.5)	-	-	-	
Race							>0.9999
Caucasian	1/42 (2.4)	-	2/50 (4.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9965
< 18 months	1/21 (4.8)	-	1/19 (5.3)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	
MRD before treatment start							>0.9999
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	2/26 (7.7)	-	-	-	
Extramedullary Disease at relapse							0.9966
Yes	1/14 (7.1)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	2/44 (4.5)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Decreased immunoglobulins (AMQ) - Narrow	6/52 (11.5)	NE (NE, NE)	9/54 (16.7)	NE (NE, NE)	1.40 (0.50, 3.95)	0.5223	
Age group							0.6803
1-9 years	4/38 (10.5)	-	5/39 (12.8)	-	-	-	
Other	2/14 (14.3)	-	4/15 (26.7)	-	-	-	
Sex							0.6827
Male	3/20 (15.0)	-	5/30 (16.7)	-	-	-	
Female	3/32 (9.4)	-	4/24 (16.7)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	6/50 (12.0)	-	7/49 (14.3)	-	-	-	
Rest of world	0/2 (0.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.3142
M1 with MRD level < 10 ⁻³	4/33 (12.1)	NE (NE, NE)	8/35 (22.9)	NE (NE, NE)	1.84 (0.55, 6.12)	0.3136	
M1 with MRD level ≥ 10 ⁻³ or M2	2/19 (10.5)	NE (NE, NE)	1/19 (5.3)	NE (NE, NE)	0.51 (0.05, 5.62)	0.5742	
Race							0.7521
Caucasian	4/42 (9.5)	NE (NE, NE)	8/50 (16.0)	NE (NE, NE)	1.69 (0.51, 5.62)	0.3891	
Others	2/10 (20.0)	NE (0.5, NE)	1/4 (25.0)	NE (1.8, NE)	1.05 (0.09, 11.67)	0.9688	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOIs i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.5032
< 18 months	4/21 (19.0)	-	4/19 (21.1)	-	-	-	
≥ 18 months	2/31 (6.5)	-	5/35 (14.3)	-	-	-	
MRD before treatment start							0.3875
<10 ⁻⁴	3/29 (10.3)	-	6/28 (21.4)	-	-	-	
≥10 ⁻⁴	3/23 (13.0)	-	3/26 (11.5)	-	-	-	
Extramedullary Disease at relapse							0.4261
Yes	2/14 (14.3)	-	4/10 (40.0)	-	-	-	
No	4/38 (10.5)	-	5/44 (11.4)	-	-	-	

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Embotic and thrombotic events (SMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	NE (NE, NE)	0.0459	
Age group							>0.9999
1-9 years	0/38 (0.0)	-	3/39 (7.7)	-	-	-	
Other	0/14 (0.0)	-	1/15 (6.7)	-	-	-	
Sex							>0.9999
Male	0/20 (0.0)	-	2/30 (6.7)	-	-	-	
Female	0/32 (0.0)	-	2/24 (8.3)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	3/49 (6.1)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							>0.9999
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	3/35 (8.6)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	1/19 (5.3)	-	-	-	
Race							0.9989
Caucasian	0/42 (0.0)	-	4/50 (8.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							>0.9999
< 18 months	0/21 (0.0)	-	2/19 (10.5)	-	-	-	
≥ 18 months	0/31 (0.0)	-	2/35 (5.7)	-	-	-	
MRD before treatment start							0.9999
<10 ⁻⁴	0/29 (0.0)	-	3/28 (10.7)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9986
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	4/44 (9.1)	-	-	-	

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Infections and infestations (SOC)	18/52 (34.6)	NE (NE, NE)	25/54 (46.3)	1.9 (1.7, NE)	1.09 (0.60, 2.01)	0.7760	
Age group							0.1144
1-9 years	16/38 (42.1)	NE (0.7, NE)	18/39 (46.2)	1.9 (1.6, NE)	0.80 (0.41, 1.58)	0.5226	
Other	2/14 (14.3)	NE (NE, NE)	7/15 (46.7)	1.9 (0.7, NE)	3.28 (0.68, 15.81)	0.1158	
Sex							0.1389
Male	5/20 (25.0)	NE (1.2, NE)	15/30 (50.0)	1.9 (1.3, NE)	2.01 (0.73, 5.53)	0.1717	
Female	13/32 (40.6)	NE (0.6, NE)	10/24 (41.7)	NE (1.5, NE)	0.71 (0.31, 1.64)	0.4208	

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	17/50 (34.0)	-	21/49 (42.9)	-	-	-	
Rest of world	1/2 (50.0)	-	4/5 (80.0)	-	-	-	
Marrow/MRD Status at baseline							0.5791
M1 with MRD level < 10 ⁻³	10/33 (30.3)	NE (NE, NE)	16/35 (45.7)	1.9 (1.8, NE)	1.23 (0.56, 2.73)	0.6041	
M1 with MRD level ≥ 10 ⁻³ or M2	8/19 (42.1)	NE (0.4, NE)	9/19 (47.4)	1.9 (0.7, NE)	0.89 (0.34, 2.32)	0.8048	
Race							0.9845
Caucasian	13/42 (31.0)	NE (NE, NE)	25/50 (50.0)	1.9 (1.6, NE)	1.37 (0.70, 2.68)	0.3633	
Others	5/10 (50.0)	NE (0.3, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1087	

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.8445
< 18 months	7/21 (33.3)	NE (0.4, NE)	9/19 (47.4)	1.9 (0.7, NE)	1.17 (0.43, 3.15)	0.7592	
≥ 18 months	11/31 (35.5)	NE (1.0, NE)	16/35 (45.7)	1.9 (1.6, NE)	0.99 (0.46, 2.15)	0.9794	
MRD before treatment start							0.0476
<10 ⁻⁴	9/29 (31.0)	NE (1.2, NE)	17/28 (60.7)	1.8 (1.4, NE)	1.86 (0.83, 4.19)	0.1264	
≥10 ⁻⁴	9/23 (39.1)	NE (0.6, NE)	8/26 (30.8)	NE (1.8, NE)	0.56 (0.21, 1.45)	0.2212	
Extramedullary Disease at relapse							0.6423
Yes	3/14 (21.4)	NE (1.0, NE)	4/10 (40.0)	1.9 (0.5, NE)	1.51 (0.33, 6.79)	0.5915	
No	15/38 (39.5)	NE (0.7, NE)	21/44 (47.7)	1.9 (1.5, NE)	0.97 (0.50, 1.88)	0.9191	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Infusion reactions (AMQ) - Narrow	2/52 (3.8)	NE (NE, NE)	26/54 (48.1)	NE (0.1, NE)	16.92 (4.01, 71.40)	<0.0001	
Age group							0.3973
1-9 years	1/38 (2.6)	NE (NE, NE)	20/39 (51.3)	0.1 (0.1, NE)	26.86 (3.60, 200.48)	<0.0001	
Other	1/14 (7.1)	NE (NE, NE)	6/15 (40.0)	NE (0.03, NE)	7.07 (0.85, 58.87)	0.0373	
Sex							0.5950
Male	1/20 (5.0)	NE (NE, NE)	13/30 (43.3)	NE (0.1, NE)	11.13 (1.45, 85.20)	0.0033	
Female	1/32 (3.1)	NE (NE, NE)	13/24 (54.2)	0.1 (0.03, NE)	24.43 (3.19, 187.32)	<0.0001	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	2/50 (4.0)	-	24/49 (49.0)	-	-	-	
Rest of world	0/2 (0.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.6733
M1 with MRD level < 10 ⁻³	1/33 (3.0)	NE (NE, NE)	17/35 (48.6)	NE (0.1, NE)	21.61 (2.87, 162.55)	<0.0001	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	NE (NE, NE)	9/19 (47.4)	NE (0.03, NE)	11.83 (1.49, 93.61)	0.0030	
Race							0.9925
Caucasian	2/42 (4.8)	NE (NE, NE)	25/50 (50.0)	NE (0.1, NE)	14.41 (3.41, 60.94)	<0.0001	
Others	0/10 (0.0)	NE (NE, NE)	1/4 (25.0)	NE (0.1, NE)	NE (NE, NE)	0.1138	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9921
< 18 months	0/21 (0.0)	NE (NE, NE)	10/19 (52.6)	0.1 (0.03, NE)	NE (NE, NE)	0.0001	
≥ 18 months	2/31 (6.5)	NE (NE, NE)	16/35 (45.7)	NE (0.1, NE)	9.30 (2.13, 40.51)	0.0003	
MRD before treatment start							0.9280
<10 ⁻⁴	1/29 (3.4)	NE (NE, NE)	13/28 (46.4)	NE (0.1, NE)	17.77 (2.32, 136.09)	0.0001	
≥10 ⁻⁴	1/23 (4.3)	NE (NE, NE)	13/26 (50.0)	NE (0.03, NE)	15.59 (2.04, 119.46)	0.0004	
Extramedullary Disease at relapse							0.9902
Yes	0/14 (0.0)	NE (NE, NE)	5/10 (50.0)	NE (0.03, NE)	NE (NE, NE)	0.0031	
No	2/38 (5.3)	NE (NE, NE)	21/44 (47.7)	NE (0.1, NE)	12.18 (2.85, 52.03)	<0.0001	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Elevated liver enzymes (SMQ) - Narrow	15/52 (28.8)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	0.39 (0.16, 0.97)	0.0337	
Age group							0.9564
1-9 years	11/38 (28.9)	NE (NE, NE)	5/39 (12.8)	NE (NE, NE)	0.38 (0.13, 1.10)	0.0640	
Other	4/14 (28.6)	NE (0.5, NE)	2/15 (13.3)	NE (1.9, NE)	0.41 (0.07, 2.25)	0.2913	
Sex							0.9887
Male	8/20 (40.0)	NE (0.3, NE)	5/30 (16.7)	NE (NE, NE)	0.33 (0.11, 1.01)	0.0386	
Female	7/32 (21.9)	NE (NE, NE)	2/24 (8.3)	NE (NE, NE)	0.36 (0.07, 1.72)	0.1800	

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No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	15/50 (30.0)	-	6/49 (12.2)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.8250
M1 with MRD level < 10 ⁻³	9/33 (27.3)	NE (NE, NE)	4/35 (11.4)	NE (NE, NE)	0.36 (0.11, 1.18)	0.0753	
M1 with MRD level ≥ 10 ⁻³ or M2	6/19 (31.6)	NE (0.2, NE)	3/19 (15.8)	NE (NE, NE)	0.45 (0.11, 1.81)	0.2443	
Race							0.3010
Caucasian	13/42 (31.0)	NE (NE, NE)	6/50 (12.0)	NE (NE, NE)	0.33 (0.12, 0.86)	0.0166	
Others	2/10 (20.0)	NE (0.4, NE)	1/4 (25.0)	NE (0.5, NE)	1.28 (0.12, 14.16)	0.8404	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.8735
< 18 months	6/21 (28.6)	NE (0.8, NE)	2/19 (10.5)	NE (1.9, NE)	0.37 (0.07, 1.83)	0.2029	
≥ 18 months	9/31 (29.0)	NE (NE, NE)	5/35 (14.3)	NE (NE, NE)	0.40 (0.13, 1.22)	0.0961	
MRD before treatment start							0.9593
<10 ⁻⁴	11/29 (37.9)	NE (0.5, NE)	5/28 (17.9)	NE (1.9, NE)	0.38 (0.13, 1.10)	0.0613	
≥10 ⁻⁴	4/23 (17.4)	NE (NE, NE)	2/26 (7.7)	NE (NE, NE)	0.45 (0.08, 2.45)	0.3358	
Extramedullary Disease at relapse							0.5325
Yes	4/14 (28.6)	NE (0.2, NE)	2/10 (20.0)	NE (0.03, NE)	0.68 (0.12, 3.72)	0.6518	
No	11/38 (28.9)	NE (NE, NE)	5/44 (11.4)	NE (NE, NE)	0.33 (0.11, 0.96)	0.0314	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Lymphopenia (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	NE (NE, NE)	0.3264	
Age group							0.9993
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	0/20 (0.0)	-	1/30 (3.3)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9992
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9994
Caucasian	0/42 (0.0)	-	1/50 (2.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9992
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	
MRD before treatment start							0.9994
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9993
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	1/44 (2.3)	-	-	-	

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Medication errors (SMQ) - Broad	0/52 (0.0)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	NE (NE, NE)	0.3264	
Age group							0.9993
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	0/20 (0.0)	-	1/30 (3.3)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9992
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9994
Caucasian	0/42 (0.0)	-	1/50 (2.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9992
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	
MRD before treatment start							0.9994
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9993
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	1/44 (2.3)	-	-	-	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Neutropenia and febrile neutropenia (AMQ) - Narrow	28/52 (53.8)	0.5 (0.4, NE)	12/54 (22.2)	NE (NE, NE)	0.35 (0.17, 0.69)	0.0016	
Age group							0.7456
1-9 years	20/38 (52.6)	0.5 (0.4, NE)	8/39 (20.5)	NE (NE, NE)	0.35 (0.15, 0.80)	0.0097	
Other	8/14 (57.1)	1.0 (0.3, NE)	4/15 (26.7)	NE (1.4, NE)	0.36 (0.11, 1.20)	0.0811	
Sex							0.4233
Male	12/20 (60.0)	0.4 (0.3, NE)	6/30 (20.0)	NE (NE, NE)	0.24 (0.09, 0.66)	0.0030	
Female	16/32 (50.0)	NE (0.4, NE)	6/24 (25.0)	NE (NE, NE)	0.47 (0.18, 1.21)	0.1130	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	27/50 (54.0)	-	10/49 (20.4)	-	-	-	
Rest of world	1/2 (50.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.7417
M1 with MRD level < 10 ⁻³	17/33 (51.5)	1.4 (0.4, NE)	8/35 (22.9)	NE (NE, NE)	0.38 (0.16, 0.88)	0.0201	
M1 with MRD level ≥ 10 ⁻³ or M2	11/19 (57.9)	0.5 (0.3, NE)	4/19 (21.1)	NE (NE, NE)	0.30 (0.10, 0.96)	0.0346	
Race							0.1497
Caucasian	22/42 (52.4)	1.0 (0.4, NE)	10/50 (20.0)	NE (NE, NE)	0.31 (0.14, 0.65)	0.0014	
Others	6/10 (60.0)	0.5 (0.2, NE)	2/4 (50.0)	NE (0.03, NE)	1.13 (0.23, 5.65)	0.9038	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.0878
< 18 months	11/21 (52.4)	0.5 (0.4, NE)	1/19 (5.3)	NE (NE, NE)	0.08 (0.01, 0.62)	0.0019	
≥ 18 months	17/31 (54.8)	0.5 (0.3, NE)	11/35 (31.4)	NE (1.6, NE)	0.50 (0.23, 1.09)	0.0754	
MRD before treatment start							0.0782
<10 ⁻⁴	18/29 (62.1)	0.5 (0.3, NE)	4/28 (14.3)	NE (NE, NE)	0.17 (0.06, 0.51)	0.0004	
≥10 ⁻⁴	10/23 (43.5)	NE (0.4, NE)	8/26 (30.8)	NE (1.6, NE)	0.66 (0.26, 1.70)	0.3893	
Extramedullary Disease at relapse							0.2223
Yes	9/14 (64.3)	0.4 (0.3, NE)	1/10 (10.0)	NE (0.03, NE)	0.12 (0.01, 0.94)	0.0163	
No	19/38 (50.0)	1.4 (0.4, NE)	11/44 (25.0)	NE (NE, NE)	0.43 (0.20, 0.92)	0.0255	

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^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Neurologic events (AMQ) - Narrow	15/52 (28.8)	NE (NE, NE)	26/54 (48.1)	NE (0.2, NE)	1.96 (1.03, 3.70)	0.0379	
Age group							0.8180
1-9 years	8/38 (21.1)	NE (NE, NE)	15/39 (38.5)	NE (0.5, NE)	2.11 (0.89, 4.99)	0.0836	
Other	7/14 (50.0)	NE (0.1, NE)	11/15 (73.3)	0.2 (0.03, 1.7)	1.81 (0.70, 4.68)	0.2219	
Sex							0.0158
Male	4/20 (20.0)	NE (NE, NE)	19/30 (63.3)	0.4 (0.1, NE)	4.56 (1.55, 13.47)	0.0026	
Female	11/32 (34.4)	NE (0.4, NE)	7/24 (29.2)	NE (1.7, NE)	0.79 (0.30, 2.06)	0.6337	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	15/50 (30.0)	-	24/49 (49.0)	-	-	-	
Rest of world	0/2 (0.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.6620
M1 with MRD level < 10 ⁻³	10/33 (30.3)	NE (1.5, NE)	16/35 (45.7)	NE (0.2, NE)	1.79 (0.81, 3.94)	0.1520	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	NE (1.2, NE)	10/19 (52.6)	1.7 (0.1, NE)	2.32 (0.79, 6.80)	0.1166	
Race							0.4942
Caucasian	12/42 (28.6)	NE (NE, NE)	25/50 (50.0)	1.7 (0.2, NE)	2.03 (1.02, 4.04)	0.0424	
Others	3/10 (30.0)	NE (0.2, NE)	1/4 (25.0)	NE (0.1, NE)	0.95 (0.10, 9.15)	0.9643	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.11. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.1102
< 18 months	8/21 (38.1)	NE (0.4, NE)	7/19 (36.8)	NE (0.2, NE)	1.01 (0.37, 2.79)	0.9907	
≥ 18 months	7/31 (22.6)	NE (NE, NE)	19/35 (54.3)	1.5 (0.1, NE)	2.90 (1.22, 6.92)	0.0121	
MRD before treatment start							0.8627
<10 ⁻⁴	10/29 (34.5)	NE (0.4, NE)	16/28 (57.1)	1.0 (0.1, NE)	2.13 (0.96, 4.71)	0.0588	
≥10 ⁻⁴	5/23 (21.7)	NE (NE, NE)	10/26 (38.5)	NE (0.5, NE)	1.91 (0.65, 5.61)	0.2306	
Extramedullary Disease at relapse							0.3379
Yes	7/14 (50.0)	NE (0.3, NE)	6/10 (60.0)	1.2 (0.03, NE)	1.27 (0.42, 3.80)	0.6813	
No	8/38 (21.1)	NE (NE, NE)	20/44 (45.5)	NE (0.2, NE)	2.56 (1.13, 5.82)	0.0213	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

