Dossier zur Nutzenbewertung gemäß § 35a SGB V

Blinatumomab (BLINCYTO®)

Amgen GmbH

Modul 4 E – Anhang 4-G

Als Monotherapie zur Behandlung von pädiatrischen Patienten im Alter von 1 Jahr oder älter mit Hochrisiko-Erstrezidiv einer Philadelphia-Chromosom-negativen CD19-positiven B-Vorläufer akuter lymphatischer Leukämie (ALL) im Rahmen der Konsolidierungstherapie

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 19.07.2021

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G.1: Ergänzende Tabellen

Table 14-4.2.1. Overall Survival (Full Analysis Set)

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference	Overall
Subject status				
Number of subjects	54	54		
Events - n (%)	16 (29.6)	8 (14.8)		
Deaths from any cause	16 (29.6)	8 (14.8)		
Censored - n (%)	38 (70.4)	46 (85.2)		
Alive at last follow-up	38 (70.4)	46 (85.2)		
Stratified log-rank test[a]				
n	54	54		
Normal score[b]			-4.84	
p-value			0.047	
Unstratified log-rank test				
n	54	54		
Normal score[b]			-5.00	
p-value			0.040	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-os-fas.sas
Output: t14-04-002-001-os-fas.rtf (Date generated: 25FEB2021:01:29) Source data: adampc.adsl, adampc.adtteeff

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference	Overall
Time to event (KM) (months)[c]				
Median	NE	NE		
95% CI (median)	(15.7, NE)	(NE, NE)		
Q1, Q3	11.1, NE	NE, NE		
Min, Max	1.7, 20.1	3.3, 13.5		
Time to censoring (KM) (months)[c,d]				
Median	16.1	22.1		19.5
95% CI (median)	(10.7, 23.1)	(13.6, 28.5)		(15.6, 23.3)
Q1, Q3	7.6, 28.9	8.3, 32.0		7.8, 31.6
Min, Max	0.1, 41.8	0.2, 44.1		0.1, 44.1

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Data cut-off date: 17JUL2019

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Output: t14-04-002-001-os-fas.rtf (Date generated: 25FEB2021:01:29) Source data: adampc.adsl, adampc.adtteeff

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference	Overall
KM estimate - %				
At time 3 months[c]	95.8	100.0		
(95% CI)	(84.4, 98.9)	(100.0, 100.0)		
At time 6 months[c]	91.4	93.9		
(95% CI)	(78.6, 96.7)	(82.3, 98.0)		
At time 12 months[c]	70.6	86.7		
(95% CI)	(53.7, 82.3)	(72.6, 93.9)		
At time 18 months[c]	64.2	81.1		
(95% CI)	(46.5, 77.3)	(65.5, 90.2)		
At time 24 months[c]	55.8	81.1		
(95% CI)	(36.9, 71.0)	(65.5, 90.2)		
At time 36 months[c]	55.8	81.1		
(95% CI)	(36.9, 71.0)	(65.5, 90.2)		
At time 48 months[c]	NE	NE		
(95% CI)	(NE, NE)	(NE, NE)		
At time 60 months[c]	NE	NE		
(95% CI)	(NE, NE)	(NE, NE)		

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-os-fas.sas
Output: t14-04-002-001-os-fas.rtf (Date generated: 25FEB2021:01:29) Source data: adampc.adsl, adampc.adtteeff

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference	Overall
Stratified hazard ratio[a,e]			0.43	
(95% CI)			(0.18, 1.01)	
p-value			0.053	
Unstratified hazard ratio[e]			0.42	
(95% CI)			(0.18, 0.99)	
p-value			0.046	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-os-fas.sas
Output: t14-04-002-001-os-fas.rtf (Date generated: 25FEB2021:01:29) Source data: adampc.adsl, adampc.adtteeff

Table 14-4.2.6. Overall Survival (Full Analysis Set)

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference	Overall
Subject status				
Number of subjects	57	54		
Events - n (%)	23 (40.4)	9 (16.7)		
Deaths from any cause	23 (40.4)	9 (16.7)		
Censored - n (%)	34 (59.6)	45 (83.3)		
Alive at last follow-up	34 (59.6)	45 (83.3)		
Stratified log-rank test[a]				
n	57	54		
Normal score[b]			-8.19	
p-value			0.003	
Unstratified log-rank test				
n	57	54		
Normal score[b]			-8.20	
p-value			0.004	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Snapshot date: 14SEP2020

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_202009/tables/t-os-fas.sas
Output: t14-04-002-006-os-fas.rtf (Date generated: 28FEB2021:22:42) Source data: adamhta.adsl, adamhta.adtteeff

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference	Overall
Time to event (KM) (months)[c]				
Median	NE	NE		
95% CI (median)	(17.5, NE)	(NE, NE)		
Q1, Q3	11.1, NE	NE, NE		
Min, Max	1.7, 24.8	3.3, 18.1		
Time to censoring (KM) (months)[c,d]				
Median	31.0	34.4		31.4
95% CI (median)	(22.9, 36.2)	(23.3, 39.7)		(24.8, 36.2)
Q1, Q3	19.7, 38.5	20.4, 44.9		20.2, 41.1
Min, Max	0.1, 54.2	1.0, 54.8		0.1, 54.8

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Snapshot date: 14SEP2020

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_202009/tables/t-os-fas.sas
Output: t14-04-002-006-os-fas.rtf (Date generated: 28FEB2021:22:42) Source data: adamhta.adsl, adamhta.adtteeff

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference	Overall
KM estimate - %				
At time 3 months[c]	96.1	100.0		
(95% CI)	(85.2, 99.0)	(100.0, 100.0)		
At time 6 months[c]	92.2	94.3		
(95% CI)	(80.4, 97.0)	(83.5, 98.1)		
At time 12 months[c]	72.5	88.4		
(95% CI)	(58.1, 82.7)	(76.1, 94.6)		
At time 18 months[c]	64.0	84.4		
(95% CI)	(49.0, 75.6)	(71.2, 91.9)		
At time 24 months[c]	54.8	82.2		
(95% CI)	(39.6, 67.6)	(68.5, 90.3)		
At time 36 months[c]	51.9	82.2		
(95% CI)	(36.6, 65.1)	(68.5, 90.3)		
At time 48 months[c]	51.9	82.2		
(95% CI)	(36.6, 65.1)	(68.5, 90.3)		
At time 60 months[c]	NE	NE		
(95% CI)	(NE, NE)	(NE, NE)		

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Snapshot date: 14SEP2020

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_202009/tables/t-os-fas.sas
Output: t14-04-002-006-os-fas.rtf (Date generated: 28FEB2021:22:42) Source data: adamhta.adsl, adamhta.adtteeff

	HC3 (N=57)	Blinatumomab (N=54)	Treatment Difference	Overall
Stratified hazard ratio[a,e]			0.33	
(95% CI)			(0.15, 0.72)	
p-value			0.005	
Unstratified hazard ratio[e]			0.34	
(95% CI)			(0.16, 0.73)	
p-value			0.006	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = not estimable
Overall Survival (OS) time is calculated from time of randomization until death due to any cause.
[a] 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).
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to HC3 and therefore a longer survival time.
[c] Months are calculated as days from randomization date to event/censor date, divided by 30.5.
[d] Time to censoring measures follow-up time by reversing the status indicator for censored and events.
[e] The hazard ratio estimates are obtained from 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.
Snapshot date: 14SEP2020

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_202009/tables/t-os-fas.sas
Output: t14-04-002-006-os-fas.rtf (Date generated: 28FEB2021:22:42) Source data: adamhta.adsl, adamhta.adtteeff