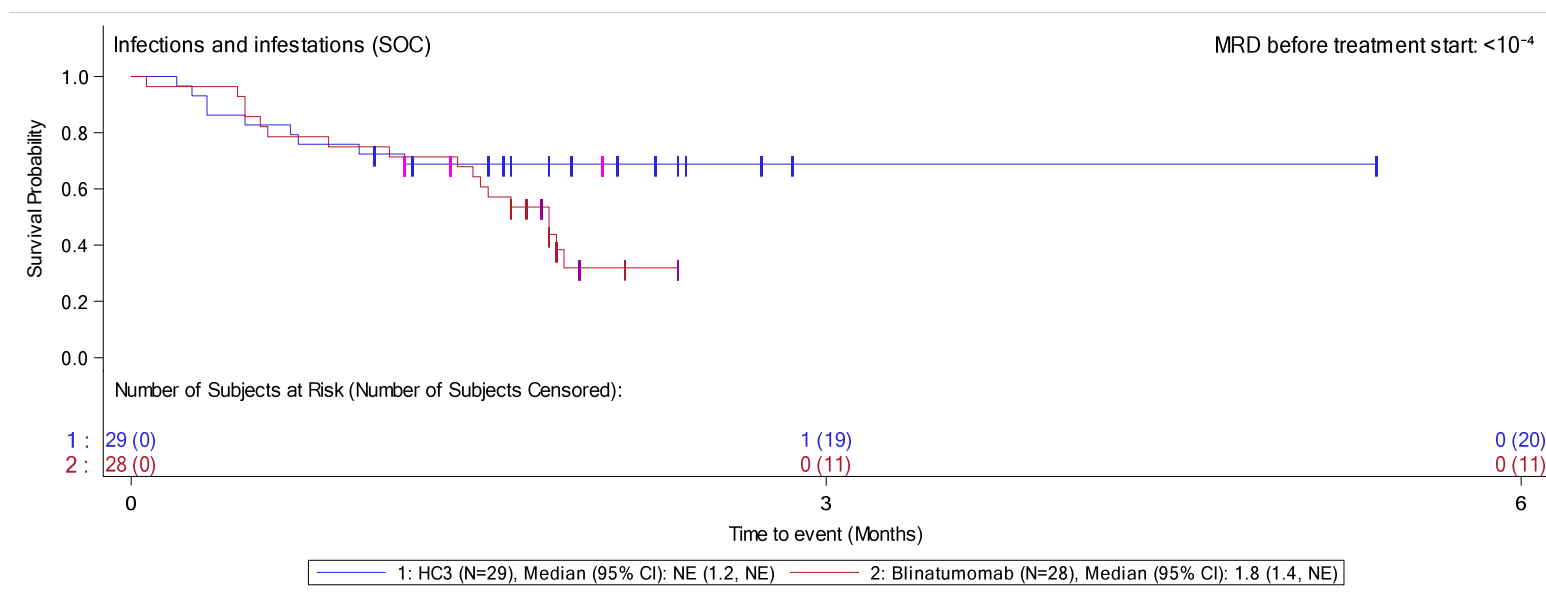
^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-aesi-saf.sas

Output: t14-06-012-011-ae-tte-sub-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:48) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

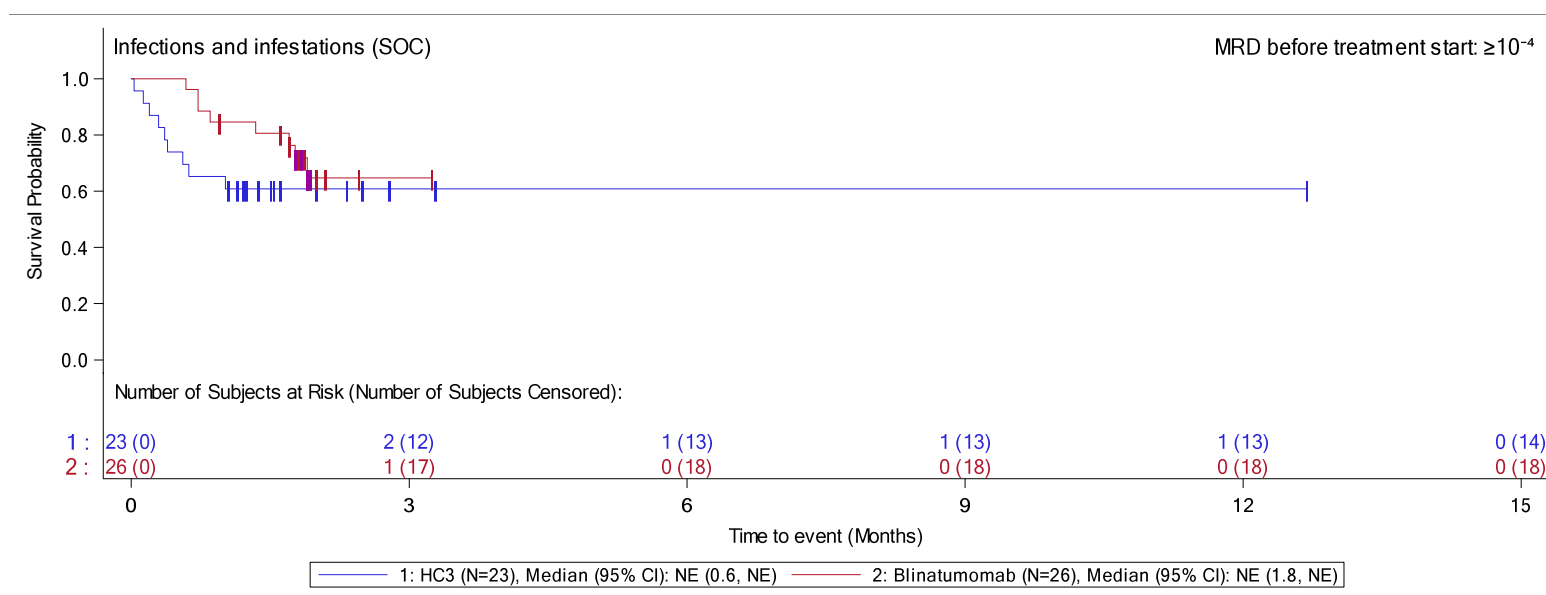


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sub-teae-eoi-saf.sas

Output: f14-06-002-012-km-sub-teae-eoi-saf.rtf (Date Generated: 23JAN26 03:24) Source Data: a215up.adsl, a215up.adbase, adam.adtteae

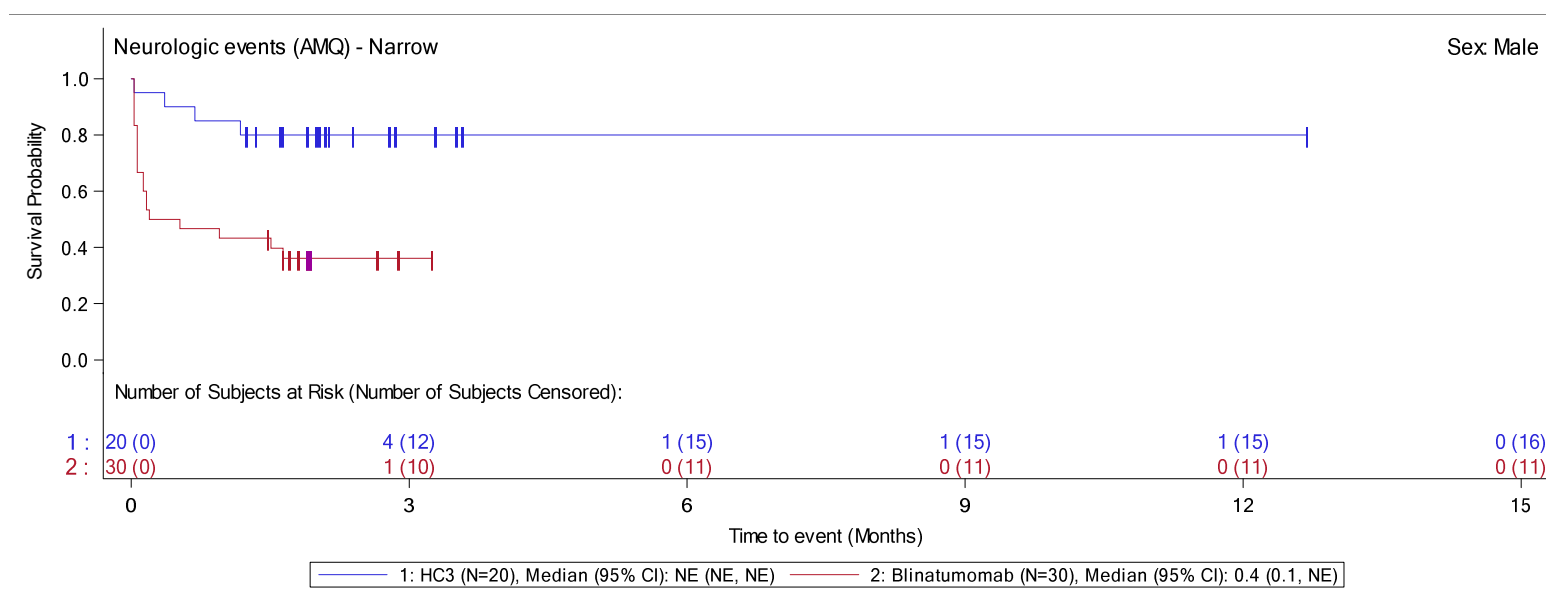
Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sub-teae-eoi-saf.sas
 Output: f14-06-002-012-km-sub-teae-eoi-saf.rtf (Date Generated: 23JAN26 03:24) Source Data: a215up.adsl, a215up.adbase, adam.adtteae

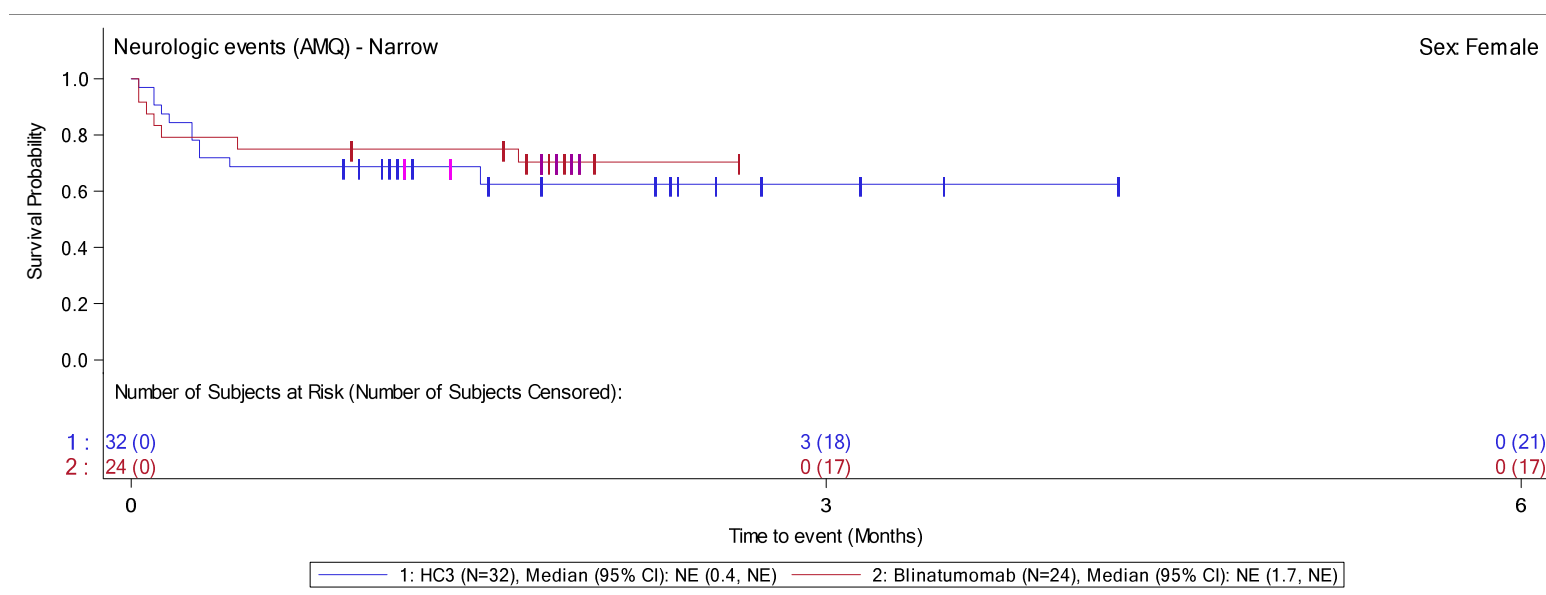
Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sub-teae-eoi-saf.sas
 Output: f14-06-002-012-km-sub-teae-eoi-saf.rtf (Date Generated: 23JAN26 03:24) Source Data: a215up.adsl, a215up.adbase, adam.adtteae

Figure 14-6.2.12. Kaplan-Meier plot for Subgroup Analysis of Time to First Onset of Any Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/figures/f-km-sub-teae-eoi-saf.sas
 Output: f14-06-002-012-km-sub-teae-eoi-saf.rtf (Date Generated: 23JAN26 03:24) Source Data: a215up.adsl, a215up.adbase, adam.adtteae

Anhang 4-G3.4.3: Subgruppenanalysen zu SUE von besonderem Interesse

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Capillary leak syndrome (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2658	
Age group							0.9993
1-9 years	1/38 (2.6)	-	0/39 (0.0)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	1/20 (5.0)	-	0/30 (0.0)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	0/49 (0.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9995
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	0/19 (0.0)	-	-	-	
Race							0.9995
Caucasian	1/42 (2.4)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9994
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	1/31 (3.2)	-	0/35 (0.0)	-	-	-	
MRD before treatment start							0.9993
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9994
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	1/38 (2.6)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		p-value ^b
Cytokine release syndrome (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	0/54 (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.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Decreased immunoglobulins (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	NE (NE, NE)	0.4173	
Age group							0.9993
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9994
Male	0/20 (0.0)	-	0/30 (0.0)	-	-	-	
Female	0/32 (0.0)	-	1/24 (4.2)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	0/49 (0.0)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9992
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9997
Caucasian	0/42 (0.0)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	1/4 (25.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9992
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	
MRD before treatment start							0.9993
<10 ⁻⁴	0/29 (0.0)	-	1/28 (3.6)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9995
Yes	0/14 (0.0)	-	1/10 (10.0)	-	-	-	
No	0/38 (0.0)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Emboolic and thrombotic events (SMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	0/54 (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.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Infections and infestations (SOC)	6/52 (11.5)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	0.54 (0.15, 1.93)	0.3376	
Age group							0.9999
1-9 years	6/38 (15.8)	NE (NE, NE)	4/39 (10.3)	NE (NE, NE)	0.54 (0.15, 1.92)	0.3321	
Other	0/14 (0.0)	NE (NE, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	NE	
Sex							0.1998
Male	3/20 (15.0)	-	1/30 (3.3)	-	-	-	
Female	3/32 (9.4)	-	3/24 (12.5)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	6/50 (12.0)	-	4/49 (8.2)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.4482
M1 with MRD level < 10 ⁻³	3/33 (9.1)	-	3/35 (8.6)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	3/19 (15.8)	-	1/19 (5.3)	-	-	-	
Race							0.9938
Caucasian	5/42 (11.9)	-	4/50 (8.0)	-	-	-	
Others	1/10 (10.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.4922
< 18 months	2/21 (9.5)	-	2/19 (10.5)	-	-	-	
≥ 18 months	4/31 (12.9)	-	2/35 (5.7)	-	-	-	
MRD before treatment start							0.3325
<10 ⁻⁴	3/29 (10.3)	-	3/28 (10.7)	-	-	-	
≥10 ⁻⁴	3/23 (13.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9938
Yes	1/14 (7.1)	-	0/10 (0.0)	-	-	-	
No	5/38 (13.2)	-	4/44 (9.1)	-	-	-	

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Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Infusion reactions (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	NE (NE, NE)	0.3264	
Age group							0.9993
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	0/20 (0.0)	-	1/30 (3.3)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9994
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	1/19 (5.3)	-	-	-	
Race							>0.9999
Caucasian	0/42 (0.0)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	1/4 (25.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9992
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	
MRD before treatment start							0.9994
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9993
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	1/44 (2.3)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Elevated liver enzymes (SMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.3082	
Age group							0.9993
1-9 years	1/38 (2.6)	-	0/39 (0.0)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	1/20 (5.0)	-	0/30 (0.0)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	0/49 (0.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9993
M1 with MRD level < 10 ⁻³	1/33 (3.0)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9995
Caucasian	1/42 (2.4)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9993
< 18 months	1/21 (4.8)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	0/35 (0.0)	-	-	-	
MRD before treatment start							0.9993
<10 ⁻⁴	1/29 (3.4)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9994
Yes	1/14 (7.1)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Lymphopenia (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	0/54 (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.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Medication errors (SMQ) - Broad	0/52 (0.0)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	NE (NE, NE)	0.3264	
Age group							0.9993
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	0/20 (0.0)	-	1/30 (3.3)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9992
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	
Race							0.9994
Caucasian	0/42 (0.0)	-	1/50 (2.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9992
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	
MRD before treatment start							0.9994
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9993
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	1/44 (2.3)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Neutropenia and febrile neutropenia (AMQ) - Narrow	12/52 (23.1)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0002	
Age group							0.9999
1-9 years	10/38 (26.3)	NE (NE, NE)	0/39 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0006	
Other	2/14 (14.3)	NE (NE, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1358	
Sex							>0.9999
Male	4/20 (20.0)	-	0/30 (0.0)	-	-	-	
Female	8/32 (25.0)	-	0/24 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	11/50 (22.0)	-	0/49 (0.0)	-	-	-	
Rest of world	1/2 (50.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9999
M1 with MRD level < 10 ⁻³	6/33 (18.2)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	6/19 (31.6)	-	0/19 (0.0)	-	-	-	
Race							>0.9999
Caucasian	9/42 (21.4)	-	0/50 (0.0)	-	-	-	
Others	3/10 (30.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							>0.9999
< 18 months	4/21 (19.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	8/31 (25.8)	-	0/35 (0.0)	-	-	-	
MRD before treatment start							>0.9999
<10 ⁻⁴	7/29 (24.1)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	5/23 (21.7)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							>0.9999
Yes	4/14 (28.6)	-	0/10 (0.0)	-	-	-	
No	8/38 (21.1)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Neurologic events (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	5.05 (0.59, 43.25)	0.1013	
Age group							0.9961
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	1/14 (7.1)	-	4/15 (26.7)	-	-	-	
Sex							0.9998
Male	1/20 (5.0)	-	5/30 (16.7)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	4/49 (8.2)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9949
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	3/35 (8.6)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	2/19 (10.5)	-	-	-	
Race							0.9955
Caucasian	0/42 (0.0)	-	4/50 (8.0)	-	-	-	
Others	1/10 (10.0)	-	1/4 (25.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.12. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9949
< 18 months	1/21 (4.8)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	5/35 (14.3)	-	-	-	
MRD before treatment start							0.9956
<10 ⁻⁴	0/29 (0.0)	-	4/28 (14.3)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9952
Yes	1/14 (7.1)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	5/44 (11.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EO's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-aesi-saf.sas

Output: t14-06-012-012-ae-tte-sub-ser-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:50) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Anhang 4-G3.4.4: Subgruppenanalysen zu schweren UE von besonderem Interesse

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Capillary leak syndrome (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2658	
Age group							0.9993
1-9 years	1/38 (2.6)	-	0/39 (0.0)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	1/20 (5.0)	-	0/30 (0.0)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	0/49 (0.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9995
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	0/35 (0.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	0/19 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.9995
Caucasian	1/42 (2.4)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9994
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	1/31 (3.2)	-	0/35 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9993
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9994
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	1/38 (2.6)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Cytokine release syndrome (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	0/54 (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.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Decreased immunoglobulins (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	0.78 (0.05, 12.66)	0.8609	
Age group							>0.9999
1-9 years	1/38 (2.6)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9966
Male	1/20 (5.0)	-	0/30 (0.0)	-	-	-	
Female	0/32 (0.0)	-	1/24 (4.2)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	0/49 (0.0)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9971
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	0/19 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.9976
Caucasian	1/42 (2.4)	-	0/50 (0.0)	-	-	-	
Others	0/10 (0.0)	-	1/4 (25.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9969
< 18 months	1/21 (4.8)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9967
<10 ⁻⁴	0/29 (0.0)	-	1/28 (3.6)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							>0.9999
Yes	1/14 (7.1)	-	1/10 (10.0)	-	-	-	
No	0/38 (0.0)	-	0/44 (0.0)	-	-	-	

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Embotic and thrombotic events (SMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	2/54 (3.7)	NE (NE, NE)	NE (NE, NE)	0.1612	
Age group							0.9990
1-9 years	0/38 (0.0)	-	2/39 (5.1)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							>0.9999
Male	0/20 (0.0)	-	1/30 (3.3)	-	-	-	
Female	0/32 (0.0)	-	1/24 (4.2)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	2/49 (4.1)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9989
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	2/35 (5.7)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.9992
Caucasian	0/42 (0.0)	-	2/50 (4.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9990
< 18 months	0/21 (0.0)	-	2/19 (10.5)	-	-	-	
≥ 18 months	0/31 (0.0)	-	0/35 (0.0)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9991
<10 ⁻⁴	0/29 (0.0)	-	2/28 (7.1)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9990
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	2/44 (4.5)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Infections and infestations (SOC)	6/52 (11.5)	NE (NE, NE)	11/54 (20.4)	NE (2.0, NE)	1.50 (0.55, 4.08)	0.4290	
Age group							0.9912
1-9 years	6/38 (15.8)	NE (NE, NE)	9/39 (23.1)	NE (NE, NE)	1.17 (0.42, 3.32)	0.7628	
Other	0/14 (0.0)	NE (NE, NE)	2/15 (13.3)	NE (2.0, NE)	NE (NE, NE)	0.2014	
Sex							0.5758
Male	3/20 (15.0)	-	6/30 (20.0)	-	-	-	
Female	3/32 (9.4)	-	5/24 (20.8)	-	-	-	

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No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	6/50 (12.0)	-	9/49 (18.4)	-	-	-	
Rest of world	0/2 (0.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.2696
M1 with MRD level < 10 ⁻³	2/33 (6.1)	-	7/35 (20.0)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	4/19 (21.1)	-	4/19 (21.1)	-	-	-	

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	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.9913
Caucasian	5/42 (11.9)	NE (NE, NE)	11/50 (22.0)	NE (2.0, NE)	1.53 (0.52, 4.46)	0.4329	
Others	1/10 (10.0)	NE (0.3, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.5271	
Time from 1 st diagnosis to relapse							0.8854
< 18 months	3/21 (14.3)	NE (NE, NE)	4/19 (21.1)	NE (1.9, NE)	1.24 (0.27, 5.56)	0.7814	
≥ 18 months	3/31 (9.7)	NE (NE, NE)	7/35 (20.0)	NE (2.0, NE)	1.59 (0.41, 6.21)	0.5041	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.3864
<10 ⁻⁴	3/29 (10.3)	NE (NE, NE)	7/28 (25.0)	NE (2.0, NE)	2.24 (0.57, 8.77)	0.2363	
≥10 ⁻⁴	3/23 (13.0)	NE (NE, NE)	4/26 (15.4)	NE (1.9, NE)	0.90 (0.20, 4.10)	0.8953	
Extramedullary Disease at relapse							0.7311
Yes	2/14 (14.3)	NE (NE, NE)	2/10 (20.0)	NE (0.5, NE)	1.27 (0.18, 9.09)	0.8089	
No	4/38 (10.5)	NE (NE, NE)	9/44 (20.5)	NE (2.0, NE)	1.65 (0.50, 5.43)	0.4035	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Infusion reactions (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	NE

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Elevated liver enzymes (SMQ) - Narrow	9/52 (17.3)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	0.30 (0.08, 1.11)	0.0559	
Age group							0.9920
1-9 years	6/38 (15.8)	-	3/39 (7.7)	-	-	-	
Other	3/14 (21.4)	-	0/15 (0.0)	-	-	-	
Sex							0.1090
Male	6/20 (30.0)	-	1/30 (3.3)	-	-	-	
Female	3/32 (9.4)	-	2/24 (8.3)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	9/50 (18.0)	-	2/49 (4.1)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.5164
M1 with MRD level < 10 ⁻³	4/33 (12.1)	-	2/35 (5.7)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	-	1/19 (5.3)	-	-	-	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.1033
Caucasian	8/42 (19.0)	NE (NE, NE)	2/50 (4.0)	NE (NE, NE)	0.19 (0.04, 0.91)	0.0200	
Others	1/10 (10.0)	NE (0.5, NE)	1/4 (25.0)	NE (0.5, NE)	2.89 (0.18, 46.48)	0.4338	
Time from 1 st diagnosis to relapse							0.8916
< 18 months	4/21 (19.0)	-	1/19 (5.3)	-	-	-	
≥ 18 months	5/31 (16.1)	-	2/35 (5.7)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.7419
<10 ⁻⁴	7/29 (24.1)	-	2/28 (7.1)	-	-	-	
≥10 ⁻⁴	2/23 (8.7)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.7328
Yes	3/14 (21.4)	-	1/10 (10.0)	-	-	-	
No	6/38 (15.8)	-	2/44 (4.5)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Lymphopenia (AMQ) - Narrow	0/52 (0.0)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	NE (NE, NE)	0.3264	
Age group							0.9993
1-9 years	0/38 (0.0)	-	1/39 (2.6)	-	-	-	
Other	0/14 (0.0)	-	0/15 (0.0)	-	-	-	
Sex							0.9993
Male	0/20 (0.0)	-	1/30 (3.3)	-	-	-	
Female	0/32 (0.0)	-	0/24 (0.0)	-	-	-	

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Severity graded using CTCAE version 4.03.

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	1/49 (2.0)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9992
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	0/19 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.9994
Caucasian	0/42 (0.0)	-	1/50 (2.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9992
< 18 months	0/21 (0.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	1/35 (2.9)	-	-	-	

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Severity graded using CTCAE version 4.03.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9994
<10 ⁻⁴	0/29 (0.0)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9993
Yes	0/14 (0.0)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	1/44 (2.3)	-	-	-	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Medication errors (SMQ) - Broad	0/52 (0.0)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	NE

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Neutropenia and febrile neutropenia (AMQ) - Narrow	27/52 (51.9)	0.5 (0.4, NE)	11/54 (20.4)	NE (NE, NE)	0.33 (0.16, 0.67)	0.0013	
Age group							0.8812
1-9 years	20/38 (52.6)	0.5 (0.4, NE)	8/39 (20.5)	NE (NE, NE)	0.33 (0.14, 0.75)	0.0059	
Other	7/14 (50.0)	NE (0.3, NE)	3/15 (20.0)	NE (1.4, NE)	0.34 (0.09, 1.34)	0.1041	
Sex							0.4070
Male	11/20 (55.0)	0.4 (0.3, NE)	5/30 (16.7)	NE (NE, NE)	0.25 (0.09, 0.73)	0.0066	
Female	16/32 (50.0)	NE (0.4, NE)	6/24 (25.0)	NE (NE, NE)	0.43 (0.17, 1.11)	0.0760	

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Severity graded using CTCAE version 4.03.

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No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	26/50 (52.0)	-	9/49 (18.4)	-	-	-	
Rest of world	1/2 (50.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.8361
M1 with MRD level < 10 ⁻³	16/33 (48.5)	NE (0.4, NE)	7/35 (20.0)	NE (NE, NE)	0.35 (0.14, 0.86)	0.0177	
M1 with MRD level ≥ 10 ⁻³ or M2	11/19 (57.9)	0.5 (0.3, NE)	4/19 (21.1)	NE (NE, NE)	0.30 (0.10, 0.96)	0.0346	

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No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.1333
Caucasian	21/42 (50.0)	NE (0.4, NE)	9/50 (18.0)	NE (NE, NE)	0.29 (0.13, 0.64)	0.0013	
Others	6/10 (60.0)	0.5 (0.2, NE)	2/4 (50.0)	NE (0.03, NE)	1.13 (0.23, 5.65)	0.9038	
Time from 1 st diagnosis to relapse							0.0995
< 18 months	11/21 (52.4)	0.5 (0.4, NE)	1/19 (5.3)	NE (NE, NE)	0.08 (0.01, 0.62)	0.0019	
≥ 18 months	16/31 (51.6)	0.5 (0.3, NE)	10/35 (28.6)	NE (NE, NE)	0.49 (0.22, 1.09)	0.0730	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.1301
<10 ⁻⁴	17/29 (58.6)	0.5 (0.3, NE)	4/28 (14.3)	NE (NE, NE)	0.18 (0.06, 0.53)	0.0005	
≥10 ⁻⁴	10/23 (43.5)	NE (0.4, NE)	7/26 (26.9)	NE (NE, NE)	0.61 (0.23, 1.62)	0.3180	
Extramedullary Disease at relapse							0.2433
Yes	9/14 (64.3)	0.4 (0.3, NE)	1/10 (10.0)	NE (0.03, NE)	0.12 (0.01, 0.94)	0.0163	
No	18/38 (47.4)	NE (0.4, NE)	10/44 (22.7)	NE (NE, NE)	0.42 (0.19, 0.91)	0.0245	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Neurologic events (AMQ) - Narrow	1/52 (1.9)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	2.61 (0.27, 25.37)	0.3913	
Age group							0.9997
1-9 years	0/38 (0.0)	-	0/39 (0.0)	-	-	-	
Other	1/14 (7.1)	-	3/15 (20.0)	-	-	-	
Sex							0.9965
Male	0/20 (0.0)	-	2/30 (6.7)	-	-	-	
Female	1/32 (3.1)	-	1/24 (4.2)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	2/49 (4.1)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9952
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	3/35 (8.6)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	-	0/19 (0.0)	-	-	-	

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Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Race							0.9961
Caucasian	1/42 (2.4)	-	2/50 (4.0)	-	-	-	
Others	0/10 (0.0)	-	1/4 (25.0)	-	-	-	
Time from 1 st diagnosis to relapse							0.9953
< 18 months	1/21 (4.8)	-	0/19 (0.0)	-	-	-	
≥ 18 months	0/31 (0.0)	-	3/35 (8.6)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Table 14-6.12.13. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Event of Special Interest (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
MRD before treatment start							0.9955
<10 ⁻⁴	0/29 (0.0)	-	3/28 (10.7)	-	-	-	
≥10 ⁻⁴	1/23 (4.3)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							0.9958
Yes	1/14 (7.1)	-	0/10 (0.0)	-	-	-	
No	0/38 (0.0)	-	3/44 (6.8)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Severity graded using CTCAE version 4.03.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

No data is available to report for the three EOI's i.e. Tumor lysis syndrome (narrow), Progressive multifocal leukoencephalopathy (broad) and Immunogenicity (narrow).

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-grd3-teae-aesi-saf.sas

Output: t14-06-012-013-ae-tte-sub-grd3-teae-aesi-saf.rtf (Date generated: 13JUN2025:05:52) Source data: a215up.adsl, a215up.adbase, adam.adtteae

Anhang 4-G3.4.5: Subgruppenanalysen häufiger UE nach SOC und PT

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Blood and lymphatic system disorders							
Overall	39/52 (75.0)	0.3 (0.3, 0.4)	20/54 (37.0)	NE (1.6, NE)	0.32 (0.18, 0.56)	<0.0001	
Age group							0.9334
1-9 years	29/38 (76.3)	0.3 (0.3, 0.4)	15/39 (38.5)	NE (1.6, NE)	0.32 (0.17, 0.61)	0.0003	
Other	10/14 (71.4)	0.3 (0.2, NE)	5/15 (33.3)	NE (0.3, NE)	0.32 (0.11, 0.96)	0.0324	
Sex							0.9483
Male	17/20 (85.0)	0.3 (0.3, 0.4)	13/30 (43.3)	NE (1.4, NE)	0.29 (0.13, 0.62)	0.0009	
Female	22/32 (68.8)	0.4 (0.3, 0.5)	7/24 (29.2)	NE (1.6, NE)	0.29 (0.12, 0.70)	0.0037	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	38/50 (76.0)	-	18/49 (36.7)	-	-	-	
Rest of world	1/2 (50.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.8595
M1 with MRD level < 10 ⁻³	24/33 (72.7)	0.4 (0.3, 0.5)	12/35 (34.3)	NE (1.6, NE)	0.31 (0.15, 0.64)	0.0010	
M1 with MRD level ≥ 10 ⁻³ or M2	15/19 (78.9)	0.3 (0.2, 0.3)	8/19 (42.1)	NE (1.3, NE)	0.34 (0.14, 0.82)	0.0128	
Race							0.7324
Caucasian	31/42 (73.8)	0.3 (0.3, 0.4)	18/50 (36.0)	NE (1.7, NE)	0.32 (0.17, 0.58)	0.0001	
Others	8/10 (80.0)	0.3 (0.2, 0.4)	2/4 (50.0)	NE (0.3, NE)	0.40 (0.08, 1.92)	0.2320	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.1442
< 18 months	15/21 (71.4)	0.3 (0.2, 0.5)	4/19 (21.1)	NE (NE, NE)	0.16 (0.05, 0.51)	0.0004	
≥ 18 months	24/31 (77.4)	0.3 (0.3, 0.4)	16/35 (45.7)	NE (1.4, NE)	0.42 (0.22, 0.81)	0.0085	
MRD before treatment start							0.0991
<10 ⁻⁴	22/29 (75.9)	0.3 (0.3, 0.4)	7/28 (25.0)	NE (NE, NE)	0.17 (0.07, 0.41)	<0.0001	
≥10 ⁻⁴	17/23 (73.9)	0.3 (0.3, 0.5)	13/26 (50.0)	NE (0.1, NE)	0.54 (0.26, 1.15)	0.1010	
Extramedullary Disease at relapse							0.0710
Yes	11/14 (78.6)	0.3 (0.1, 0.5)	1/10 (10.0)	NE (1.6, NE)	0.06 (0.01, 0.50)	0.0006	
No	28/38 (73.7)	0.3 (0.3, 0.4)	19/44 (43.2)	NE (1.5, NE)	0.41 (0.22, 0.75)	0.0029	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Anaemia							
Overall	24/52 (46.2)	NE (0.4, NE)	13/54 (24.1)	NE (NE, NE)	0.42 (0.21, 0.84)	0.0109	
Age group							0.8446
1-9 years	18/38 (47.4)	NE (0.4, NE)	10/39 (25.6)	NE (NE, NE)	0.42 (0.19, 0.92)	0.0233	
Other	6/14 (42.9)	NE (0.2, NE)	3/15 (20.0)	NE (0.3, NE)	0.44 (0.11, 1.78)	0.2327	
Sex							0.8107
Male	10/20 (50.0)	NE (0.3, NE)	8/30 (26.7)	NE (NE, NE)	0.44 (0.17, 1.13)	0.0803	
Female	14/32 (43.8)	NE (0.4, NE)	5/24 (20.8)	NE (NE, NE)	0.38 (0.14, 1.08)	0.0616	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	23/50 (46.0)	-	11/49 (22.4)	-	-	-	
Rest of world	1/2 (50.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.7688
M1 with MRD level < 10 ⁻³	13/33 (39.4)	NE (0.5, NE)	6/35 (17.1)	NE (NE, NE)	0.37 (0.14, 0.99)	0.0379	
M1 with MRD level ≥ 10 ⁻³ or M2	11/19 (57.9)	0.3 (0.2, NE)	7/19 (36.8)	NE (1.5, NE)	0.49 (0.19, 1.30)	0.1443	
Race							0.7522
Caucasian	18/42 (42.9)	NE (0.4, NE)	12/50 (24.0)	NE (NE, NE)	0.46 (0.22, 0.96)	0.0333	
Others	6/10 (60.0)	0.4 (0.2, NE)	1/4 (25.0)	NE (0.3, NE)	0.35 (0.04, 2.91)	0.3033	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.2828
< 18 months	10/21 (47.6)	NE (0.3, NE)	3/19 (15.8)	NE (NE, NE)	0.23 (0.06, 0.85)	0.0169	
≥ 18 months	14/31 (45.2)	NE (0.4, NE)	10/35 (28.6)	NE (NE, NE)	0.57 (0.25, 1.29)	0.1674	
MRD before treatment start							0.2101
<10 ⁻⁴	13/29 (44.8)	NE (0.4, NE)	4/28 (14.3)	NE (NE, NE)	0.24 (0.08, 0.75)	0.0078	
$\geq 10^{-4}$	11/23 (47.8)	NE (0.3, NE)	9/26 (34.6)	NE (1.6, NE)	0.63 (0.26, 1.54)	0.2806	
Extramedullary Disease at relapse							0.2223
Yes	7/14 (50.0)	NE (0.2, NE)	1/10 (10.0)	NE (1.6, NE)	0.12 (0.01, 1.02)	0.0233	
No	17/38 (44.7)	NE (0.4, NE)	12/44 (27.3)	NE (NE, NE)	0.53 (0.25, 1.12)	0.0889	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Neutropenia							
Overall	16/52 (30.8)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	0.26 (0.10, 0.73)	0.0058	
Age group							0.9895
1-9 years	12/38 (31.6)	NE (NE, NE)	5/39 (12.8)	NE (NE, NE)	0.37 (0.13, 1.07)	0.0570	
Other	4/14 (28.6)	NE (0.4, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0231	
Sex							0.9366
Male	7/20 (35.0)	NE (0.4, NE)	3/30 (10.0)	NE (NE, NE)	0.24 (0.06, 0.93)	0.0252	
Female	9/32 (28.1)	NE (NE, NE)	2/24 (8.3)	NE (NE, NE)	0.28 (0.06, 1.32)	0.0874	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	16/50 (32.0)	-	5/49 (10.2)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.1900
M1 with MRD level < 10 ⁻³	11/33 (33.3)	NE (1.4, NE)	2/35 (5.7)	NE (NE, NE)	0.15 (0.03, 0.67)	0.0043	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	NE (0.8, NE)	3/19 (15.8)	NE (NE, NE)	0.56 (0.13, 2.36)	0.4230	
Race							0.9915
Caucasian	13/42 (31.0)	NE (1.4, NE)	5/50 (10.0)	NE (NE, NE)	0.28 (0.10, 0.80)	0.0111	
Others	3/10 (30.0)	NE (0.2, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2464	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.5868
< 18 months	6/21 (28.6)	NE (0.5, NE)	1/19 (5.3)	NE (NE, NE)	0.17 (0.02, 1.43)	0.0648	
≥ 18 months	10/31 (32.3)	NE (1.4, NE)	4/35 (11.4)	NE (NE, NE)	0.30 (0.09, 0.98)	0.0347	
MRD before treatment start							0.9904
<10 ⁻⁴	10/29 (34.5)	NE (0.8, NE)	0/28 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0005	
≥10 ⁻⁴	6/23 (26.1)	NE (NE, NE)	5/26 (19.2)	NE (NE, NE)	0.72 (0.22, 2.37)	0.5839	
Extramedullary Disease at relapse							0.9914
Yes	4/14 (28.6)	NE (0.5, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0727	
No	12/38 (31.6)	NE (1.4, NE)	5/44 (11.4)	NE (NE, NE)	0.32 (0.11, 0.91)	0.0250	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Thrombocytopenia							
Overall	13/52 (25.0)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	0.23 (0.08, 0.72)	0.0063	0.9914
Age group							
1-9 years	11/38 (28.9)	NE (NE, NE)	4/39 (10.3)	NE (NE, NE)	0.27 (0.09, 0.86)	0.0185	
Other	2/14 (14.3)	NE (NE, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1358	0.6071
Sex							
Male	6/20 (30.0)	-	2/30 (6.7)	-	-	-	
Female	7/32 (21.9)	-	2/24 (8.3)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	13/50 (26.0)	-	4/49 (8.2)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.3070
M1 with MRD level < 10 ⁻³	7/33 (21.2)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	6/19 (31.6)	-	3/19 (15.8)	-	-	-	
Race							0.9925
Caucasian	10/42 (23.8)	NE (NE, NE)	4/50 (8.0)	NE (NE, NE)	0.26 (0.08, 0.83)	0.0152	
Others	3/10 (30.0)	NE (0.2, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2464	