Table 14-4.6.2. Summary of Duration of Observation of MRD response (MRD Evaluable Set)

	HC3 (N=54)	Blinatumomab (N=54)	Total (N=108)
Duration of observation of MRD response (months)[a]			
n	51	54	105
Mean	0.33	0.98	0.67
SD	0.14	0.21	0.37
Median	0.26	1.00	0.62
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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sum-obs-dur-mes-fas.sas
Output: t14-04-006-002-sum-dur-obs-mrd-mes.rtf (Date generated: 24JAN2021:22:21) Source data: adampc.adsl

Table 14-4.3.1. MRD Response (MRD Evaluable Set)

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
MRD response by PCR			
Subject status			
Number of subjects assessed	48	49	
MRD response - n (%)	26 (54.2)	44 (89.8)	35.6
(95% CI)	(39.2, 68.6)	(77.8, 96.6)	(19.2, 52.1)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			7.4
(95% CI)			(2.5, 22.0)
p-value			<0.001
Stratified odds ratio[b, c]			7.0
(95% CI)			(2.4, 20.5)
p-value			<0.001
Unstratified risk ratio[c]			1.7
(95% CI)			(1.3, 2.2)
p-value			<0.001
Stratified risk ratio[b, c, d]			1.4
(95% CI)			(1.1, 1.8)
p-value			0.017

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N = Number of subjects in MRD evaluable set. MRD = minimal residual disease. PCR = polymerase chain reaction. CI = Exact Binomial Confidence Interval.
MRD evaluable set includes subjects for which evaluable baseline MRD marker can be found with either of the MRD assessment methods of PCR or flow cytometry. Number of subjects assessed includes subjects in the MRD evaluable set who had a baseline MRD marker for the respective assessment methods.
MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of MRD evaluable 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. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.
[a] Cochran-Mantel-Haenszel test adjusting for the stratification factors.
[b] 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).
[c] The odds ratio and risk ratio are obtained from a logistic regression model with logit link An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.
[d] The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-mrd-mes.sas
Output: t14-04-003-001-mrd-mes.rtf (Date generated: 28JAN2021:00:20) Source data: adampc.adsl, adampc.adrs

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Absolute risk reduction			0.4
(95% CI)			(0.2, 0.5)
p-value			<0.001
MRD response by flow cytometry			
Subject status			
Number of subjects assessed	53	53	
MRD response - n (%)	32 (60.4)	48 (90.6)	30.2
(95% CI)	(46.0, 73.5)	(79.3, 96.9)	(14.8, 45.5)
p-value[a, b]			<0.001
Unstratified odds ratio[c]			6.3
(95% CI)			(2.2, 18.4)
p-value			<0.001
Stratified odds ratio[b, c]			6.1
(95% CI)			(2.1, 17.5)
p-value			<0.001
Unstratified risk ratio[c]			1.5
(95% CI)			(1.2, 1.9)
p-value			<0.001

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N = Number of subjects in MRD evaluable set. MRD = minimal residual disease. PCR = polymerase chain reaction. CI = Exact Binomial Confidence Interval.
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MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of MRD evaluable 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. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.
[a] Cochran-Mantel-Haenszel test adjusting for the stratification factors.
[b] 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).
[c] The odds ratio and risk ratio are obtained from a logistic regression model with logit link An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.
[d] The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-mrd-mes.sas
Output: t14-04-003-001-mrd-mes.rtf (Date generated: 28JAN2021:00:20) Source data: adampc.adsl, adampc.adrs

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Stratified risk ratio[b, c]			1.5
(95% CI)			(1.1, 1.9)
p-value			0.003
Absolute risk reduction			0.3
(95% CI)			(0.1, 0.5)
p-value			<0.001

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N = Number of subjects in MRD evaluable set. MRD = minimal residual disease. PCR = polymerase chain reaction. CI = Exact Binomial Confidence Interval.
MRD evaluable set includes subjects for which evaluable baseline MRD marker can be found with either of the MRD assessment methods of PCR or flow cytometry. Number of subjects assessed includes subjects in the MRD evaluable set who had a baseline MRD marker for the respective assessment methods.
MRD response is analyzed at end of treatment (Cycle 1 Day 29) of investigational product. Subjects who are part of MRD evaluable 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. Percentages are based on number of subjects assessed with respective methods PCR and flow cytometry.
[a] Cochran-Mantel-Haenszel test adjusting for the stratification factors.
[b] 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).
[c] The odds ratio and risk ratio are obtained from a logistic regression model with logit link An odds ratio or risk ratio < 1.0 indicates a lower event rate / risk for Blinatumomab relative to HC3.
[d] The relative Hessian convergence criterion is greater than the limit of 0.0001. The convergence is questionable.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-mrd-mes.sas Output: t14-04-003-001-mrd-mes.rtf (Date generated: 28JAN2021:00:20) Source data: adampc.adsl, adampc.adrs

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

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Cumulative incidence of relapse			
Subject status			
Number of subjects	54	54	
Events - n (%)	30 (55.6)	13 (24.1)	
Relapse	29 (53.7)	13 (24.1)	
Death due to disease progression	1 (1.9)	0 (0.0)	
Competing event - n (%)	1 (1.9)	4 (7.4)	
Death due to other cause	1 (1.9)	4 (7.4)	
Censored - n (%)	23 (42.6)	37 (68.5)	
Alive w/o relapse	23 (42.6)	37 (68.5)	
Unstratified Gray's test			
p-value			<0.001
Stratified Gray's test[c]			
p-value			<0.001

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CIF = Cumulative Incidence Function. CI = Confidence Interval. NE = not estimable. N = Number of subjects in the analysis set. n = Number of subjects with observed data
[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 are: age (1-9 years vs. other (<1 year or >9 years)), and marrow/MRD status (M1 with MRD level < 10^{-3} vs. M1 with MRD level ≥ 10^{-3} vs. M2).
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-cif-dth-fas.sas
Output: t14-04-005-001-cif-dth-fas.rtf (Date generated: 04JAN2021:03:13) Source data: adampc.adsl, adampc.adtteeff

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Time to event (CIF) (months)[a]			
Median	7.9	NE	
95% CI (median)	5.8, 23.1	NE, NE	
Q1, Q3	3.9, NE	24.4, NE	
Min, Max	0.3, 23.1	3.2, 24.8	
CIF estimate - %			
At time 3 months[a]	22.3	0.0	
(95% CI)	(11.8, 34.8)	(NE, NE)	
At time 6 months[a]	42.1	10.7	
(95% CI)	(27.7, 55.8)	(3.9, 21.5)	
At time 12 months[a]	59.5	24.9	
(95% CI)	(43.0, 72.6)	(13.2, 38.5)	
At time 18 months[a]	65.4	24.9	
(95% CI)	(48.2, 78.1)	(13.2, 38.5)	
At time 24 months[a]	70.8	24.9	
(95% CI)	(50.7, 83.9)	(13.2, 38.5)	
At time 36 months[a]	70.8	33.2	
(95% CI)	(50.7, 83.9)	(18.0, 49.1)	

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CIF = Cumulative Incidence Function. CI = Confidence Interval. NE = not estimable. N = Number of subjects in the analysis set. n = Number of subjects with observed data
[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 are: age (1-9 years vs. other (<1 year or >9 years)), and marrow/MRD status (M1 with MRD level < 10^{-3} vs. M1 with MRD level ≥ 10^{-3} vs. M2).
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-cif-dth-fas.sas
Output: t14-04-005-001-cif-dth-fas.rtf (Date generated: 04JAN2021:03:13) Source data: adampc.adsl, adampc.adtteeff

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Hazard ratio[b]			0.28
(95% CI)			(0.15, 0.53)
p-value			<0.001
Stratified hazard ratio[b, c]			0.24
(95% CI)			(0.13, 0.46)
p-value			<0.001

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

[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 are: age (1-9 years vs. other (<1 year or >9 years)), and marrow/MRD status (M1 with MRD level < 10^{-3} vs. M1 with MRD level ≥ 10^{-3} vs. M2).

Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-cif-dth-fas.sas
Output: t14-04-005-001-cif-dth-fas.rtf (Date generated: 04JAN2021:03:13) Source data: adampc.adsl, adampc.adtteeff

Table 14-4.4.3. Allogeneic HSCT - Time to Event Analysis (Full Analysis Set)

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	54	54	
Events - n (%)[a]	38 (70.4)	48 (88.9)	
HSCT	38 (70.4)	48 (88.9)	
Censored - n (%)	16 (29.6)	6 (11.1)	
Relapse	11 (20.4)	1 (1.9)	
Alive w/o HSCT/Relapse	5 (9.3)	5 (9.3)	
Unstratified log-rank test			
n	54	54	
Normal score[b]			0.57
p-value			0.90
Stratified log-rank test[c]			
n	54	54	
Normal score[b]			0.85
p-value			0.84

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allogeneic HSCT = allogeneic hematopoietic stem cell transplantation. N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are transplant prior to relapse.
[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 randomization 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-allohsct-tte-fas.sas
Output: t14-04-004-003-allohsct-tte-fas.rtf (Date generated: 04JAN2021:03:57) Source data: adampc.adsl, adampc.adtteeff

	HC3 (N=54)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	1.7	1.9	
95% CI (median)	(1.6, 2.0)	(1.8, 1.9)	
Q1, Q3	1.5, 2.3	1.7, 2.0	
Min, Max	1.2, 3.2	1.2, 2.8	
Unstratified hazard ratio[e]			1.04
(95% CI)			(0.67, 1.60)
p-value			0.87
Stratified hazard ratio[c,e]			1.05
(95% CI)			(0.67, 1.65)
p-value			0.82

allogeneic HSCT = allogeneic hematopoietic stem cell transplantation. N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are transplant prior to relapse.
[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 randomization 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-allohsct-tte-fas.sas
Output: t14-04-004-003-allohsct-tte-fas.rtf (Date generated: 04JAN2021:03:57) Source data: adampc.adsl, adampc.adtteeff

Table 14-4.4.2. Survival Status Following Allogeneic HSCT (HSCT Analysis Set)

	HC3 (N=38)	Blinatumomab (N=48)	Treatment Difference
Mortality following alloHSCT			
KM estimate - %			
At time 100 days[a]	5.6	4.2	
(95% CI)	(1.4, 20.5)	(1.1, 15.6)	
Subject status			
Number of subjects with alloHSCT	38	48	
Events - n (%)	12 (31.6)	7 (14.6)	
Death from any cause	12 (31.6)	7 (14.6)	
Censored - n (%)	26 (68.4)	41 (85.4)	
Alive	26 (68.4)	41 (85.4)	
Unstratified log-rank test			
n	38	48	
Normal score[d]			-4.49
p-value			0.035

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alloHSCT = allogeneic hematopoietic stem cell transplantation. KM = Kaplan-Meier. CI = Confidence Interval. N = Number of subjects in the analysis set. n = Number of subjects with observed data. 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 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] 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-tte-hsct-has.sas Output: t14-04-004-002-tte-hsct-has.rtf (Date generated: 11DEC2020:04:26) Source data: adampc.adtteeff, adampc.adsl

	HC3 (N=38)	Blinatumomab (N=48)	Treatment Difference
Stratified log-rank test[c]			
n	38	48	
Normal score[d]			-4.75
p-value			0.019
Time to event (KM) (days)[a]			
Median	NE	NE	
95% CI (median)	(341.0, NE)	(NE, NE)	
Q1, Q3	275.0, NE	NE, NE	
Min, Max	22, 524	63, 355	
Time to censoring (days)[a,b]			
Median	541.0	652.0	
95% CI (median)	(271.0, 642.0)	(465.0, 820.0)	
Q1, Q3	183.0, 832.0	281.0, 973.0	
Min, Max	1, 1195	91, 1304	

alloHSCT = allogeneic hematopoietic stem cell transplantation. KM = Kaplan-Meier. CI = Confidence Interval. N = Number of subjects in the analysis set. n = Number of subjects with observed data. 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 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 $\geq 10^{-3}$ 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.

Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-tte-hsct-has.sas Output: t14-04-004-002-tte-hsct-has.rtf (Date generated: 11DEC2020:04:26) Source data: adampc.adtteeff, adampc.adsl

	HC3 (N=38)	Blinatumomab (N=48)	Treatment Difference
Unstratified hazard ratio[e]			0.38
(95% CI)			(0.15, 0.97)
p-value			0.042
Stratified hazard ratio[c,e]			0.31
(95% CI)			(0.11, 0.88)
p-value			0.027

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alloHSCT = allogeneic hematopoietic stem cell transplantation. KM = Kaplan-Meier. CI = Confidence Interval. N = Number of subjects in the analysis set. n = Number of subjects with observed data. 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 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] 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-tte-hsct-has.sas Output: t14-04-004-002-tte-hsct-has.rtf (Date generated: 11DEC2020:04:26) Source data: adampc.adtteeff, adampc.adsl

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

	HC3 (N = 51)	Blinatumomab (N = 54)	Total (N = 105)
Duration of exposure (days)			
n	51	53	104
Mean	8.2	26.5	17.5
SD	4.1	6.0	10.6
Median	6.0	28.0	16.5
Q1, Q3	6.0, 7.0	27.8, 28.0	6.0, 28.0
Min, Max	3, 17	1, 29	1, 29
Subjects completing treatment cycle – n (%)		50 (92.6)	
Subjects discontinuing treatment cycle - n (%)		4 (7.4)	
Subjects re-starting treatment cycle – n (%)		0 (0.0)	
Relative treatment duration[a] (%)			
n		53	
Mean		94.8	
SD		21.4	
Median		99.9	
Q1, Q3		99.4, 100.0	
Min, Max		2, 105	
Cumulative dose (µg/m^2)			
n		53	
Mean		378.2	
SD		110.1	
Median		419.1	
Q1, Q3		415.1, 420.0	
Min, Max		8, 441	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
For subject 21526002001, exposure could not be calculated since dosing was ongoing by the data cut-off date. For subject 21525006003, partial exposure is evaluated until latest dosing before the data cut-off date.
[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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ex-sum-saf.sas Output: t14-05-001-ex-sum-saf.rtf (Date generated: 23DEC2020:02:29) Source data: adampc.adsl, adampc.adexcyc, adampc.adex

	HC3 (N = 51)	Blinatumomab (N = 54)	Total (N = 105)
Percent of intended dose[b]			
n		53	
Mean		90.0	
SD		26.2	
Median		99.8	
Q1, Q3		98.8, 100.0	
Min, Max		2, 105	

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N = Number of subjects in the analysis set. n = Number of subjects with observed data.
For subject 21526002001, exposure could not be calculated since dosing was ongoing by the data cut-off date. For subject 21525006003, partial exposure is evaluated until latest dosing before the data cut-off date.
[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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ex-sum-saf.sas Output: t14-05-001-ex-sum-saf.rtf (Date generated: 23DEC2020:02:29) Source data: adampc.adsl, adampc.adexcyc, adampc.adex