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Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.5331
< 18 months	5/21 (23.8)	NE (NE, NE)	2/19 (10.5)	NE (NE, NE)	0.32 (0.06, 1.67)	0.1559	
≥ 18 months	8/31 (25.8)	NE (NE, NE)	2/35 (5.7)	NE (NE, NE)	0.19 (0.04, 0.89)	0.0187	
MRD before treatment start							0.9704
<10 ⁻⁴	7/29 (24.1)	-	2/28 (7.1)	-	-	-	
≥10 ⁻⁴	6/23 (26.1)	-	2/26 (7.7)	-	-	-	
Extramedullary Disease at relapse							0.9929
Yes	2/14 (14.3)	NE (NE, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2233	
No	11/38 (28.9)	NE (NE, NE)	4/44 (9.1)	NE (NE, NE)	0.24 (0.08, 0.76)	0.0089	

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Febrile neutropenia							
Overall	13/52 (25.0)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	0.18 (0.05, 0.62)	0.0024	0.1610
Age group							
1-9 years	10/38 (26.3)	NE (NE, NE)	1/39 (2.6)	NE (NE, NE)	0.08 (0.01, 0.63)	0.0021	
Other	3/14 (21.4)	NE (0.5, NE)	2/15 (13.3)	NE (NE, NE)	0.46 (0.08, 2.80)	0.3879	0.4943
Sex							
Male	5/20 (25.0)	NE (0.4, NE)	1/30 (3.3)	NE (NE, NE)	0.11 (0.01, 0.93)	0.0143	
Female	8/32 (25.0)	NE (NE, NE)	2/24 (8.3)	NE (NE, NE)	0.26 (0.06, 1.24)	0.0705	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	12/50 (24.0)	-	2/49 (4.1)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9905
M1 with MRD level < 10 ⁻³	7/33 (21.2)	NE (NE, NE)	3/35 (8.6)	NE (NE, NE)	0.31 (0.08, 1.22)	0.0781	
M1 with MRD level ≥ 10 ⁻³ or M2	6/19 (31.6)	NE (0.3, NE)	0/19 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0084	
Race							0.9930
Caucasian	10/42 (23.8)	NE (NE, NE)	3/50 (6.0)	NE (NE, NE)	0.20 (0.05, 0.72)	0.0064	
Others	3/10 (30.0)	NE (0.3, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2464	

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^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9936
< 18 months	5/21 (23.8)	NE (NE, NE)	0/19 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0250	
≥ 18 months	8/31 (25.8)	NE (NE, NE)	3/35 (8.6)	NE (NE, NE)	0.25 (0.07, 0.96)	0.0302	
MRD before treatment start							0.9416
<10 ⁻⁴	9/29 (31.0)	NE (1.1, NE)	2/28 (7.1)	NE (NE, NE)	0.18 (0.04, 0.86)	0.0157	
≥10 ⁻⁴	4/23 (17.4)	NE (NE, NE)	1/26 (3.8)	NE (NE, NE)	0.17 (0.02, 1.57)	0.0792	
Extramedullary Disease at relapse							0.9918
Yes	6/14 (42.9)	NE (0.3, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0210	
No	7/38 (18.4)	NE (NE, NE)	3/44 (6.8)	NE (NE, NE)	0.29 (0.08, 1.14)	0.0612	

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^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Eye disorders							
Overall	9/52 (17.3)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	0.28 (0.08, 1.05)	0.0439	
Age group							0.9495
1-9 years	6/38 (15.8)	-	2/39 (5.1)	-	-	-	
Other	3/14 (21.4)	-	1/15 (6.7)	-	-	-	
Sex							0.6175
Male	3/20 (15.0)	-	2/30 (6.7)	-	-	-	
Female	6/32 (18.8)	-	1/24 (4.2)	-	-	-	

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^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	9/50 (18.0)	-	3/49 (6.1)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9498
M1 with MRD level $< 10^{-3}$	6/33 (18.2)	-	2/35 (5.7)	-	-	-	
M1 with MRD level $\geq 10^{-3}$ or M2	3/19 (15.8)	-	1/19 (5.3)	-	-	-	
Race							0.4066
Caucasian	6/42 (14.3)	-	2/50 (4.0)	-	-	-	
Others	3/10 (30.0)	-	1/4 (25.0)	-	-	-	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.5964
< 18 months	5/21 (23.8)	-	1/19 (5.3)	-	-	-	
≥ 18 months	4/31 (12.9)	-	2/35 (5.7)	-	-	-	
MRD before treatment start							0.8874
<10 ⁻⁴	6/29 (20.7)	-	2/28 (7.1)	-	-	-	
$\geq 10^{-4}$	3/23 (13.0)	-	1/26 (3.8)	-	-	-	
Extramedullary Disease at relapse							0.9934
Yes	3/14 (21.4)	-	0/10 (0.0)	-	-	-	
No	6/38 (15.8)	-	3/44 (6.8)	-	-	-	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Gastrointestinal disorders							
Overall	39/52 (75.0)	0.2 (0.2, 0.3)	39/54 (72.2)	1.5 (1.0, 1.7)	0.63 (0.40, 0.99)	0.0446	
Age group							0.8288
1-9 years	27/38 (71.1)	0.2 (0.2, 0.4)	25/39 (64.1)	1.6 (0.4, 1.8)	0.63 (0.36, 1.10)	0.1039	
Other	12/14 (85.7)	0.1 (0.1, 0.3)	14/15 (93.3)	1.5 (0.3, 1.8)	0.58 (0.26, 1.29)	0.1745	
Sex							0.0281
Male	13/20 (65.0)	0.3 (0.1, NE)	25/30 (83.3)	1.4 (0.3, 1.7)	1.13 (0.57, 2.23)	0.7278	
Female	26/32 (81.3)	0.2 (0.1, 0.3)	14/24 (58.3)	1.7 (0.7, NE)	0.37 (0.19, 0.72)	0.0030	

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	38/50 (76.0)	-	35/49 (71.4)	-	-	-	
Rest of world	1/2 (50.0)	-	4/5 (80.0)	-	-	-	
Marrow/MRD Status at baseline							0.8891
M1 with MRD level < 10 ⁻³	24/33 (72.7)	0.2 (0.2, 0.3)	24/35 (68.6)	1.5 (1.0, 1.8)	0.63 (0.36, 1.13)	0.1268	
M1 with MRD level ≥ 10 ⁻³ or M2	15/19 (78.9)	0.2 (0.1, 0.4)	15/19 (78.9)	1.7 (0.2, 1.7)	0.60 (0.29, 1.26)	0.1555	
Race							0.0636
Caucasian	31/42 (73.8)	0.2 (0.1, 0.3)	35/50 (70.0)	1.6 (1.3, 1.8)	0.58 (0.36, 0.96)	0.0328	
Others	8/10 (80.0)	0.2 (0.1, 0.3)	4/4 (100.0)	0.1 (0.1, NE)	1.49 (0.45, 5.01)	0.4776	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.5692
< 18 months	14/21 (66.7)	0.3 (0.1, NE)	13/19 (68.4)	1.7 (0.7, NE)	0.68 (0.32, 1.47)	0.3356	
≥ 18 months	25/31 (80.6)	0.2 (0.1, 0.3)	26/35 (74.3)	1.5 (0.4, 1.7)	0.57 (0.32, 0.99)	0.0509	
MRD before treatment start							0.0981
<10 ⁻⁴	22/29 (75.9)	0.3 (0.1, 0.3)	24/28 (85.7)	1.4 (0.5, 1.7)	0.84 (0.46, 1.52)	0.5804	
≥10 ⁻⁴	17/23 (73.9)	0.2 (0.1, 0.4)	15/26 (57.7)	1.7 (0.4, NE)	0.43 (0.21, 0.89)	0.0192	
Extramedullary Disease at relapse							0.8953
Yes	10/14 (71.4)	0.3 (0.1, NE)	7/10 (70.0)	1.6 (0.1, NE)	0.62 (0.23, 1.67)	0.3252	
No	29/38 (76.3)	0.2 (0.1, 0.3)	32/44 (72.7)	1.5 (0.7, 1.7)	0.61 (0.37, 1.02)	0.0595	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Nausea							
Overall	9/52 (17.3)	NE (NE, NE)	23/54 (42.6)	2.0 (1.7, NE)	2.35 (1.08, 5.10)	0.0268	
Age group							0.4431
1-9 years	5/38 (13.2)	NE (NE, NE)	15/39 (38.5)	NE (1.7, NE)	2.73 (0.99, 7.54)	0.0440	
Other	4/14 (28.6)	NE (0.1, NE)	8/15 (53.3)	1.9 (1.3, NE)	1.65 (0.49, 5.54)	0.4125	
Sex							0.5560
Male	3/20 (15.0)	NE (NE, NE)	14/30 (46.7)	2.0 (1.7, NE)	3.19 (0.91, 11.16)	0.0548	
Female	6/32 (18.8)	NE (NE, NE)	9/24 (37.5)	NE (1.6, NE)	1.77 (0.62, 5.01)	0.2803	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	9/50 (18.0)	-	20/49 (40.8)	-	-	-	
Rest of world	0/2 (0.0)	-	3/5 (60.0)	-	-	-	
Marrow/MRD Status at baseline							0.5178
M1 with MRD level < 10 ⁻³	6/33 (18.2)	NE (NE, NE)	13/35 (37.1)	NE (1.6, NE)	1.94 (0.73, 5.13)	0.1763	
M1 with MRD level ≥ 10 ⁻³ or M2	3/19 (15.8)	NE (NE, NE)	10/19 (52.6)	1.9 (1.7, NE)	3.26 (0.89, 11.94)	0.0608	
Race							0.9877
Caucasian	9/42 (21.4)	NE (NE, NE)	21/50 (42.0)	2.0 (1.7, NE)	1.74 (0.79, 3.83)	0.1638	
Others	0/10 (0.0)	NE (NE, NE)	2/4 (50.0)	NE (0.1, NE)	NE (NE, NE)	0.0280	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.8689
< 18 months	2/21 (9.5)	NE (NE, NE)	4/19 (21.1)	NE (NE, NE)	1.85 (0.34, 10.20)	0.4693	
≥ 18 months	7/31 (22.6)	NE (NE, NE)	19/35 (54.3)	1.9 (1.4, NE)	2.35 (0.98, 5.62)	0.0472	
MRD before treatment start							0.1597
<10 ⁻⁴	4/29 (13.8)	NE (NE, NE)	14/28 (50.0)	1.9 (1.5, NE)	3.95 (1.29, 12.11)	0.0094	
≥10 ⁻⁴	5/23 (21.7)	NE (NE, NE)	9/26 (34.6)	NE (1.7, NE)	1.22 (0.40, 3.71)	0.7371	
Extramedullary Disease at relapse							0.8089
Yes	2/14 (14.3)	NE (NE, NE)	3/10 (30.0)	NE (1.4, NE)	1.47 (0.24, 8.94)	0.6749	
No	7/38 (18.4)	NE (NE, NE)	20/44 (45.5)	2.0 (1.7, NE)	2.43 (1.02, 5.79)	0.0380	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Vomiting						
Overall	11/52 (21.2)	NE (NE, NE)	17/54 (31.5)	NE (2.0, NE)	1.36 (0.63, 2.92)	0.4288

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Diarrhoea						
Overall	9/52 (17.3)	NE (NE, NE)	12/54 (22.2)	NE (NE, NE)	1.07 (0.45, 2.56)	0.8653

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Stomatitis							
Overall	28/52 (53.8)	0.8 (0.3, NE)	12/54 (22.2)	NE (NE, NE)	0.24 (0.12, 0.48)	<0.0001	
Age group							0.7131
1-9 years	17/38 (44.7)	NE (0.3, NE)	7/39 (17.9)	NE (NE, NE)	0.25 (0.10, 0.62)	0.0012	
Other	11/14 (78.6)	0.3 (0.1, 1.1)	5/15 (33.3)	NE (1.8, NE)	0.18 (0.06, 0.54)	0.0007	
Sex							0.0469
Male	7/20 (35.0)	NE (0.3, NE)	8/30 (26.7)	NE (2.0, NE)	0.52 (0.19, 1.46)	0.2161	
Female	21/32 (65.6)	0.3 (0.2, 1.1)	4/24 (16.7)	NE (NE, NE)	0.13 (0.04, 0.39)	<0.0001	

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Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	27/50 (54.0)	-	11/49 (22.4)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9941
M1 with MRD level < 10 ⁻³	18/33 (54.5)	1.1 (0.3, NE)	8/35 (22.9)	NE (2.0, NE)	0.23 (0.10, 0.54)	0.0003	
M1 with MRD level ≥ 10 ⁻³ or M2	10/19 (52.6)	0.4 (0.2, NE)	4/19 (21.1)	NE (1.9, NE)	0.25 (0.08, 0.80)	0.0120	
Race							0.5658
Caucasian	21/42 (50.0)	1.1 (0.3, NE)	11/50 (22.0)	NE (2.0, NE)	0.26 (0.12, 0.55)	0.0002	
Others	7/10 (70.0)	0.2 (0.1, NE)	1/4 (25.0)	NE (1.4, NE)	0.20 (0.02, 1.69)	0.1056	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.3129
< 18 months	9/21 (42.9)	NE (0.3, NE)	4/19 (21.1)	NE (NE, NE)	0.35 (0.11, 1.14)	0.0656	
≥ 18 months	19/31 (61.3)	0.3 (0.2, NE)	8/35 (22.9)	NE (2.0, NE)	0.17 (0.07, 0.40)	<0.0001	
MRD before treatment start							0.5722
<10 ⁻⁴	19/29 (65.5)	0.3 (0.2, NE)	9/28 (32.1)	NE (1.8, NE)	0.27 (0.12, 0.60)	0.0008	
≥10 ⁻⁴	9/23 (39.1)	NE (0.3, NE)	3/26 (11.5)	NE (NE, NE)	0.18 (0.05, 0.68)	0.0052	
Extramedullary Disease at relapse							0.9189
Yes	9/14 (64.3)	0.4 (0.2, NE)	3/10 (30.0)	NE (1.7, NE)	0.25 (0.07, 0.94)	0.0261	
No	19/38 (50.0)	1.1 (0.3, NE)	9/44 (20.5)	NE (2.0, NE)	0.25 (0.11, 0.55)	0.0003	

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^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Abdominal pain						
Overall	11/52 (21.2)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	0.53 (0.20, 1.37)	0.1834

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Constipation						
Overall	7/52 (13.5)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	0.62 (0.20, 1.95)	0.4079

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: General disorders and administration site conditions							
Overall	19/52 (36.5)	NE (1.5, NE)	48/54 (88.9)	0.1 (0.03, 0.1)	4.90 (2.86, 8.39)	<0.0001	
Age group							0.1024
1-9 years	13/38 (34.2)	NE (1.0, NE)	37/39 (94.9)	0.1 (0.03, 0.1)	6.82 (3.57, 13.03)	<0.0001	
Other	6/14 (42.9)	1.5 (0.3, NE)	11/15 (73.3)	0.1 (0.03, 1.5)	2.31 (0.85, 6.31)	0.1128	
Sex							0.9447
Male	6/20 (30.0)	NE (0.5, NE)	24/30 (80.0)	0.1 (0.03, 0.6)	5.02 (2.03, 12.38)	0.0001	
Female	13/32 (40.6)	NE (0.5, NE)	24/24 (100.0)	0.1 (0.03, 0.1)	5.37 (2.70, 10.68)	<0.0001	

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Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	19/50 (38.0)	-	44/49 (89.8)	-	-	-	
Rest of world	0/2 (0.0)	-	4/5 (80.0)	-	-	-	
Marrow/MRD Status at baseline							0.6030
M1 with MRD level < 10 ⁻³	11/33 (33.3)	NE (1.5, NE)	31/35 (88.6)	0.1 (0.03, 0.6)	4.65 (2.33, 9.29)	<0.0001	
M1 with MRD level ≥ 10 ⁻³ or M2	8/19 (42.1)	NE (0.4, NE)	17/19 (89.5)	0.03 (0.03, 0.1)	6.13 (2.56, 14.71)	<0.0001	
Race							0.3454
Caucasian	15/42 (35.7)	NE (1.5, NE)	45/50 (90.0)	0.1 (0.03, 0.1)	5.27 (2.91, 9.53)	<0.0001	
Others	4/10 (40.0)	NE (0.2, NE)	3/4 (75.0)	0.8 (0.03, NE)	2.43 (0.53, 11.16)	0.2388	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.1871
< 18 months	7/21 (33.3)	NE (1.0, NE)	18/19 (94.7)	0.03 (0.03, 0.1)	7.57 (3.08, 18.64)	<0.0001	
≥ 18 months	12/31 (38.7)	NE (0.5, NE)	30/35 (85.7)	0.1 (0.1, 0.6)	3.85 (1.96, 7.56)	<0.0001	
MRD before treatment start							0.6906
<10 ⁻⁴	10/29 (34.5)	NE (0.5, NE)	24/28 (85.7)	0.1 (0.03, 1.3)	4.34 (2.07, 9.14)	<0.0001	
$\geq 10^{-4}$	9/23 (39.1)	NE (0.7, NE)	24/26 (92.3)	0.1 (0.03, 0.1)	5.99 (2.73, 13.15)	<0.0001	
Extramedullary Disease at relapse							0.3461
Yes	4/14 (28.6)	NE (0.3, NE)	10/10 (100.0)	0.05 (0.03, 0.3)	7.54 (2.31, 24.57)	0.0002	
No	15/38 (39.5)	NE (1.0, NE)	38/44 (86.4)	0.1 (0.03, 0.1)	4.27 (2.33, 7.82)	<0.0001	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Pyrexia							
Overall	10/52 (19.2)	NE (NE, NE)	44/54 (81.5)	0.1 (0.03, 0.1)	7.76 (3.88, 15.53)	<0.0001	
Age group							0.0763
1-9 years	6/38 (15.8)	NE (NE, NE)	35/39 (89.7)	0.1 (0.03, 0.1)	12.57 (5.17, 30.59)	<0.0001	
Other	4/14 (28.6)	NE (1.0, NE)	9/15 (60.0)	0.1 (0.03, NE)	2.92 (0.89, 9.56)	0.0808	
Sex							0.9192
Male	3/20 (15.0)	NE (NE, NE)	21/30 (70.0)	0.1 (0.03, 1.5)	7.51 (2.23, 25.28)	0.0002	
Female	7/32 (21.9)	NE (NE, NE)	23/24 (95.8)	0.1 (0.03, 0.1)	9.43 (3.98, 22.35)	<0.0001	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	10/50 (20.0)	-	40/49 (81.6)	-	-	-	
Rest of world	0/2 (0.0)	-	4/5 (80.0)	-	-	-	
Marrow/MRD Status at baseline							0.7985
M1 with MRD level < 10 ⁻³	5/33 (15.2)	NE (NE, NE)	28/35 (80.0)	0.1 (0.03, 1.5)	8.77 (3.37, 22.84)	<0.0001	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	NE (1.0, NE)	16/19 (84.2)	0.1 (0.03, 0.1)	7.12 (2.55, 19.90)	<0.0001	
Race							0.2858
Caucasian	8/42 (19.0)	NE (NE, NE)	42/50 (84.0)	0.1 (0.03, 0.1)	8.45 (3.94, 18.14)	<0.0001	
Others	2/10 (20.0)	NE (0.3, NE)	2/4 (50.0)	NE (0.1, NE)	2.54 (0.35, 18.36)	0.3382	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.3590
< 18 months	4/21 (19.0)	NE (NE, NE)	17/19 (89.5)	0.03 (0.03, 0.1)	10.84 (3.57, 32.92)	<0.0001	
≥ 18 months	6/31 (19.4)	NE (NE, NE)	27/35 (77.1)	0.1 (0.1, 1.5)	6.38 (2.62, 15.54)	<0.0001	
MRD before treatment start							0.4898
<10 ⁻⁴	6/29 (20.7)	NE (NE, NE)	21/28 (75.0)	0.1 (0.03, 1.5)	6.00 (2.41, 14.95)	<0.0001	
≥10 ⁻⁴	4/23 (17.4)	NE (NE, NE)	23/26 (88.5)	0.1 (0.03, 0.1)	10.75 (3.65, 31.68)	<0.0001	
Extramedullary Disease at relapse							0.4376
Yes	2/14 (14.3)	NE (NE, NE)	9/10 (90.0)	0.05 (0.03, 1.5)	11.67 (2.48, 54.95)	0.0002	
No	8/38 (21.1)	NE (NE, NE)	35/44 (79.5)	0.1 (0.03, 1.3)	6.82 (3.14, 14.80)	<0.0001	

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Mucosal inflammation						
Overall	4/52 (7.7)	NE (NE, NE)	9/54 (16.7)	NE (NE, NE)	1.69 (0.52, 5.50)	0.3831

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Hepatobiliary disorders						
Overall	10/52 (19.2)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	0.44 (0.15, 1.30)	0.1314

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Immune system disorders							
Overall	3/52 (5.8)	NE (NE, NE)	15/54 (27.8)	NE (2.1, NE)	4.95 (1.43, 17.13)	0.0052	
Age group							0.9132
1-9 years	2/38 (5.3)	NE (NE, NE)	10/39 (25.6)	NE (2.1, NE)	5.33 (1.16, 24.36)	0.0159	
Other	1/14 (7.1)	NE (NE, NE)	5/15 (33.3)	NE (1.2, NE)	3.84 (0.44, 33.28)	0.1909	
Sex							0.9218
Male	1/20 (5.0)	-	8/30 (26.7)	-	-	-	
Female	2/32 (6.3)	-	7/24 (29.2)	-	-	-	

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	3/50 (6.0)	-	14/49 (28.6)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.8508
M1 with MRD level < 10 ⁻³	2/33 (6.1)	NE (NE, NE)	11/35 (31.4)	NE (1.9, NE)	5.08 (1.13, 22.95)	0.0188	
M1 with MRD level ≥ 10 ⁻³ or M2	1/19 (5.3)	NE (NE, NE)	4/19 (21.1)	NE (2.1, NE)	4.46 (0.50, 39.95)	0.1443	
Race							0.9913
Caucasian	2/42 (4.8)	NE (NE, NE)	15/50 (30.0)	NE (2.1, NE)	6.53 (1.49, 28.61)	0.0042	
Others	1/10 (10.0)	NE (0.7, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.5271	

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.2829
< 18 months	2/21 (9.5)	NE (NE, NE)	4/19 (21.1)	NE (NE, NE)	2.28 (0.42, 12.49)	0.3298	
≥ 18 months	1/31 (3.2)	NE (NE, NE)	11/35 (31.4)	NE (1.9, NE)	9.61 (1.24, 74.58)	0.0080	
MRD before treatment start							0.6890
<10 ⁻⁴	1/29 (3.4)	NE (NE, NE)	6/28 (21.4)	NE (NE, NE)	6.23 (0.75, 51.87)	0.0531	
≥10 ⁻⁴	2/23 (8.7)	NE (NE, NE)	9/26 (34.6)	NE (1.9, NE)	4.07 (0.88, 18.92)	0.0526	
Extramedullary Disease at relapse							0.9731
Yes	1/14 (7.1)	NE (NE, NE)	4/10 (40.0)	NE (0.9, NE)	4.73 (0.52, 42.67)	0.1281	
No	2/38 (5.3)	NE (NE, NE)	11/44 (25.0)	NE (NE, NE)	5.18 (1.15, 23.41)	0.0173	

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The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Hypogammaglobulinaemia						
Overall	2/52 (3.8)	NE (NE, NE)	6/54 (11.1)	NE (NE, NE)	2.92 (0.59, 14.48)	0.1707

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Infections and infestations						
Overall	18/52 (34.6)	NE (NE, NE)	25/54 (46.3)	1.9 (1.7, NE)	1.09 (0.60, 2.01)	0.7760

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Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Injury, poisoning and procedural complications						
Overall	6/52 (11.5)	NE (NE, NE)	9/54 (16.7)	NE (NE, NE)	1.19 (0.42, 3.36)	0.7400

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Investigations						
Overall	22/52 (42.3)	NE (0.5, NE)	22/54 (40.7)	NE (1.5, NE)	0.90 (0.50, 1.63)	0.7142

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Platelet count decreased						
Overall	8/52 (15.4)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	0.66 (0.24, 1.84)	0.4265

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Alanine aminotransferase increased						
Overall	7/52 (13.5)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	0.54 (0.16, 1.84)	0.3135

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Metabolism and nutrition disorders						
Overall	13/52 (25.0)	NE (NE, NE)	19/54 (35.2)	NE (1.9, NE)	1.49 (0.74, 3.03)	0.2697

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Hypokalaemia						
Overall	5/52 (9.6)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	1.32 (0.42, 4.17)	0.6307

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Musculoskeletal and connective tissue disorders							
Overall	15/52 (28.8)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	0.37 (0.15, 0.91)	0.0242	
Age group							0.1122
1-9 years	8/38 (21.1)	NE (NE, NE)	6/39 (15.4)	NE (NE, NE)	0.62 (0.21, 1.79)	0.3714	
Other	7/14 (50.0)	NE (0.3, NE)	1/15 (6.7)	NE (NE, NE)	0.10 (0.01, 0.85)	0.0097	
Sex							0.0348
Male	2/20 (10.0)	NE (NE, NE)	5/30 (16.7)	NE (NE, NE)	1.54 (0.30, 7.96)	0.6039	
Female	13/32 (40.6)	NE (0.4, NE)	2/24 (8.3)	NE (NE, NE)	0.16 (0.04, 0.71)	0.0062	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	15/50 (30.0)	-	7/49 (14.3)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.1889
M1 with MRD level < 10 ⁻³	12/33 (36.4)	NE (0.7, NE)	4/35 (11.4)	NE (NE, NE)	0.24 (0.08, 0.76)	0.0087	
M1 with MRD level ≥ 10 ⁻³ or M2	3/19 (15.8)	NE (NE, NE)	3/19 (15.8)	NE (NE, NE)	0.90 (0.18, 4.47)	0.8933	
Race							0.8172
Caucasian	11/42 (26.2)	NE (NE, NE)	6/50 (12.0)	NE (NE, NE)	0.37 (0.14, 1.01)	0.0441	
Others	4/10 (40.0)	NE (0.03, NE)	1/4 (25.0)	NE (0.5, NE)	0.53 (0.06, 4.80)	0.5701	

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^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9916
< 18 months	6/21 (28.6)	NE (0.4, NE)	0/19 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0127	
≥ 18 months	9/31 (29.0)	NE (NE, NE)	7/35 (20.0)	NE (NE, NE)	0.57 (0.21, 1.55)	0.2690	
MRD before treatment start							0.0299
<10 ⁻⁴	12/29 (41.4)	NE (0.4, NE)	2/28 (7.1)	NE (NE, NE)	0.14 (0.03, 0.65)	0.0032	
≥10 ⁻⁴	3/23 (13.0)	NE (NE, NE)	5/26 (19.2)	NE (NE, NE)	1.17 (0.28, 4.98)	0.8269	
Extramedullary Disease at relapse							0.9905
Yes	4/14 (28.6)	NE (0.1, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0723	
No	11/38 (28.9)	NE (NE, NE)	7/44 (15.9)	NE (NE, NE)	0.46 (0.18, 1.19)	0.1001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Back pain						
Overall	6/52 (11.5)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	0.41 (0.10, 1.65)	0.1958

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

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^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Nervous system disorders							
Overall	12/52 (23.1)	NE (NE, NE)	24/54 (44.4)	NE (1.0, NE)	2.18 (1.09, 4.37)	0.0249	
Age group							0.9379
1-9 years	6/38 (15.8)	NE (NE, NE)	13/39 (33.3)	NE (1.6, NE)	2.31 (0.88, 6.09)	0.0826	
Other	6/14 (42.9)	NE (0.1, NE)	11/15 (73.3)	0.2 (0.03, 1.7)	2.21 (0.82, 6.00)	0.1103	
Sex							0.0393
Male	3/20 (15.0)	NE (NE, NE)	17/30 (56.7)	1.2 (0.1, NE)	5.00 (1.46, 17.10)	0.0043	
Female	9/32 (28.1)	NE (1.5, NE)	7/24 (29.2)	NE (1.7, NE)	0.95 (0.35, 2.58)	0.9209	

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Months are calculated as days from treatment start date to event date, divided by 30.5.

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^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	12/50 (24.0)	-	22/49 (44.9)	-	-	-	
Rest of world	0/2 (0.0)	-	2/5 (40.0)	-	-	-	
Marrow/MRD Status at baseline							0.5247
M1 with MRD level < 10 ⁻³	8/33 (24.2)	NE (NE, NE)	14/35 (40.0)	NE (0.5, NE)	1.86 (0.78, 4.44)	0.1622	
M1 with MRD level ≥ 10 ⁻³ or M2	4/19 (21.1)	NE (NE, NE)	10/19 (52.6)	1.7 (0.1, NE)	2.91 (0.91, 9.28)	0.0592	
Race							0.4079
Caucasian	9/42 (21.4)	NE (NE, NE)	23/50 (46.0)	NE (0.5, NE)	2.41 (1.11, 5.21)	0.0221	
Others	3/10 (30.0)	NE (0.2, NE)	1/4 (25.0)	NE (0.1, NE)	0.95 (0.10, 9.15)	0.9643	

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Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.1595
< 18 months	6/21 (28.6)	NE (0.7, NE)	6/19 (31.6)	NE (1.0, NE)	1.14 (0.37, 3.54)	0.8234	
≥ 18 months	6/31 (19.4)	NE (NE, NE)	18/35 (51.4)	1.6 (0.2, NE)	3.14 (1.25, 7.92)	0.0110	
MRD before treatment start							0.8121
<10 ⁻⁴	8/29 (27.6)	NE (1.5, NE)	15/28 (53.6)	1.5 (0.1, NE)	2.42 (1.02, 5.71)	0.0409	
$\geq 10^{-4}$	4/23 (17.4)	NE (NE, NE)	9/26 (34.6)	NE (1.0, NE)	2.09 (0.64, 6.80)	0.2098	
Extramedullary Disease at relapse							0.4195
Yes	5/14 (35.7)	NE (0.4, NE)	5/10 (50.0)	NE (0.03, NE)	1.29 (0.37, 4.50)	0.6981	
No	7/38 (18.4)	NE (NE, NE)	19/44 (43.2)	NE (0.2, NE)	2.71 (1.14, 6.46)	0.0199	

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^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Headache							
Overall	9/52 (17.3)	NE (NE, NE)	20/54 (37.0)	NE (1.6, NE)	2.20 (1.00, 4.84)	0.0456	
Age group							0.3341
1-9 years	4/38 (10.5)	NE (NE, NE)	12/39 (30.8)	NE (NE, NE)	3.13 (1.01, 9.71)	0.0388	
Other	5/14 (35.7)	NE (0.1, NE)	8/15 (53.3)	1.7 (0.1, NE)	1.40 (0.46, 4.30)	0.5420	
Sex							0.0693
Male	2/20 (10.0)	NE (NE, NE)	14/30 (46.7)	NE (0.5, NE)	5.49 (1.25, 24.18)	0.0109	
Female	7/32 (21.9)	NE (NE, NE)	6/24 (25.0)	NE (NE, NE)	1.00 (0.33, 3.00)	0.9937	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 10% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	9/50 (18.0)	-	19/49 (38.8)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.3971
M1 with MRD level < 10 ⁻³	6/33 (18.2)	NE (NE, NE)	11/35 (31.4)	NE (NE, NE)	1.68 (0.62, 4.55)	0.3054	
M1 with MRD level ≥ 10 ⁻³ or M2	3/19 (15.8)	NE (NE, NE)	9/19 (47.4)	1.7 (0.1, NE)	3.38 (0.91, 12.51)	0.0518	
Race							0.9883
Caucasian	7/42 (16.7)	NE (NE, NE)	20/50 (40.0)	NE (1.6, NE)	2.45 (1.03, 5.79)	0.0362	
Others	2/10 (20.0)	NE (0.2, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.3582	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9294
< 18 months	3/21 (14.3)	NE (NE, NE)	6/19 (31.6)	NE (1.0, NE)	2.35 (0.59, 9.44)	0.2137	
≥ 18 months	6/31 (19.4)	NE (NE, NE)	14/35 (40.0)	NE (1.5, NE)	2.07 (0.79, 5.40)	0.1300	
MRD before treatment start							0.9634
<10 ⁻⁴	6/29 (20.7)	NE (NE, NE)	12/28 (42.9)	NE (1.4, NE)	2.18 (0.82, 5.81)	0.1157	
$\geq 10^{-4}$	3/23 (13.0)	NE (NE, NE)	8/26 (30.8)	NE (1.7, NE)	2.42 (0.64, 9.15)	0.1768	
Extramedullary Disease at relapse							0.8875
Yes	3/14 (21.4)	NE (0.7, NE)	5/10 (50.0)	NE (0.03, NE)	2.30 (0.55, 9.70)	0.2474	
No	6/38 (15.8)	NE (NE, NE)	15/44 (34.1)	NE (1.7, NE)	2.20 (0.85, 5.68)	0.0961	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Psychiatric disorders						
Overall	5/52 (9.6)	NE (NE, NE)	9/54 (16.7)	NE (NE, NE)	1.72 (0.58, 5.15)	0.3231

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Renal and urinary disorders						
Overall	7/52 (13.5)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	0.48 (0.14, 1.64)	0.2317

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Respiratory, thoracic and mediastinal disorders						
Overall	10/52 (19.2)	NE (NE, NE)	12/54 (22.2)	NE (2.2, NE)	0.96 (0.41, 2.22)	0.9240

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Epistaxis						
Overall	7/52 (13.5)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	0.52 (0.16, 1.67)	0.2657

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Skin and subcutaneous tissue disorders						
Overall	14/52 (26.9)	NE (NE, NE)	24/54 (44.4)	NE (1.6, NE)	1.52 (0.78, 2.94)	0.2133

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Rash						
Overall	5/52 (9.6)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	1.18 (0.37, 3.73)	0.7800

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Erythema						
Overall	2/52 (3.8)	NE (NE, NE)	6/54 (11.1)	NE (NE, NE)	2.34 (0.47, 11.67)	0.2866

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Pruritus						
Overall	5/52 (9.6)	NE (NE, NE)	6/54 (11.1)	NE (NE, NE)	0.95 (0.29, 3.13)	0.9321

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Vascular disorders						
Overall	11/52 (21.2)	NE (NE, NE)	16/54 (29.6)	NE (NE, NE)	1.23 (0.57, 2.66)	0.6154

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Hypertension						
Overall	4/52 (7.7)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	1.44 (0.42, 4.98)	0.5612

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.1. Subgroup Analysis of Time to First Onset of Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 10\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Hypotension						
Overall	4/52 (7.7)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	1.49 (0.43, 5.13)	0.5244