Table 14-6.14. Summary of per Subject Treatment Emergent Adverse Event Period (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Total (N=105)
Duration of observation of Treatment Emergent Adverse Event (months)[a]			
n	51	54	105
Mean	1.24	1.83	1.54
SD	0.17	0.38	0.42
Median	1.18	1.93	1.51
Min, Max	0.5, 1.5	0.2, 2.2	0.2, 2.2

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[a] Months are calculated as days from start of treatment to end of treatment + 30 days or last observation on study whichever occurs first, divided by 30.5.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-sum-dur-obs-saf.sas
Output: t14-06-014-ae-sum-dur-obs-saf.rtf (Date generated: 24JAN2021:22:19) Source data: adampc.adsl

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

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	49 (96.1)	54 (100.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			12.06
p-value			0.002
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			12.16
p-value			0.002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-001-ae-tte-ont-teae-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			1.97
(95% CI)			(1.32, 2.94)
p-value			<0.001
Stratified hazard ratio[c,e]			1.97
(95% CI)			(1.31, 2.96)
p-value			0.001

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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-001-ae-tte-ont-teae-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

Table 14-6.11.2. Time to First Onset of Grade 3 and Above Treatment Emergent Adverse Event (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	42 (82.4)	31 (57.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-14.80
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-13.92
p-value			<0.001

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-002-ae-tte-ont-teae-grade3-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	1.70	
95% CI (median)	(0.16, 0.33)	(1.31, NE)	
Q1, Q3	0.13, 0.43	0.46, NE	
Min, Max	0.0, 0.5	0.0, 1.9	
Unstratified hazard ratio[e]			0.40
(95% CI)			(0.25, 0.65)
p-value			<0.001
Stratified hazard ratio[c,e]			0.41
(95% CI)			(0.25, 0.67)
p-value			<0.001

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-002-ae-tte-ont-teae-grade3-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

Table 14-6.11.3. Time to First Onset of Serious Treatment Emergent Adverse Event (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	22 (43.1)	13 (24.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-5.83
p-value			0.045
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-6.03
p-value			0.035

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-003-sae-tte-ont-teae-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(0.49, NE)	(NE, NE)	
Q1, Q3	0.36, NE	1.84, NE	
Min, Max	0.1, 1.2	0.1, 1.8	
Unstratified hazard ratio[e]			0.50
(95% CI)			(0.25, 1.00)
p-value			0.051
Stratified hazard ratio[c,e]			0.49
(95% CI)			(0.24, 0.98)
p-value			0.044

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-003-sae-tte-ont-teae-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

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

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.97
p-value			0.17
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.95
p-value			0.17

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N = Number of subjects in the analysis set. n = Number 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 any study treatment discontinuation.
[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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-004-ae-tte-ont-teae-trtdisc-saf.rtf (Date generated: 18JAN2021:22:21) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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

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N = Number of subjects in the analysis set. n = Number 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 any study treatment discontinuation.
[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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-004-ae-tte-ont-teae-trtdisc-saf.rtf (Date generated: 18JAN2021:22:21) Source data: adampc.adsl, adam.adtteae

Table 14-6.11.5. Time to First Onset of Fatal Treatment Emergent Adverse Event (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.00
p-value			NE
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.00
p-value			NE

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 fatal 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-005-ae-tte-ont-teae-fatal-saf.rtf (Date generated: 13JAN2021:03:01) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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			
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 fatal 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-011-005-ae-tte-ont-teae-fatal-saf.rtf (Date generated: 13JAN2021:03:01) Source data: adampc.adsl, adam.adtteae

Table 14-6.13.1. Time to First Onset of Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	49 (96.1)	54 (100.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			12.06
p-value			0.002
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			12.16
p-value			0.002

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N = Number of subjects in the analysis set. n = Number 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-013-001-ae-tte-ont-teae-edp-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			1.97
(95% CI)			(1.32, 2.94)
p-value			<0.001
Stratified hazard ratio[c,e]			1.97
(95% CI)			(1.31, 2.96)
p-value			0.001

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N = Number of subjects in the analysis set. n = Number 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-013-001-ae-tte-ont-teae-edp-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

Table 14-6.13.2. Time to First Onset of Grade 3 and Above Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	42 (82.4)	31 (57.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-14.80
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-13.92
p-value			<0.001

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-013-002-ae-tte-ont-teae-grade3-edp-saf.rtf (Date generated: 05JAN2021:04:28)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.26	1.70	
95% CI (median)	(0.16, 0.33)	(1.31, NE)	
Q1, Q3	0.13, 0.43	0.46, NE	
Min, Max	0.0, 0.5	0.0, 1.9	
Unstratified hazard ratio[e]			0.40
(95% CI)			(0.25, 0.65)
p-value			<0.001
Stratified hazard ratio[c,e]			0.41
(95% CI)			(0.25, 0.67)
p-value			<0.001

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-013-002-ae-tte-ont-teae-grade3-edp-saf.rtf (Date generated: 05JAN2021:04:28)
Source data: adampc.adsl, adam.adtteae

Table 14-6.13.3. Time to First Onset of Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	21 (41.2)	13 (24.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-5.23
p-value			0.068
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-5.43
p-value			0.054

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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-013-003-sae-tte-ont-teae-edp-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(0.49, NE)	(NE, NE)	
Q1, Q3	0.36, NE	1.84, NE	
Min, Max	0.1, 1.2	0.1, 1.8	
Unstratified hazard ratio[e]			0.53
(95% CI)			(0.27, 1.07)
p-value			0.075
Stratified hazard ratio[c,e]			0.52
(95% CI)			(0.26, 1.04)
p-value			0.066

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N = Number of subjects in the 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 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.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-saf.sas
Output: t14-06-013-003-sae-tte-ont-teae-edp-saf.rtf (Date generated: 05JAN2021:04:28) Source data: adampc.adsl, adam.adtteae

Table 14-6.12.11. Time to First Onset of Treatment Emergent Adverse Event of Interest (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Capillary leak syndrome (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.54
p-value			0.27
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.50
p-value			0.32

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			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.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Cytokine release syndrome (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.49
p-value			0.57
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.59
p-value			0.49

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			1.96
(95% CI)			(0.18, 21.68)
p-value			0.58
Stratified hazard ratio[c,e]			2.27
(95% CI)			(0.21, 25.15)
p-value			0.50

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Decreased immunoglobulins (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	6 (11.8)	9 (16.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.20
p-value			0.53
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.15
p-value			0.55

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			1.39
(95% CI)			(0.49, 3.90)
p-value			0.53
Stratified hazard ratio[c,e]			1.37
(95% CI)			(0.49, 3.86)
p-value			0.55

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Elevated liver enzymes (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	15 (29.4)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-4.91
p-value			0.034
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-4.89
p-value			0.033

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.52, NE	NE, NE	
Min, Max	0.0, 0.8	0.0, 1.9	
Unstratified hazard ratio[e]			0.39
(95% CI)			(0.16, 0.97)
p-value			0.042
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.16, 0.96)
p-value			0.040

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Embolic and thrombotic events (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.99
p-value			0.046
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			2.07
p-value			0.037

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			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.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
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Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Infections			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	16 (31.4)	23 (42.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.16
p-value			0.71
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.18
p-value			0.95

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.77, NE)	
Q1, Q3	0.69, NE	1.41, NE	
Min, Max	0.0, 1.2	0.5, 1.9	
Unstratified hazard ratio[e]			1.13
(95% CI)			(0.60, 2.14)
p-value			0.71
Stratified hazard ratio[c,e]			1.02
(95% CI)			(0.54, 1.94)
p-value			0.95