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

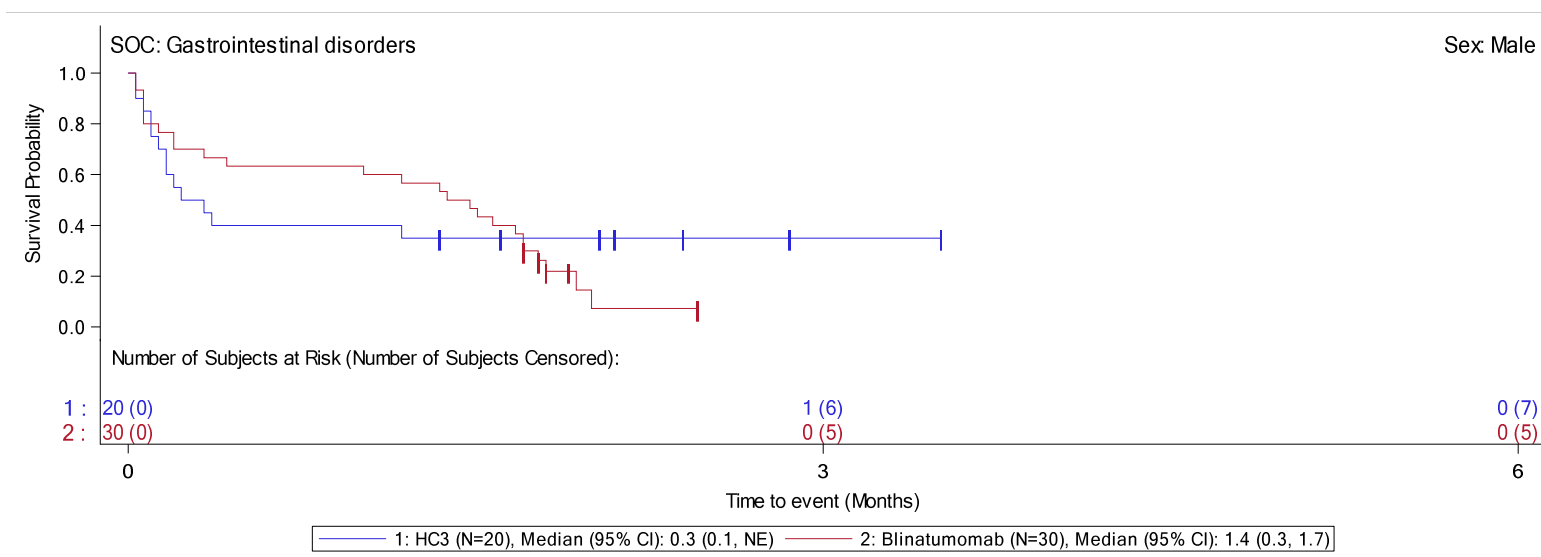
The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-teae-soc-pt-saf.sas

Output: t14-06-014-001-ae-tte-sub-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:45) Source data: a215up.adsl, a215.adae, a215up.adbase

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)