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Infusion reaction without considering duration (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	4 (7.8)	37 (68.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			18.14
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			18.33
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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, NE	
Min, Max	0.0, 0.1	0.0, 0.1	
Unstratified hazard ratio[e]			14.26
(95% CI)			(5.06, 40.18)
p-value			<0.001
Stratified hazard ratio[c,e]			18.37
(95% CI)			(5.62, 60.00)
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Medication errors (Broad)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.49
p-value			0.33
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.48
p-value			0.34

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			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.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	15 (29.4)	26 (48.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			6.34
p-value			0.043
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			6.44
p-value			0.037

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(0.20, NE)	
Q1, Q3	0.69, NE	0.10, NE	
Min, Max	0.0, 1.5	0.0, 1.7	
Unstratified hazard ratio[e]			1.92
(95% CI)			(1.02, 3.63)
p-value			0.044
Stratified hazard ratio[c,e]			1.98
(95% CI)			(1.04, 3.78)
p-value			0.038

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neutropenia (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	28 (54.9)	12 (22.2)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-9.88
p-value			0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-9.38
p-value			0.002

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.49	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]			0.34
(95% CI)			(0.17, 0.68)
p-value			0.002
Stratified hazard ratio[c,e]			0.36
(95% CI)			(0.18, 0.71)
p-value			0.003

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Pancreatitis (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.51
p-value			0.30
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.51
p-value			0.31

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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	0.6, 0.6		
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.
[a] Events are first onset of treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-011-ae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

Table 14-6.12.12. Time to First Onset of Grade 3 and Above Treatment Emergent Adverse Event of Interest (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Capillary leak syndrome (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.54
p-value			0.27
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.50
p-value			0.32

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Decreased immunoglobulins (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.12
p-value			0.86
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.06
p-value			0.94

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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, 12.72)
p-value			0.86
Stratified hazard ratio[c,e]			0.89
(95% CI)			(0.06, 14.36)
p-value			0.94

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Elevated liver enzymes (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	9 (17.6)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-3.32
p-value			0.055
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-3.14
p-value			0.068

N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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			0.070
Stratified hazard ratio[c,e]			0.31
(95% CI)			(0.08, 1.17)
p-value			0.084

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Embolic and thrombotic events (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.00
p-value			0.16
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.10
p-value			0.12

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Infections			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	5 (9.8)	10 (18.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.83
p-value			0.34
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.53
p-value			0.42

N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			1.69
(95% CI)			(0.57, 4.99)
p-value			0.34
Stratified hazard ratio[c,e]			1.56
(95% CI)			(0.53, 4.61)
p-value			0.42

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Infusion reaction without considering duration (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.98
p-value			0.17
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.07
p-value			0.13

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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, 0.1	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.84
p-value			0.40
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.88
p-value			0.36

N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			2.59
(95% CI)			(0.27, 25.09)
p-value			0.41
Stratified hazard ratio[c,e]			2.79
(95% CI)			(0.29, 27.36)
p-value			0.38

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neutropenia (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	27 (52.9)	11 (20.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-9.81
p-value			0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-9.47
p-value			0.002

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.49	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]			0.32
(95% CI)			(0.16, 0.66)
p-value			0.002
Stratified hazard ratio[c,e]			0.34
(95% CI)			(0.17, 0.68)
p-value			0.002

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Pancreatitis (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.51
p-value			0.30
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.51
p-value			0.31

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N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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	0.6, 0.6		
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

N = Number of subjects in the 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 of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-012-ae-tte-ont-teae-by-eoi-grade3-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

Table 14-6.12.13. Time to First Onset of Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Capillary leak syndrome (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.54
p-value			0.27
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.50
p-value			0.32

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Decreased immunoglobulins (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.40
p-value			0.41
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.44
p-value			0.37

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Elevated liver enzymes (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.51
p-value			0.30
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.52
p-value			0.30

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Infections			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	4 (7.8)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.83
p-value			0.53
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.85
p-value			0.51

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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	0.6, 1.8	
Unstratified hazard ratio[e]			0.62
(95% CI)			(0.14, 2.78)
p-value			0.53
Stratified hazard ratio[c,e]			0.61
(95% CI)			(0.13, 2.75)
p-value			0.52

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Infusion reaction without considering duration (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.49
p-value			0.33
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.50
p-value			0.32

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Medication errors (Broad)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.49
p-value			0.33
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.48
p-value			0.34

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.96
p-value			0.11
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.83
p-value			0.12

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 serious treatment emergent adverse event of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			4.96
(95% CI)			(0.58, 42.42)
p-value			0.14
Stratified hazard ratio[c,e]			4.82
(95% CI)			(0.56, 41.74)
p-value			0.15

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neutropenia (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	12 (23.5)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-6.45
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-6.31
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Pancreatitis (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	1 (2.0)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.51
p-value			0.30
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.51
p-value			0.31

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of serious treatment emergent adverse event of interest .
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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	0.6, 0.6		
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 serious treatment emergent adverse event of interest .
[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.
Events of Interest with 0 events are not displayed.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-013-sae-tte-ont-teae-by-eoi-saf.rtf (Date generated: 07MAR2021:22:15)
Source data: adampc.adsl, adam.adtteae

Table 14-6.12.14. Time to First Onset of Treatment Emergent Adverse Event of Interest Leading to Any Study Treatment Discontinuation (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Neurologic events (Narrow)			
Subject status			
Number of subjects	51	54	
Events - n (%)[a]	0 (0.0)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.97
p-value			0.17
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.95
p-value			0.17

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest leading to any study treatment discontinuation.
[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.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-014-ae-tte-ont-teae-by-eoi-trtdisc-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

	HC3 (N=51)	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

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event of interest leading to any study treatment discontinuation.
[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.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-014-ae-tte-ont-teae-by-eoi-trtdisc-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

Table 14-6.12.15. Time to First Onset of Fatal Treatment Emergent Adverse Event of Interest (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
--- No event observed. ---			

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N = Number of subjects in the analysis set.
Events are first onset of fatal treatment emergent advese event of interest.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-teae-eoi-saf.sas
Output: t14-06-012-015-ae-tte-ont-teae-by-eoi-fatal-saf.rtf (Date generated: 07MAR2021:22:15) Source data: adampc.adsl, adam.adtteae

Table 14-6.15.1. Time to First Onset of Treatment-Emergent Adverse Events (at least 10 % in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Number of subjects reporting treatment emergent adverse events	49 (96.1)	54 (100.0)	
SOC: General disorders and administration site conditions			
Events - n (%)[a]	18 (35.3)	48 (88.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			22.35
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			23.41
p-value			<0.001

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	0.43, NE	0.03, 1.28	
Min, Max	0.1, 1.5	0.0, 1.9	
Unstratified hazard ratio[e]			5.01
(95% CI)			(2.90, 8.67)
p-value			<0.001
Stratified hazard ratio[c,e]			6.68
(95% CI)			(3.62, 12.33)
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Pyrexia			
Events - n (%)[a]	10 (19.6)	44 (81.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			21.65
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			22.65
p-value			<0.001

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			7.56
(95% CI)			(3.78, 15.11)
p-value			<0.001
Stratified hazard ratio[c,e]			11.21
(95% CI)			(4.98, 25.25)
p-value			<0.001

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Mucosal inflammation			
Events - n (%)[a]	4 (7.8)	9 (16.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.60
p-value			0.37
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.42
p-value			0.42

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.72
(95% CI)			(0.53, 5.60)
p-value			0.37
Stratified hazard ratio[c,e]			1.62
(95% CI)			(0.50, 5.31)
p-value			0.42

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Gastrointestinal disorders			
Events - n (%)[a]	38 (74.5)	37 (68.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-8.80
p-value			0.030
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-8.98
p-value			0.021

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.23	1.57	
95% CI (median)	(0.16, 0.30)	(1.02, 1.70)	
Q1, Q3	0.10, 1.18	0.33, 2.00	
Min, Max	0.0, 1.2	0.0, 2.0	
Unstratified hazard ratio[e]			0.60
(95% CI)			(0.38, 0.95)
p-value			0.030
Stratified hazard ratio[c,e]			0.58
(95% CI)			(0.36, 0.93)
p-value			0.025

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Nausea			
Events - n (%)[a]	9 (17.6)	22 (40.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			5.77
p-value			0.035
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			5.50
p-value			0.042

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	1.64, NE	
Min, Max	0.0, 1.0	0.0, 2.0	
Unstratified hazard ratio[e]			2.27
(95% CI)			(1.04, 4.95)
p-value			0.040
Stratified hazard ratio[c,e]			2.19
(95% CI)			(1.00, 4.78)
p-value			0.049

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Vomiting			
Events - n (%)[a]	11 (21.6)	16 (29.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.67
p-value			0.51
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.76
p-value			0.49

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.93, NE)	
Q1, Q3	1.48, NE	1.57, NE	
Min, Max	0.0, 1.5	0.0, 2.0	
Unstratified hazard ratio[e]			1.29
(95% CI)			(0.60, 2.80)
p-value			0.52
Stratified hazard ratio[c,e]			1.30
(95% CI)			(0.60, 2.82)
p-value			0.51

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Diarrhoea			
Events - n (%)[a]	9 (17.6)	11 (20.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.02
p-value			0.99
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.01
p-value			1.00

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			0.99
(95% CI)			(0.41, 2.40)
p-value			0.99
Stratified hazard ratio[c,e]			1.00
(95% CI)			(0.41, 2.44)
p-value			1.00

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Stomatitis			
Events - n (%)[a]	28 (54.9)	10 (18.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-13.74
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-13.84
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.43	NE	
95% CI (median)	(0.26, NE)	(NE, NE)	
Q1, Q3	0.20, NE	2.00, NE	
Min, Max	0.0, 1.1	0.3, 2.0	
Unstratified hazard ratio[e]			0.20
(95% CI)			(0.10, 0.41)
p-value			<0.001
Stratified hazard ratio[c,e]			0.18
(95% CI)			(0.09, 0.39)
p-value			<0.001

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Abdominal pain			
Events - n (%)[a]	11 (21.6)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-2.84
p-value			0.18
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-2.63
p-value			0.21

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
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	HC3 (N=51)	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]			0.52
(95% CI)			(0.20, 1.35)
p-value			0.18
Stratified hazard ratio[c,e]			0.55
(95% CI)			(0.21, 1.42)
p-value			0.21

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Constipation			
Events - n (%)[a]	7 (13.7)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.45
p-value			0.40
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.66
p-value			0.33

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
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	HC3 (N=51)	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]			0.61
(95% CI)			(0.19, 1.93)
p-value			0.40
Stratified hazard ratio[c,e]			0.57
(95% CI)			(0.18, 1.80)
p-value			0.34

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Infections and infestations			
Events - n (%)[a]	16 (31.4)	23 (42.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.16
p-value			0.71
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.18
p-value			0.95

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.77, NE)	
Q1, Q3	0.69, NE	1.41, NE	
Min, Max	0.0, 1.2	0.5, 1.9	
Unstratified hazard ratio[e]			1.13
(95% CI)			(0.60, 2.14)
p-value			0.71
Stratified hazard ratio[c,e]			1.02
(95% CI)			(0.54, 1.94)
p-value			0.95

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Nervous system disorders			
Events - n (%)[a]	12 (23.5)	23 (42.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			6.04
p-value			0.038
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			6.27
p-value			0.026

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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Data cut-off date: 17JUL2019

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	HC3 (N=51)	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]			2.08
(95% CI)			(1.03, 4.18)
p-value			0.040
Stratified hazard ratio[c,e]			2.21
(95% CI)			(1.09, 4.49)
p-value			0.029

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Headache			
Events - n (%)[a]	9 (17.6)	19 (35.2)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			4.78
p-value			0.067
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			4.97
p-value			0.054

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.67, NE)	
Q1, Q3	NE, NE	0.52, NE	
Min, Max	0.0, 1.5	0.0, 1.7	
Unstratified hazard ratio[e]			2.08
(95% CI)			(0.94, 4.60)
p-value			0.071
Stratified hazard ratio[c,e]			2.15
(95% CI)			(0.97, 4.77)
p-value			0.061

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Skin and subcutaneous tissue disorders			
Events - n (%)[a]	13 (25.5)	23 (42.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			3.92
p-value			0.19
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			3.36
p-value			0.25

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.61, NE)	
Q1, Q3	1.18, NE	1.31, NE	
Min, Max	0.0, 1.2	0.1, 1.9	
Unstratified hazard ratio[e]			1.57
(95% CI)			(0.80, 3.11)
p-value			0.19
Stratified hazard ratio[c,e]			1.50
(95% CI)			(0.75, 2.99)
p-value			0.25

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Rash			
Events - n (%)[a]	4 (7.8)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.00
p-value			0.54
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.14
p-value			0.49

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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	HC3 (N=51)	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]			1.46
(95% CI)			(0.43, 5.02)
p-value			0.54
Stratified hazard ratio[c,e]			1.54
(95% CI)			(0.45, 5.32)
p-value			0.49

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Erythema			
Events - n (%)[a]	2 (3.9)	6 (11.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.49
p-value			0.28
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.47
p-value			0.29

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			2.36
(95% CI)			(0.47, 11.76)
p-value			0.29
Stratified hazard ratio[c,e]			2.32
(95% CI)			(0.46, 11.64)
p-value			0.31

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Pruritus			
Events - n (%)[a]	5 (9.8)	6 (11.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.13
p-value			0.94
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.28
p-value			0.86

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 3.14)
p-value			0.94
Stratified hazard ratio[c,e]			0.90
(95% CI)			(0.27, 2.99)
p-value			0.86

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Investigations			
Events - n (%)[a]	22 (43.1)	21 (38.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.74
p-value			0.59
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.54
p-value			0.62

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(0.39, 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]			0.85
(95% CI)			(0.47, 1.56)
p-value			0.61
Stratified hazard ratio[c,e]			0.87
(95% CI)			(0.47, 1.60)
p-value			0.65

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Platelet count decreased			
Events - n (%)[a]	8 (15.7)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.51
p-value			0.43
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.27
p-value			0.50

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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			0.43
Stratified hazard ratio[c,e]			0.71
(95% CI)			(0.26, 1.97)
p-value			0.51

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Alanine aminotransferase increased			
Events - n (%)[a]	7 (13.7)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.70
p-value			0.30
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.43
p-value			0.39

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			0.53
(95% CI)			(0.16, 1.82)
p-value			0.32
Stratified hazard ratio[c,e]			0.59
(95% CI)			(0.17, 2.02)
p-value			0.40

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Events - n (%)[a]	38 (74.5)	19 (35.2)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-15.31
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-14.60
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	0.33	NE	
95% CI (median)	(0.26, 0.39)	(1.67, NE)	
Q1, Q3	0.26, NE	1.48, NE	
Min, Max	0.0, 0.5	0.0, 1.7	
Unstratified hazard ratio[e]			0.30
(95% CI)			(0.17, 0.52)
p-value			<0.001
Stratified hazard ratio[c,e]			0.31
(95% CI)			(0.17, 0.55)
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Anaemia			
Events - n (%)[a]	23 (45.1)	12 (22.2)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-7.72
p-value			0.007
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-7.86
p-value			0.005