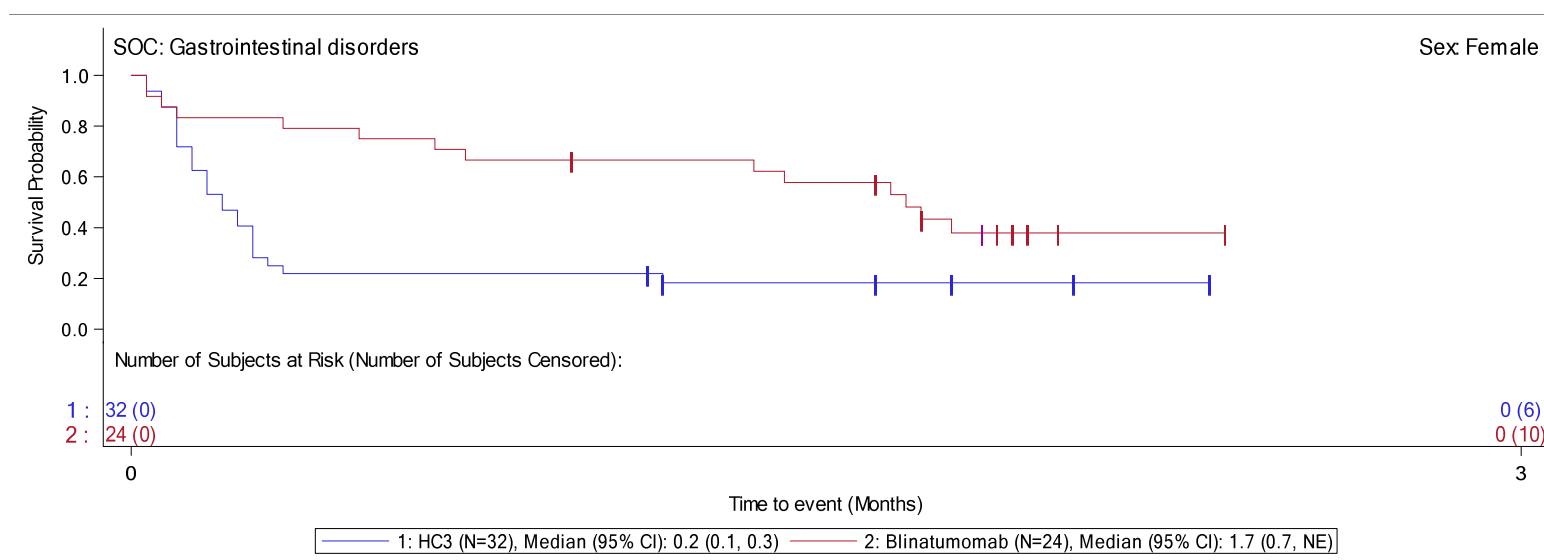


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

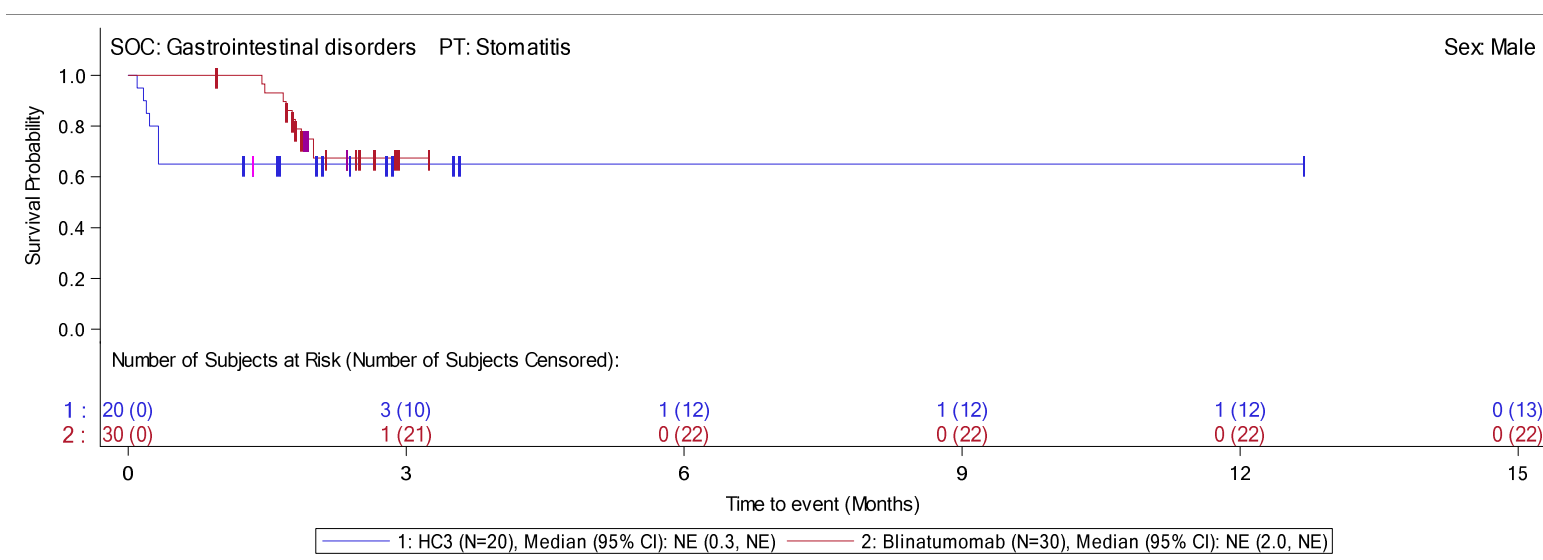


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

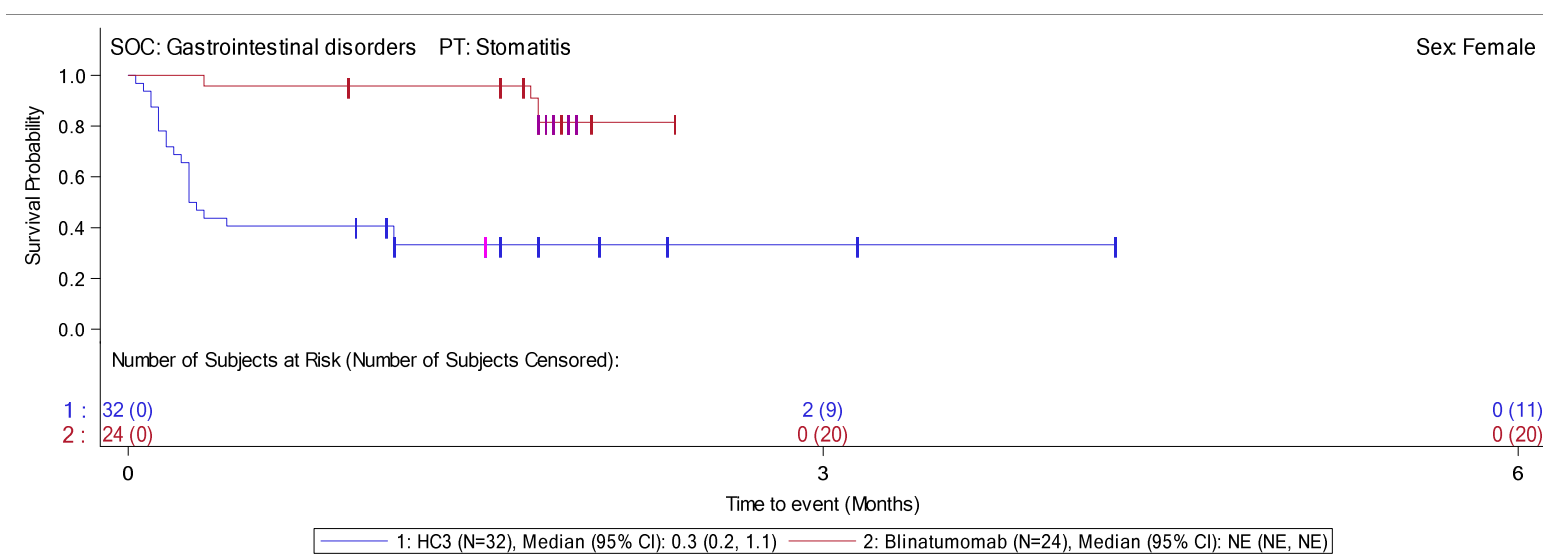


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

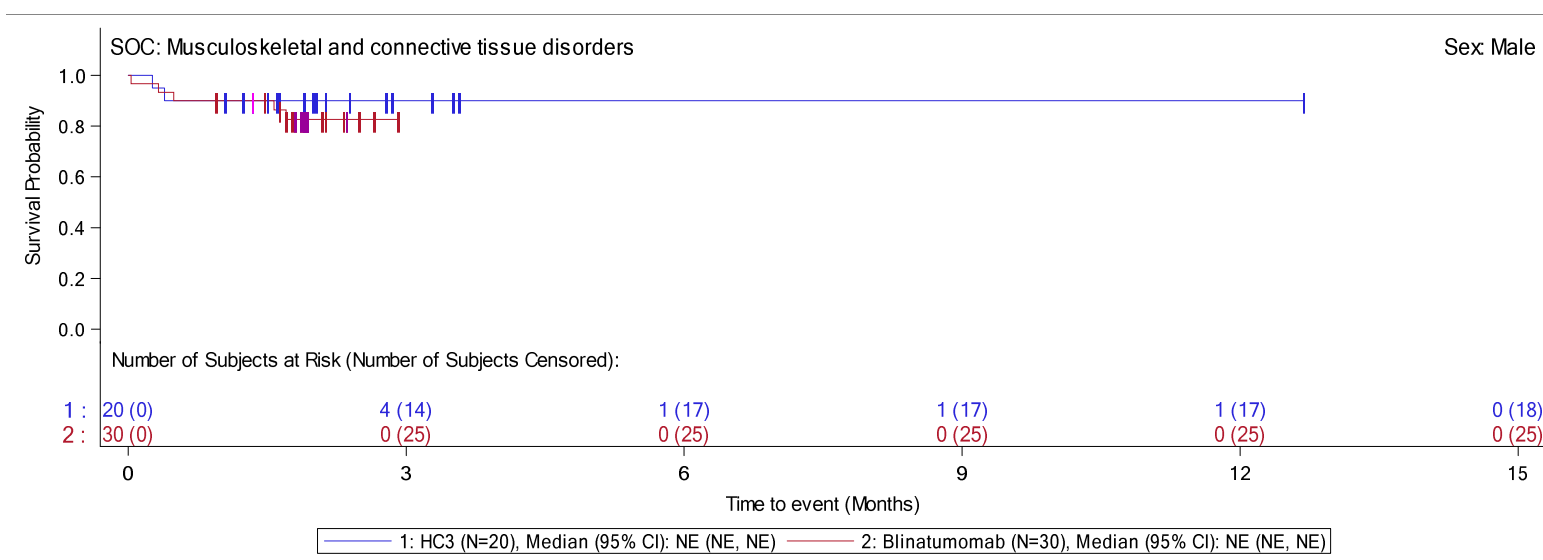


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

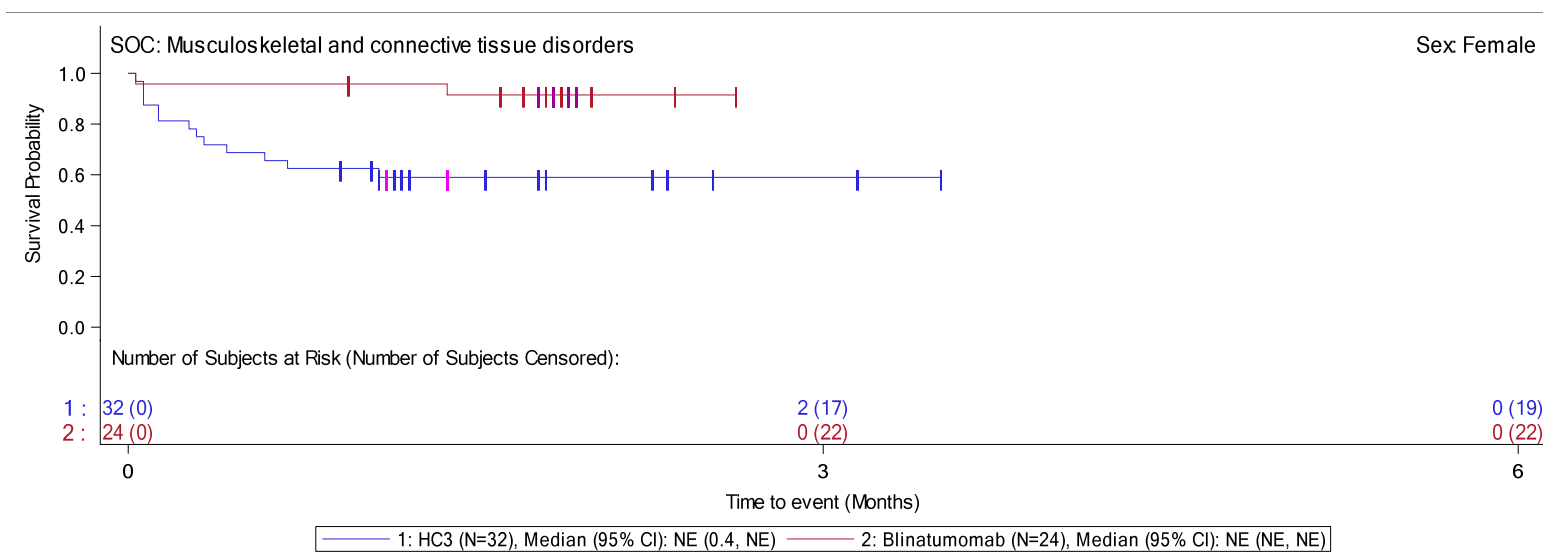


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

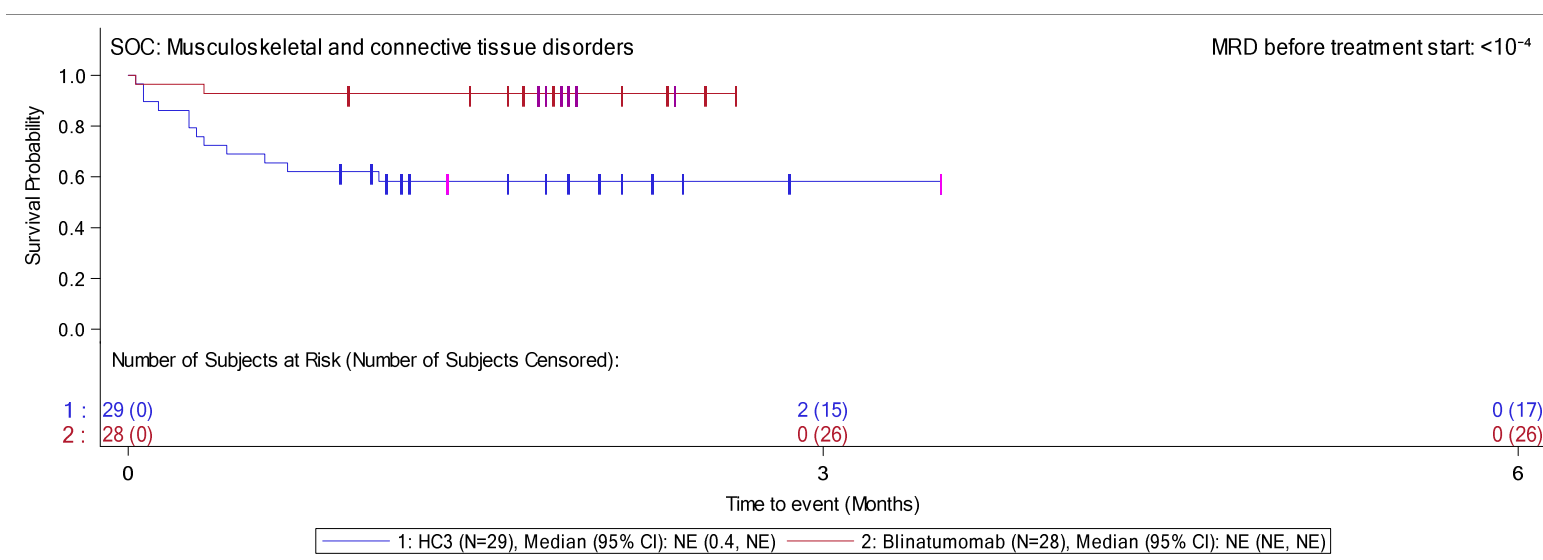


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

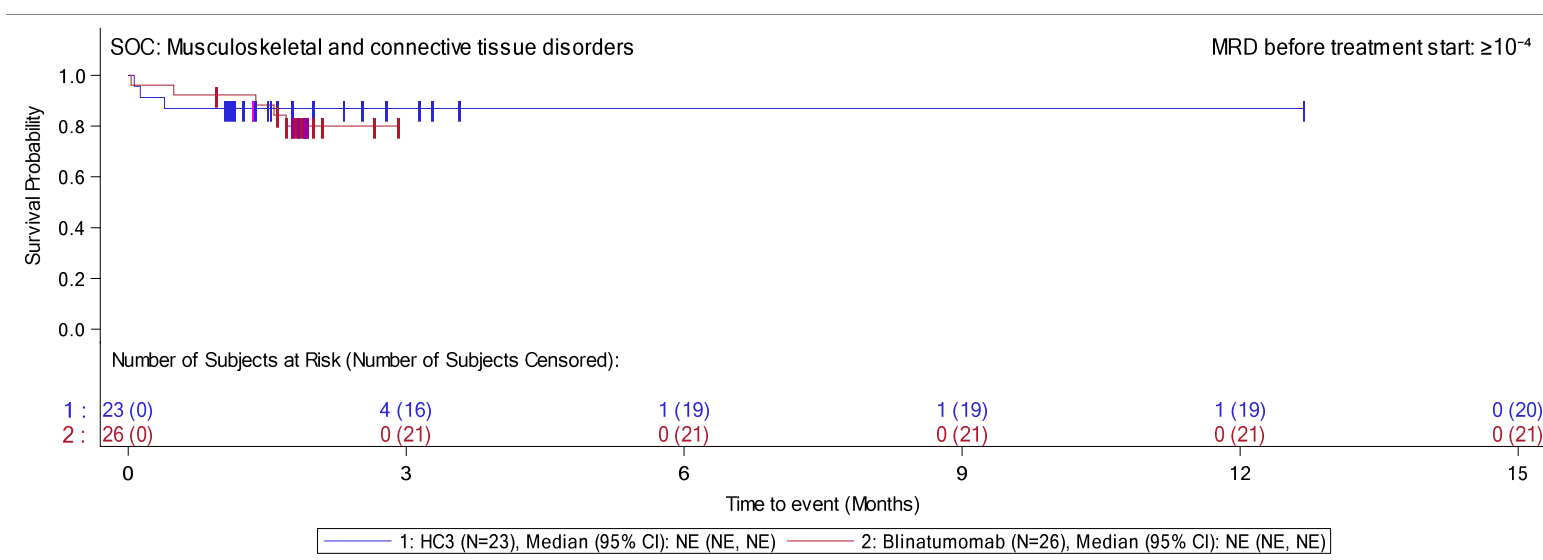


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

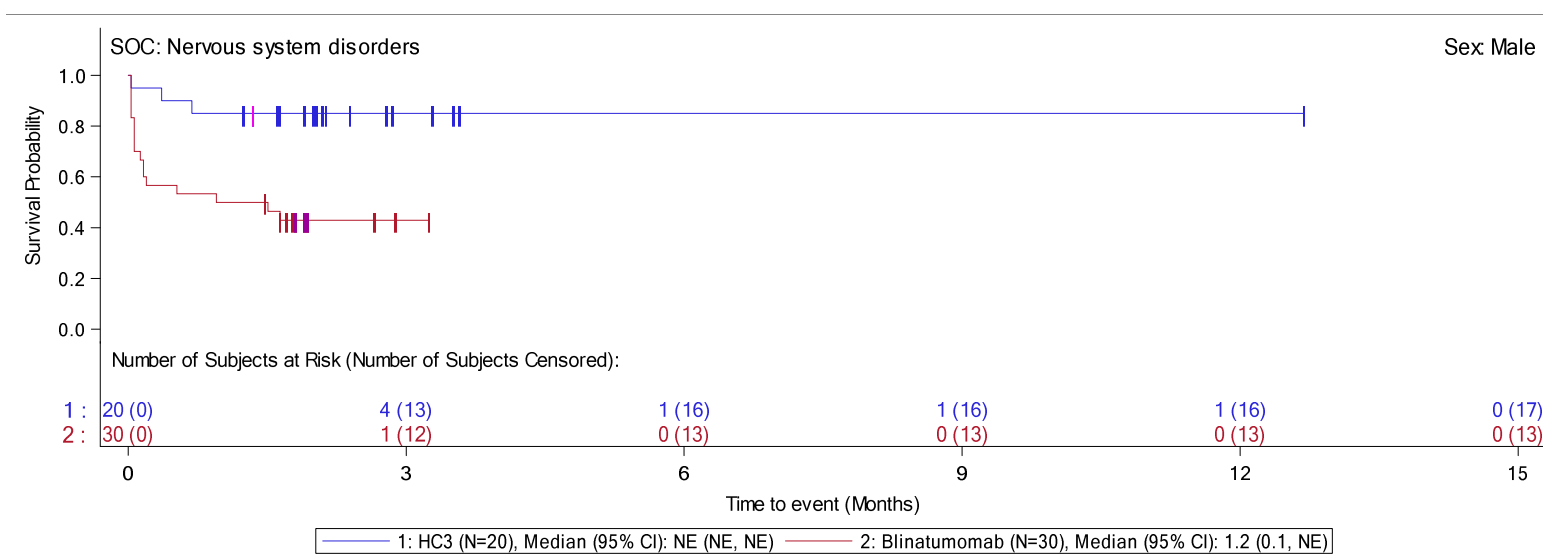


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)

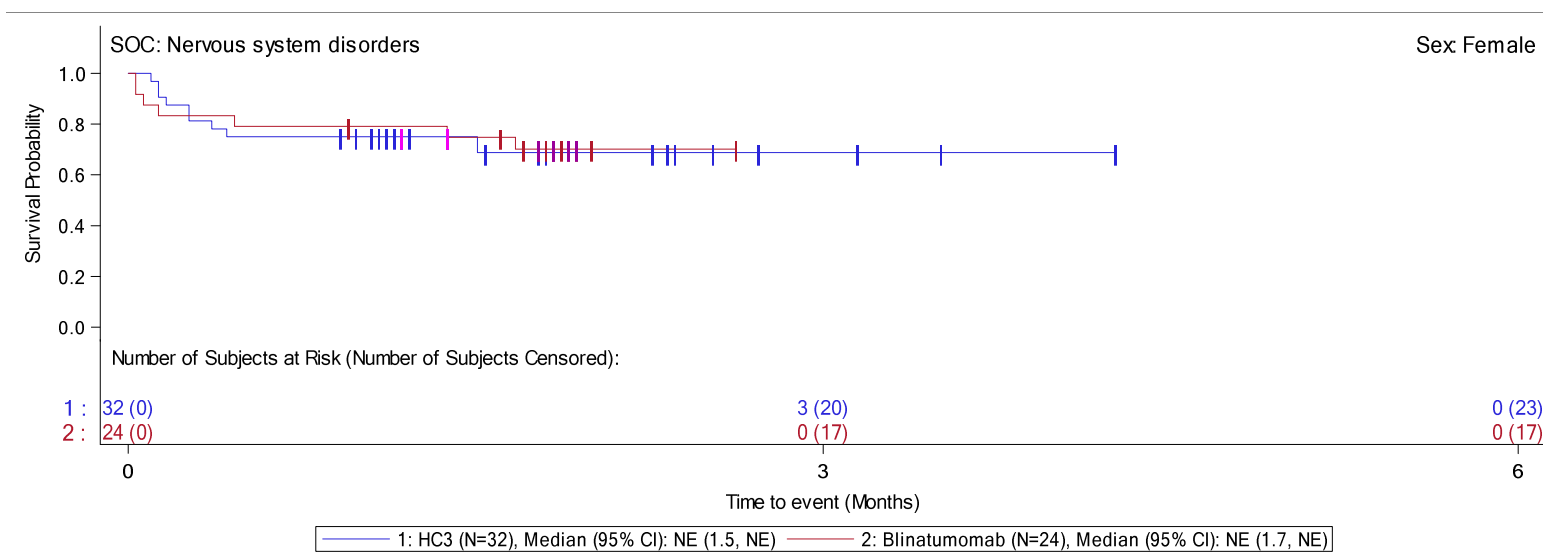


N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.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)



N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.
 Censor indicated by vertical bar |.

Program: /userdata/stat/amg103/onc/20120215/analysis/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: 28OCT25 06:50) Source Data: a215up.adsl, a215up.adbase, outtab.t_aette_socpref

Anhang 4-G3.4.6: Subgruppenanalysen häufiger SUE nach SOC und PT

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Blood and lymphatic system disorders							
Overall	13/52 (25.0)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	<0.0001	
Age group							0.9998
1-9 years	11/38 (28.9)	NE (NE, NE)	0/39 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0003	
Other	2/14 (14.3)	NE (NE, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1358	
Sex							0.9999
Male	4/20 (20.0)	-	0/30 (0.0)	-	-	-	
Female	9/32 (28.1)	-	0/24 (0.0)	-	-	-	

Page 1 of 10

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	12/50 (24.0)	-	0/49 (0.0)	-	-	-	
Rest of world	1/2 (50.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9999
M1 with MRD level $< 10^{-3}$	7/33 (21.2)	-	0/35 (0.0)	-	-	-	
M1 with MRD level $\geq 10^{-3}$ or M2	6/19 (31.6)	-	0/19 (0.0)	-	-	-	
Race							>0.9999
Caucasian	9/42 (21.4)	-	0/50 (0.0)	-	-	-	
Others	4/10 (40.0)	-	0/4 (0.0)	-	-	-	

Page 2 of 10

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9999
< 18 months	4/21 (19.0)	-	0/19 (0.0)	-	-	-	
≥ 18 months	9/31 (29.0)	-	0/35 (0.0)	-	-	-	
MRD before treatment start							>0.9999
<10 ⁻⁴	8/29 (27.6)	-	0/28 (0.0)	-	-	-	
≥10 ⁻⁴	5/23 (21.7)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							>0.9999
Yes	4/14 (28.6)	-	0/10 (0.0)	-	-	-	
No	9/38 (23.7)	-	0/44 (0.0)	-	-	-	

Page 3 of 10

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Febrile neutropenia						
Overall	9/52 (17.3)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0014
Age group						>0.9999
1-9 years	7/38 (18.4)	-	0/39 (0.0)	-	-	-
Other	2/14 (14.3)	-	0/15 (0.0)	-	-	-
Sex						>0.9999
Male	3/20 (15.0)	-	0/30 (0.0)	-	-	-
Female	6/32 (18.8)	-	0/24 (0.0)	-	-	-

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	8/50 (16.0)	-	0/49 (0.0)	-	-	-	
Rest of world	1/2 (50.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9999
M1 with MRD level $< 10^{-3}$	4/33 (12.1)	-	0/35 (0.0)	-	-	-	
M1 with MRD level $\geq 10^{-3}$ or M2	5/19 (26.3)	-	0/19 (0.0)	-	-	-	
Race							>0.9999
Caucasian	7/42 (16.7)	-	0/50 (0.0)	-	-	-	
Others	2/10 (20.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9998
< 18 months	2/21 (9.5)	-	0/19 (0.0)	-	-	-	
≥ 18 months	7/31 (22.6)	-	0/35 (0.0)	-	-	-	
MRD before treatment start							>0.9999
<10 ⁻⁴	6/29 (20.7)	-	0/28 (0.0)	-	-	-	
$\geq 10^{-4}$	3/23 (13.0)	-	0/26 (0.0)	-	-	-	
Extramedullary Disease at relapse							>0.9999
Yes	3/14 (21.4)	-	0/10 (0.0)	-	-	-	
No	6/38 (15.8)	-	0/44 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Neutropenia						
Overall	3/52 (5.8)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0747

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Gastrointestinal disorders						
Overall	3/52 (5.8)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	0.35 (0.04, 3.39)	0.3431

Page 8 of 10

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Infections and infestations						
Overall	6/52 (11.5)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	0.54 (0.15, 1.93)	0.3376

Page 9 of 10

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.2. Subgroup Analysis of Time to First Onset of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or ≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Nervous system disorders						
Overall	1/52 (1.9)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	5.05 (0.59, 43.25)	0.1013

Page 10 of 10

N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-ser-teae-soc-pt-saf.sas

Output: t14-06-014-002-ae-tte-sub-ser-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:47) Source data: a215up.adsl, a215.adae, a215up.adbase

Anhang 4-G3.4.7: Subgruppenanalysen häufiger schwerer UE nach SOC und PT

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Blood and lymphatic system disorders							
Overall	38/52 (73.1)	0.3 (0.3, 0.4)	15/54 (27.8)	NE (NE, NE)	0.23 (0.13, 0.43)	<0.0001	
Age group							0.2433
1-9 years	28/38 (73.7)	0.3 (0.3, 0.4)	13/39 (33.3)	NE (1.7, NE)	0.28 (0.14, 0.56)	0.0001	
Other	10/14 (71.4)	0.3 (0.2, NE)	2/15 (13.3)	NE (NE, NE)	0.11 (0.02, 0.51)	0.0007	
Sex							0.7730
Male	16/20 (80.0)	0.3 (0.3, 0.4)	9/30 (30.0)	NE (1.7, NE)	0.20 (0.08, 0.48)	<0.0001	
Female	22/32 (68.8)	0.4 (0.3, 0.5)	6/24 (25.0)	NE (NE, NE)	0.24 (0.09, 0.59)	0.0010	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	37/50 (74.0)	-	14/49 (28.6)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.8267
M1 with MRD level < 10 ⁻³	23/33 (69.7)	0.4 (0.3, 0.5)	9/35 (25.7)	NE (NE, NE)	0.23 (0.11, 0.52)	0.0001	
M1 with MRD level ≥ 10 ⁻³ or M2	15/19 (78.9)	0.3 (0.2, 0.3)	6/19 (31.6)	NE (1.6, NE)	0.24 (0.09, 0.63)	0.0021	
Race							0.8399
Caucasian	30/42 (71.4)	0.3 (0.3, 0.5)	14/50 (28.0)	NE (NE, NE)	0.24 (0.12, 0.45)	<0.0001	
Others	8/10 (80.0)	0.3 (0.2, 0.4)	1/4 (25.0)	NE (0.3, NE)	0.22 (0.03, 1.81)	0.1186	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.5547
< 18 months	14/21 (66.7)	0.4 (0.2, NE)	4/19 (21.1)	NE (NE, NE)	0.18 (0.06, 0.57)	0.0012	
≥ 18 months	24/31 (77.4)	0.3 (0.3, 0.4)	11/35 (31.4)	NE (1.7, NE)	0.26 (0.12, 0.54)	0.0002	
MRD before treatment start							0.1077
<10 ⁻⁴	22/29 (75.9)	0.3 (0.3, 0.4)	5/28 (17.9)	NE (NE, NE)	0.12 (0.04, 0.32)	<0.0001	
≥10 ⁻⁴	16/23 (69.6)	0.3 (0.3, 0.5)	10/26 (38.5)	NE (1.5, NE)	0.41 (0.18, 0.94)	0.0293	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Extramedullary Disease at relapse							0.1448
Yes	11/14 (78.6)	0.3 (0.2, 0.5)	1/10 (10.0)	NE (1.6, NE)	0.06 (0.01, 0.50)	0.0006	
No	27/38 (71.1)	0.4 (0.3, 0.5)	14/44 (31.8)	NE (NE, NE)	0.29 (0.15, 0.56)	0.0001	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Anaemia							
Overall	22/52 (42.3)	NE (0.4, NE)	8/54 (14.8)	NE (NE, NE)	0.25 (0.11, 0.57)	0.0004	
Age group							0.3392
1-9 years	16/38 (42.1)	NE (0.4, NE)	7/39 (17.9)	NE (NE, NE)	0.30 (0.12, 0.74)	0.0059	
Other	6/14 (42.9)	NE (0.2, NE)	1/15 (6.7)	NE (NE, NE)	0.13 (0.02, 1.05)	0.0220	
Sex							0.6045
Male	8/20 (40.0)	NE (0.3, NE)	5/30 (16.7)	NE (NE, NE)	0.32 (0.10, 0.97)	0.0349	
Female	14/32 (43.8)	NE (0.4, NE)	3/24 (12.5)	NE (NE, NE)	0.20 (0.06, 0.72)	0.0065	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	21/50 (42.0)	-	7/49 (14.3)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.7623
M1 with MRD level < 10 ⁻³	11/33 (33.3)	NE (0.9, NE)	4/35 (11.4)	NE (NE, NE)	0.28 (0.09, 0.88)	0.0199	
M1 with MRD level ≥ 10 ⁻³ or M2	11/19 (57.9)	0.4 (0.2, NE)	4/19 (21.1)	NE (1.7, NE)	0.22 (0.07, 0.71)	0.0061	
Race							0.9190
Caucasian	16/42 (38.1)	NE (0.5, NE)	7/50 (14.0)	NE (NE, NE)	0.27 (0.11, 0.65)	0.0019	
Others	6/10 (60.0)	0.4 (0.2, NE)	1/4 (25.0)	NE (0.3, NE)	0.35 (0.04, 2.91)	0.3033	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.7857
< 18 months	8/21 (38.1)	NE (0.3, NE)	3/19 (15.8)	NE (NE, NE)	0.31 (0.08, 1.17)	0.0684	
≥ 18 months	14/31 (45.2)	NE (0.4, NE)	5/35 (14.3)	NE (NE, NE)	0.23 (0.08, 0.64)	0.0024	
MRD before treatment start							0.5695
<10 ⁻⁴	12/29 (41.4)	NE (0.4, NE)	3/28 (10.7)	NE (NE, NE)	0.19 (0.05, 0.69)	0.0048	
≥10 ⁻⁴	10/23 (43.5)	NE (0.3, NE)	5/26 (19.2)	NE (NE, NE)	0.31 (0.10, 0.92)	0.0261	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Extramedullary Disease at relapse						0.5988
Yes	6/14 (42.9)	NE (0.2, NE)	1/10 (10.0)	NE (1.6, NE)	0.15 (0.02, 1.32)	0.0523
No	16/38 (42.1)	NE (0.4, NE)	7/44 (15.9)	NE (NE, NE)	0.28 (0.11, 0.69)	0.0033