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(0.39, NE)	(NE, NE)	
Q1, Q3	0.30, NE	NE, NE	
Min, Max	0.0, 1.0	0.0, 1.7	
Unstratified hazard ratio[e]			0.39
(95% CI)			(0.19, 0.80)
p-value			0.010
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.18, 0.77)
p-value			0.007

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Neutropenia			
Events - n (%)[a]	16 (31.4)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-6.30
p-value			0.005
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-6.23
p-value			0.006

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	NE, NE	
Min, Max	0.2, 1.4	0.1, 1.6	
Unstratified hazard ratio[e]			0.26
(95% CI)			(0.10, 0.72)
p-value			0.009
Stratified hazard ratio[c,e]			0.26
(95% CI)			(0.10, 0.72)
p-value			0.010

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Thrombocytopenia			
Events - n (%)[a]	13 (25.5)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-5.57
p-value			0.006
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-5.75
p-value			0.003

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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			0.011
Stratified hazard ratio[c,e]			0.18
(95% CI)			(0.05, 0.62)
p-value			0.007

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Febrile neutropenia			
Events - n (%)[a]	13 (25.5)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-6.01
p-value			0.002
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-5.67
p-value			0.004

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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			0.007
Stratified hazard ratio[c,e]			0.19
(95% CI)			(0.05, 0.67)
p-value			0.010

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Metabolism and nutrition disorders			
Events - n (%)[a]	13 (25.5)	19 (35.2)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			2.90
p-value			0.30
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			3.49
p-value			0.21

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.46
(95% CI)			(0.72, 2.96)
p-value			0.30
Stratified hazard ratio[c,e]			1.58
(95% CI)			(0.77, 3.23)
p-value			0.21

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Hypokalaemia			
Events - n (%)[a]	5 (9.8)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.78
p-value			0.65
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.83
p-value			0.63

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.30
(95% CI)			(0.41, 4.11)
p-value			0.65
Stratified hazard ratio[c,e]			1.33
(95% CI)			(0.42, 4.26)
p-value			0.63

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Vascular disorders			
Events - n (%)[a]	11 (21.6)	16 (29.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.30
p-value			0.61
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.55
p-value			0.54

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(1.93, NE)	
Q1, Q3	NE, NE	1.64, NE	
Min, Max	0.0, 1.2	0.0, 1.9	
Unstratified hazard ratio[e]			1.23
(95% CI)			(0.57, 2.67)
p-value			0.60
Stratified hazard ratio[c,e]			1.27
(95% CI)			(0.58, 2.78)
p-value			0.54

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Hypertension			
Events - n (%)[a]	4 (7.8)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.95
p-value			0.56
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.99
p-value			0.54

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 4.99)
p-value			0.56
Stratified hazard ratio[c,e]			1.46
(95% CI)			(0.42, 5.05)
p-value			0.55

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Hypotension			
Events - n (%)[a]	4 (7.8)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.03
p-value			0.53
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.99
p-value			0.54

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.48
(95% CI)			(0.43, 5.10)
p-value			0.53
Stratified hazard ratio[c,e]			1.45
(95% CI)			(0.42, 5.04)
p-value			0.56

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Immune system disorders			
Events - n (%)[a]	3 (5.9)	14 (25.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			5.49
p-value			0.008
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			5.17
p-value			0.012

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			4.70
(95% CI)			(1.35, 16.37)
p-value			0.015
Stratified hazard ratio[c,e]			4.38
(95% CI)			(1.25, 15.30)
p-value			0.021

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Hypogammaglobulinaemia			
Events - n (%)[a]	2 (3.9)	6 (11.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.93
p-value			0.17
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.78
p-value			0.21

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			2.91
(95% CI)			(0.59, 14.44)
p-value			0.19
Stratified hazard ratio[c,e]			2.71
(95% CI)			(0.54, 13.50)
p-value			0.22

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Events - n (%)[a]	10 (19.6)	13 (24.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.42
p-value			0.86
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.13
p-value			0.95

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	0.1, 2.2	
Unstratified hazard ratio[e]			1.07
(95% CI)			(0.47, 2.46)
p-value			0.86
Stratified hazard ratio[c,e]			1.02
(95% CI)			(0.44, 2.37)
p-value			0.95

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Epistaxis			
Events - n (%)[a]	7 (13.7)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.87
p-value			0.27
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.97
p-value			0.24

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.68)
p-value			0.28
Stratified hazard ratio[c,e]			0.50
(95% CI)			(0.16, 1.62)
p-value			0.25

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Psychiatric disorders			
Events - n (%)[a]	5 (9.8)	9 (16.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.79
p-value			0.34
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.76
p-value			0.34

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.70
(95% CI)			(0.57, 5.08)
p-value			0.34
Stratified hazard ratio[c,e]			1.69
(95% CI)			(0.56, 5.06)
p-value			0.35

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Injury, poisoning and procedural complications			
Events - n (%)[a]	6 (11.8)	8 (14.8)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.19
p-value			0.92
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.06
p-value			0.97

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
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	HC3 (N=51)	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]			1.06
(95% CI)			(0.37, 3.07)
p-value			0.92
Stratified hazard ratio[c,e]			1.02
(95% CI)			(0.35, 2.97)
p-value			0.97

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Musculoskeletal and connective tissue disorders			
Events - n (%)[a]	14 (27.5)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-4.69
p-value			0.038
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-4.65
p-value			0.039

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.69, NE	NE, NE	
Min, Max	0.0, 1.1	0.0, 1.7	
Unstratified hazard ratio[e]			0.39
(95% CI)			(0.16, 0.98)
p-value			0.045
Stratified hazard ratio[c,e]			0.39
(95% CI)			(0.16, 0.98)
p-value			0.046

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Hepatobiliary disorders			
Events - n (%)[a]	9 (17.6)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-2.39
p-value			0.20
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-2.28
p-value			0.22

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			0.49
(95% CI)			(0.16, 1.47)
p-value			0.20
Stratified hazard ratio[c,e]			0.51
(95% CI)			(0.17, 1.52)
p-value			0.23

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Renal and urinary disorders			
Events - n (%)[a]	7 (13.7)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.97
p-value			0.23
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-2.37
p-value			0.14

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.65)
p-value			0.24
Stratified hazard ratio[c,e]			0.40
(95% CI)			(0.11, 1.40)
p-value			0.15

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Eye disorders			
Events - n (%)[a]	9 (17.6)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-3.49
p-value			0.042
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-3.41
p-value			0.047

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.04)
p-value			0.057
Stratified hazard ratio[c,e]			0.29
(95% CI)			(0.08, 1.06)
p-value			0.062

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-ge10-soc-pref-saf.sas
Output: t14-06-015-001-ae-tte-ont-ge10-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

Table 14-6.15.2. Time to First Onset of Grade 3 and Above Treatment-Emergent Adverse Events (≥ 5% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Number of subjects reporting grade 3 or above treatment emergent adverse events	42 (82.4)	31 (57.4)	
SOC: Blood and lymphatic system disorders			
Events - n (%)[a]	37 (72.5)	15 (27.8)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-16.41
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-15.74
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	1.57, 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			<0.001
Stratified hazard ratio[c,e]			0.24
(95% CI)			(0.13, 0.45)
p-value			<0.001