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Neutropenia							
Overall	14/52 (26.9)	NE (NE, NE)	5/54 (9.3)	NE (NE, NE)	0.32 (0.11, 0.88)	0.0208	
Age group							0.9900
1-9 years	11/38 (28.9)	NE (NE, NE)	5/39 (12.8)	NE (NE, NE)	0.41 (0.14, 1.19)	0.0936	
Other	3/14 (21.4)	NE (0.4, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0624	
Sex							0.9630
Male	6/20 (30.0)	NE (0.4, NE)	3/30 (10.0)	NE (NE, NE)	0.30 (0.07, 1.19)	0.0696	
Female	8/32 (25.0)	NE (NE, NE)	2/24 (8.3)	NE (NE, NE)	0.33 (0.07, 1.53)	0.1368	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	14/50 (28.0)	-	5/49 (10.2)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.1678
M1 with MRD level < 10 ⁻³	10/33 (30.3)	NE (NE, NE)	2/35 (5.7)	NE (NE, NE)	0.17 (0.04, 0.80)	0.0110	
M1 with MRD level ≥ 10 ⁻³ or M2	4/19 (21.1)	NE (NE, NE)	3/19 (15.8)	NE (NE, NE)	0.71 (0.16, 3.19)	0.6505	
Race							0.9917
Caucasian	11/42 (26.2)	NE (NE, NE)	5/50 (10.0)	NE (NE, NE)	0.35 (0.12, 1.02)	0.0453	
Others	3/10 (30.0)	NE (0.2, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2464	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.4722
< 18 months	6/21 (28.6)	NE (0.5, NE)	1/19 (5.3)	NE (NE, NE)	0.17 (0.02, 1.43)	0.0648	
≥ 18 months	8/31 (25.8)	NE (NE, NE)	4/35 (11.4)	NE (NE, NE)	0.41 (0.12, 1.36)	0.1320	
MRD before treatment start							0.9908
<10 ⁻⁴	8/29 (27.6)	NE (NE, NE)	0/28 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0029	
≥10 ⁻⁴	6/23 (26.1)	NE (NE, NE)	5/26 (19.2)	NE (NE, NE)	0.72 (0.22, 2.37)	0.5839	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Extramedullary Disease at relapse						0.9918
Yes	3/14 (21.4)	NE (0.5, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1281
No	11/38 (28.9)	NE (NE, NE)	5/44 (11.4)	NE (NE, NE)	0.36 (0.13, 1.05)	0.0532

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Thrombocytopenia							
Overall	11/52 (21.2)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	0.28 (0.09, 0.89)	0.0219	
Age group							0.9915
1-9 years	9/38 (23.7)	NE (NE, NE)	4/39 (10.3)	NE (NE, NE)	0.34 (0.10, 1.12)	0.0643	
Other	2/14 (14.3)	NE (NE, NE)	0/15 (0.0)	NE (NE, NE)	NE (NE, NE)	0.1358	
Sex							0.6419
Male	5/20 (25.0)	-	2/30 (6.7)	-	-	-	
Female	6/32 (18.8)	-	2/24 (8.3)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	11/50 (22.0)	-	4/49 (8.2)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.2835
M1 with MRD level < 10 ⁻³	6/33 (18.2)	-	1/35 (2.9)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	-	3/19 (15.8)	-	-	-	
Race							0.9929
Caucasian	9/42 (21.4)	NE (NE, NE)	4/50 (8.0)	NE (NE, NE)	0.29 (0.09, 0.95)	0.0313	
Others	2/10 (20.0)	NE (0.2, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.3582	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.4857
< 18 months	4/21 (19.0)	-	2/19 (10.5)	-	-	-	
≥ 18 months	7/31 (22.6)	-	2/35 (5.7)	-	-	-	
MRD before treatment start							0.7414
<10 ⁻⁴	7/29 (24.1)	-	2/28 (7.1)	-	-	-	
≥10 ⁻⁴	4/23 (17.4)	-	2/26 (7.7)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Extramedullary Disease at relapse							0.9930
Yes	2/14 (14.3)	NE (NE, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2233	
No	9/38 (23.7)	NE (NE, NE)	4/44 (9.1)	NE (NE, NE)	0.30 (0.09, 0.99)	0.0368	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Febrile neutropenia							
Overall	13/52 (25.0)	NE (NE, NE)	2/54 (3.7)	NE (NE, NE)	0.12 (0.03, 0.54)	0.0009	
Age group							0.4211
1-9 years	10/38 (26.3)	NE (NE, NE)	1/39 (2.6)	NE (NE, NE)	0.08 (0.01, 0.63)	0.0021	
Other	3/14 (21.4)	NE (0.5, NE)	1/15 (6.7)	NE (NE, NE)	0.25 (0.03, 2.42)	0.1948	
Sex							0.9926
Male	5/20 (25.0)	NE (0.4, NE)	0/30 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0039	
Female	8/32 (25.0)	NE (NE, NE)	2/24 (8.3)	NE (NE, NE)	0.26 (0.06, 1.24)	0.0705	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

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Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	12/50 (24.0)	-	1/49 (2.0)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9913
M1 with MRD level < 10 ⁻³	7/33 (21.2)	-	2/35 (5.7)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	6/19 (31.6)	-	0/19 (0.0)	-	-	-	
Race							0.9937
Caucasian	10/42 (23.8)	NE (NE, NE)	2/50 (4.0)	NE (NE, NE)	0.14 (0.03, 0.62)	0.0027	
Others	3/10 (30.0)	NE (0.3, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.2464	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9910
< 18 months	5/21 (23.8)	NE (NE, NE)	0/19 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0250	
≥ 18 months	8/31 (25.8)	NE (NE, NE)	2/35 (5.7)	NE (NE, NE)	0.18 (0.04, 0.84)	0.0140	
MRD before treatment start							0.9937
<10 ⁻⁴	9/29 (31.0)	NE (1.1, NE)	2/28 (7.1)	NE (NE, NE)	0.18 (0.04, 0.86)	0.0157	
≥10 ⁻⁴	4/23 (17.4)	NE (NE, NE)	0/26 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0278	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Extramedullary Disease at relapse							0.9932
Yes	6/14 (42.9)	-	0/10 (0.0)	-	-	-	
No	7/38 (18.4)	-	2/44 (4.5)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		p-value ^b
PT: Leukopenia						
Overall	3/52 (5.8)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0747

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Congenital, familial and genetic disorders						
Overall	4/52 (7.7)	NE (NE, NE)	2/54 (3.7)	NE (NE, NE)	0.38 (0.07, 2.09)	0.2495

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Aplasia						
Overall	4/52 (7.7)	NE (NE, NE)	2/54 (3.7)	NE (NE, NE)	0.38 (0.07, 2.09)	0.2495

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
SOC: Gastrointestinal disorders							
Overall	17/52 (32.7)	NE (NE, NE)	6/54 (11.1)	NE (NE, NE)	0.24 (0.09, 0.61)	0.0012	
Age group							0.6335
1-9 years	11/38 (28.9)	NE (NE, NE)	3/39 (7.7)	NE (NE, NE)	0.19 (0.05, 0.69)	0.0053	
Other	6/14 (42.9)	NE (0.3, NE)	3/15 (20.0)	NE (2.0, NE)	0.28 (0.07, 1.18)	0.0674	
Sex							0.4528
Male	6/20 (30.0)	NE (0.3, NE)	4/30 (13.3)	NE (NE, NE)	0.32 (0.09, 1.17)	0.0718	
Female	11/32 (34.4)	NE (0.4, NE)	2/24 (8.3)	NE (NE, NE)	0.17 (0.04, 0.76)	0.0091	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	16/50 (32.0)	-	5/49 (10.2)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.6828
M1 with MRD level < 10 ⁻³	12/33 (36.4)	NE (0.6, NE)	4/35 (11.4)	NE (2.0, NE)	0.21 (0.07, 0.68)	0.0044	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	NE (0.4, NE)	2/19 (10.5)	NE (NE, NE)	0.29 (0.06, 1.53)	0.1228	
Race							0.9899
Caucasian	11/42 (26.2)	NE (NE, NE)	6/50 (12.0)	NE (NE, NE)	0.32 (0.12, 0.89)	0.0226	
Others	6/10 (60.0)	0.3 (0.1, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0665	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.8077
< 18 months	5/21 (23.8)	NE (NE, NE)	1/19 (5.3)	NE (NE, NE)	0.17 (0.02, 1.47)	0.0692	
≥ 18 months	12/31 (38.7)	NE (0.3, NE)	5/35 (14.3)	NE (NE, NE)	0.23 (0.08, 0.67)	0.0037	
MRD before treatment start							0.3568
<10 ⁻⁴	11/29 (37.9)	NE (0.3, NE)	5/28 (17.9)	NE (2.0, NE)	0.33 (0.11, 0.96)	0.0335	
≥10 ⁻⁴	6/23 (26.1)	NE (NE, NE)	1/26 (3.8)	NE (NE, NE)	0.11 (0.01, 0.92)	0.0149	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Extramedullary Disease at relapse						0.9909
Yes	6/14 (42.9)	NE (0.2, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0196
No	11/38 (28.9)	NE (NE, NE)	6/44 (13.6)	NE (NE, NE)	0.33 (0.12, 0.90)	0.0241

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Stomatitis							
Overall	16/52 (30.8)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	0.14 (0.04, 0.48)	0.0003	
Age group							0.4137
1-9 years	10/38 (26.3)	NE (NE, NE)	1/39 (2.6)	NE (NE, NE)	0.08 (0.01, 0.62)	0.0019	
Other	6/14 (42.9)	NE (0.3, NE)	2/15 (13.3)	NE (2.0, NE)	0.21 (0.04, 1.07)	0.0400	
Sex							0.5060
Male	5/20 (25.0)	NE (0.3, NE)	2/30 (6.7)	NE (NE, NE)	0.22 (0.04, 1.13)	0.0480	
Female	11/32 (34.4)	NE (0.4, NE)	1/24 (4.2)	NE (NE, NE)	0.09 (0.01, 0.70)	0.0040	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	15/50 (30.0)	-	2/49 (4.1)	-	-	-	
Rest of world	1/2 (50.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9935
M1 with MRD level < 10 ⁻³	11/33 (33.3)	NE (1.1, NE)	3/35 (8.6)	NE (2.0, NE)	0.18 (0.05, 0.68)	0.0047	
M1 with MRD level ≥ 10 ⁻³ or M2	5/19 (26.3)	NE (0.4, NE)	0/19 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0178	
Race							0.9936
Caucasian	10/42 (23.8)	NE (NE, NE)	3/50 (6.0)	NE (NE, NE)	0.20 (0.05, 0.73)	0.0074	
Others	6/10 (60.0)	0.3 (0.1, NE)	0/4 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0665	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

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Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9906
< 18 months	5/21 (23.8)	NE (NE, NE)	0/19 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0231	
≥ 18 months	11/31 (35.5)	NE (0.3, NE)	3/35 (8.6)	NE (NE, NE)	0.17 (0.05, 0.60)	0.0022	
MRD before treatment start							0.9924
<10 ⁻⁴	10/29 (34.5)	NE (0.3, NE)	3/28 (10.7)	NE (2.0, NE)	0.23 (0.06, 0.86)	0.0182	
≥10 ⁻⁴	6/23 (26.1)	NE (NE, NE)	0/26 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0057	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
Extramedullary Disease at relapse						0.9928
Yes	6/14 (42.9)	NE (0.2, NE)	0/10 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0198
No	10/38 (26.3)	NE (NE, NE)	3/44 (6.8)	NE (NE, NE)	0.20 (0.05, 0.74)	0.0077

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: General disorders and administration site conditions						
Overall	1/52 (1.9)	NE (NE, NE)	10/54 (18.5)	NE (NE, NE)	7.97 (1.02, 62.41)	0.0188
Age group						0.9928
1-9 years	0/38 (0.0)	-	7/39 (17.9)	-	-	-
Other	1/14 (7.1)	-	3/15 (20.0)	-	-	-
Sex						0.9929
Male	0/20 (0.0)	-	4/30 (13.3)	-	-	-
Female	1/32 (3.1)	-	6/24 (25.0)	-	-	-

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	1/50 (2.0)	-	9/49 (18.4)	-	-	-	
Rest of world	0/2 (0.0)	-	1/5 (20.0)	-	-	-	
Marrow/MRD Status at baseline							0.9927
M1 with MRD level < 10 ⁻³	1/33 (3.0)	-	5/35 (14.3)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	5/19 (26.3)	-	-	-	
Race							0.9943
Caucasian	1/42 (2.4)	NE (NE, NE)	9/50 (18.0)	NE (NE, NE)	6.13 (0.78, 48.54)	0.0499	
Others	0/10 (0.0)	NE (NE, NE)	1/4 (25.0)	NE (1.6, NE)	NE (NE, NE)	0.1859	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9932
< 18 months	0/21 (0.0)	-	6/19 (31.6)	-	-	-	
≥ 18 months	1/31 (3.2)	-	4/35 (11.4)	-	-	-	
MRD before treatment start							0.9928
<10 ⁻⁴	1/29 (3.4)	-	6/28 (21.4)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	4/26 (15.4)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Extramedullary Disease at relapse							0.9939
Yes	0/14 (0.0)	-	2/10 (20.0)	-	-	-	
No	1/38 (2.6)	-	8/44 (18.2)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
PT: Mucosal inflammation							
Overall	0/52 (0.0)	NE (NE, NE)	7/54 (13.0)	NE (NE, NE)	NE (NE, NE)	0.0218	
Age group							>0.9999
1-9 years	0/38 (0.0)	-	4/39 (10.3)	-	-	-	
Other	0/14 (0.0)	-	3/15 (20.0)	-	-	-	
Sex							0.9999
Male	0/20 (0.0)	-	3/30 (10.0)	-	-	-	
Female	0/32 (0.0)	-	4/24 (16.7)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Region							-
Europe	0/50 (0.0)	-	7/49 (14.3)	-	-	-	
Rest of world	0/2 (0.0)	-	0/5 (0.0)	-	-	-	
Marrow/MRD Status at baseline							0.9999
M1 with MRD level < 10 ⁻³	0/33 (0.0)	-	3/35 (8.6)	-	-	-	
M1 with MRD level ≥ 10 ⁻³ or M2	0/19 (0.0)	-	4/19 (21.1)	-	-	-	
Race							0.9984
Caucasian	0/42 (0.0)	-	7/50 (14.0)	-	-	-	
Others	0/10 (0.0)	-	0/4 (0.0)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Time from 1 st diagnosis to relapse							0.9998
< 18 months	0/21 (0.0)	-	5/19 (26.3)	-	-	-	
≥ 18 months	0/31 (0.0)	-	2/35 (5.7)	-	-	-	
MRD before treatment start							>0.9999
<10 ⁻⁴	0/29 (0.0)	-	4/28 (14.3)	-	-	-	
≥10 ⁻⁴	0/23 (0.0)	-	3/26 (11.5)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	p-value ^b	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)			
Extramedullary Disease at relapse							>0.9999
Yes	0/14 (0.0)	-	1/10 (10.0)	-	-	-	
No	0/38 (0.0)	-	6/44 (13.6)	-	-	-	

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Pyrexia						
Overall	0/52 (0.0)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	NE (NE, NE)	0.1255

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		p-value ^b
SOC: Hepatobiliary disorders						
Overall	7/52 (13.5)	NE (NE, NE)	2/54 (3.7)	NE (NE, NE)	0.26 (0.05, 1.25)	0.0708

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Hepatotoxicity						
Overall	3/52 (5.8)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0745

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Hypertransaminasaemia						
Overall	3/52 (5.8)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0747

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Infections and infestations						
Overall	6/52 (11.5)	NE (NE, NE)	11/54 (20.4)	NE (2.0, NE)	1.50 (0.55, 4.08)	0.4290

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		p-value ^b
SOC: Investigations						
Overall	15/52 (28.8)	NE (NE, NE)	12/54 (22.2)	NE (NE, NE)	0.69 (0.32, 1.48)	0.3239

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Platelet count decreased						
Overall	8/52 (15.4)	NE (NE, NE)	6/54 (11.1)	NE (NE, NE)	0.58 (0.20, 1.69)	0.3124

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Neutrophil count decreased						
Overall	2/52 (3.8)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	2.01 (0.37, 10.96)	0.4205

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: White blood cell count decreased						
Overall	1/52 (1.9)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	4.00 (0.45, 35.81)	0.1795

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
PT: Alanine aminotransferase increased						
Overall	5/52 (9.6)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	0.18 (0.02, 1.58)	0.0830

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		p-value ^b
SOC: Nervous system disorders						
Overall	0/52 (0.0)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	NE (NE, NE)	0.1123

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Respiratory, thoracic and mediastinal disorders						
Overall	3/52 (5.8)	NE (NE, NE)	1/54 (1.9)	NE (NE, NE)	0.28 (0.03, 2.71)	0.2399

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		p-value ^b
PT: Epistaxis						
Overall	3/52 (5.8)	NE (NE, NE)	0/54 (0.0)	NE (NE, NE)	NE (NE, NE)	0.0747

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

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Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs (≥ 5% Subjects or (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Skin and subcutaneous tissue disorders						
Overall	0/52 (0.0)	NE (NE, NE)	3/54 (5.6)	NE (NE, NE)	NE (NE, NE)	0.1466

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase

Table 14-6.14.3. Subgroup Analysis of Time to First Onset of Grade 3 and Above Treatment-emergent Adverse Events by System Organ Class and Preferred Term (Most Frequent TEAEs ($\geq 5\%$ Subjects or (≥ 10 Subjects and $\geq 1\%$ Subjects in at least One Treatment Arm))) (Safety Analysis Set)

	HC3 (N = 52)		Blinatumomab (N = 54)		Hazard Ratio (95% CI)	Interaction p-value ^a
	Events/ Subjects (%)	Time to event Median (95% CI)	Events/ Subjects (%)	Time to event Median (95% CI)		
SOC: Vascular disorders						
Overall	2/52 (3.8)	NE (NE, NE)	4/54 (7.4)	NE (NE, NE)	1.76 (0.32, 9.71)	0.5087

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N = Number of subjects in the analysis set. CI = Confidence interval. NE = Not estimable.

Unstratified analysis was conducted for Overall and for Subgroups.

Months are calculated as days from treatment start date to event date, divided by 30.5.

Severity graded using CTCAE version 4.03.

^a The p-value is from the test of the interaction term in an unstratified Cox regression model with terms for the covariate and treatment group.

The hazard ratio estimate for all subjects was obtained from an unstratified Cox Proportional Hazard model.

^b p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg103/onc/20120215/analysis/german_payer_202504/tables/t-ae-tte-sub-sev-teae-soc-pt-saf.sas

Output: t14-06-014-003-ae-tte-sub-sev-teae-soc-pt-saf.rtf (Date generated: 13JUN2025:07:48) Source data: a215up.adsl, a215.adae, a215up.adbase