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Anaemia			
Events - n (%)[a]	21 (41.2)	8 (14.8)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-8.89
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-8.93
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 0.9	0.1, 1.7	
Unstratified hazard ratio[e]			0.26
(95% CI)			(0.12, 0.60)
p-value			0.001
Stratified hazard ratio[c,e]			0.24
(95% CI)			(0.10, 0.57)
p-value			0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Neutropenia			
Events - n (%)[a]	14 (27.5)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-5.04
p-value			0.019
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-5.06
p-value			0.018

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	NE, NE	
Min, Max	0.2, 0.5	0.1, 1.6	
Unstratified hazard ratio[e]			0.31
(95% CI)			(0.11, 0.87)
p-value			0.026
Stratified hazard ratio[c,e]			0.31
(95% CI)			(0.11, 0.86)
p-value			0.025

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Thrombocytopenia			
Events - n (%)[a]	11 (21.6)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-4.39
p-value			0.021
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-4.36
p-value			0.022

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 0.88)
p-value			0.030
Stratified hazard ratio[c,e]			0.28
(95% CI)			(0.09, 0.89)
p-value			0.031

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Febrile neutropenia			
Events - n (%)[a]	13 (25.5)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-6.35
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-6.06
p-value			0.002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 0.53)
p-value			0.005
Stratified hazard ratio[c,e]			0.13
(95% CI)			(0.03, 0.58)
p-value			0.007

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Leukopenia			
Events - n (%)[a]	3 (5.9)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.55
p-value			0.073
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.58
p-value			0.068

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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		
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

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Investigations			
Events - n (%)[a]	15 (29.4)	12 (22.2)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-2.51
p-value			0.33
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-2.48
p-value			0.33

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[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer than expected events for Blinatumomab relative to 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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
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Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.39, 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			0.34
Stratified hazard ratio[c,e]			0.69
(95% CI)			(0.32, 1.48)
p-value			0.34

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Platelet count decreased			
Events - n (%)[a]	8 (15.7)	6 (11.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.86
p-value			0.31
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.68
p-value			0.36

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.68)
p-value			0.32
Stratified hazard ratio[c,e]			0.61
(95% CI)			(0.21, 1.77)
p-value			0.36

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
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Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Neutrophil count decreased			
Events - n (%)[a]	2 (3.9)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.95
p-value			0.43
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.84
p-value			0.49

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
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	HC3 (N=51)	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]			1.97
(95% CI)			(0.36, 10.75)
p-value			0.43
Stratified hazard ratio[c,e]			1.83
(95% CI)			(0.33, 10.11)
p-value			0.49

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
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Data cut-off date: 17JUL2019

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Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: White blood cell count decreased			
Events - n (%)[a]	1 (2.0)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.48
p-value			0.19
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.44
p-value			0.20

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
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	HC3 (N=51)	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]			3.93
(95% CI)			(0.44, 35.12)
p-value			0.22
Stratified hazard ratio[c,e]			3.82
(95% CI)			(0.43, 34.20)
p-value			0.23

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
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Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Alanine aminotransferase increased			
Events - n (%)[a]	5 (9.8)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-2.14
p-value			0.080
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-2.01
p-value			0.10

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.56)
p-value			0.12
Stratified hazard ratio[c,e]			0.20
(95% CI)			(0.02, 1.70)
p-value			0.14

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: General disorders and administration site conditions			
Events - n (%)[a]	1 (2.0)	10 (18.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			3.91
p-value			0.017
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			3.89
p-value			0.018

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			8.14
(95% CI)			(1.04, 63.71)
p-value			0.046
Stratified hazard ratio[c,e]			8.06
(95% CI)			(1.03, 63.08)
p-value			0.047

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Mucosal inflammation			
Events - n (%)[a]	0 (0.0)	7 (13.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			3.04
p-value			0.020
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			3.04
p-value			0.020

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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		1.3, 1.9	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Pyrexia			
Events - n (%)[a]	0 (0.0)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.32
p-value			0.12
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.36
p-value			0.11

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
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Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.6	
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

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Infections and infestations			
Events - n (%)[a]	5 (9.8)	10 (18.5)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.83
p-value			0.34
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.53
p-value			0.42

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.69
(95% CI)			(0.57, 4.99)
p-value			0.34
Stratified hazard ratio[c,e]			1.56
(95% CI)			(0.53, 4.61)
p-value			0.42

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Gastrointestinal disorders			
Events - n (%)[a]	17 (33.3)	6 (11.1)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-7.56
p-value			0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-7.37
p-value			0.002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
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	HC3 (N=51)	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]			0.23
(95% CI)			(0.09, 0.60)
p-value			0.003
Stratified hazard ratio[c,e]			0.24
(95% CI)			(0.09, 0.62)
p-value			0.003

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

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Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Stomatitis			
Events - n (%)[a]	16 (31.4)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-7.79
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-7.68
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
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	HC3 (N=51)	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, 0.47)
p-value			0.002
Stratified hazard ratio[c,e]			0.14
(95% CI)			(0.04, 0.48)
p-value			0.002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
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	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Vascular disorders			
Events - n (%)[a]	2 (3.9)	4 (7.4)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			0.83
p-value			0.49
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			0.89
p-value			0.45

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			1.80
(95% CI)			(0.33, 9.89)
p-value			0.50
Stratified hazard ratio[c,e]			1.92
(95% CI)			(0.34, 10.86)
p-value			0.46

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Nervous system disorders			
Events - n (%)[a]	0 (0.0)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.35
p-value			0.11
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.31
p-value			0.12

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 1.8	
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Congenital, familial and genetic disorders			
Events - n (%)[a]	4 (7.8)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.38
p-value			0.25
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.40
p-value			0.24

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 2.10)
p-value			0.27
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.07, 2.06)
p-value			0.26

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Aplasia			
Events - n (%)[a]	4 (7.8)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.38
p-value			0.25
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.40
p-value			0.24

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 2.10)
p-value			0.27
Stratified hazard ratio[c,e]			0.37
(95% CI)			(0.07, 2.06)
p-value			0.26

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Hepatobiliary disorders			
Events - n (%)[a]	6 (11.8)	2 (3.7)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-2.18
p-value			0.12
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-2.09
p-value			0.14

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	0.2, 1.9	
Unstratified hazard ratio[e]			0.30
(95% CI)			(0.06, 1.49)
p-value			0.14
Stratified hazard ratio[c,e]			0.31
(95% CI)			(0.06, 1.56)
p-value			0.16

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Hypertransaminasaemia			
Events - n (%)[a]	3 (5.9)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.56
p-value			0.072
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.57
p-value			0.070

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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		
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

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Respiratory, thoracic and mediastinal disorders			
Events - n (%)[a]	3 (5.9)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.17
p-value			0.24
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.01
p-value			0.31

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 2.70)
p-value			0.27
Stratified hazard ratio[c,e]			0.33
(95% CI)			(0.03, 3.17)
p-value			0.33

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
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Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Epistaxis			
Events - n (%)[a]	3 (5.9)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.55
p-value			0.074
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.45
p-value			0.092

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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		
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. SOC = System organ class. PT = Preferred term. NE = Not estimable. Severity graded using CTCAE version 4.03.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-ae-tte-ont-grade3-ge5-soc-pref-saf.sas
Output: t14-06-015-002-ae-tte-ont-grade3-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:25)
Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

Table 14-6.15.3. Time to First Onset of Serious Treatment-Emergent Adverse Events (≥ 5% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Number of subjects reporting serious treatment emergent adverse events	22 (43.1)	13 (24.1)	
SOC: Nervous system disorders			
Events - n (%)[a]	1 (2.0)	5 (9.3)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			1.96
p-value			0.11
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			1.83
p-value			0.12

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			4.96
(95% CI)			(0.58, 42.42)
p-value			0.14
Stratified hazard ratio[c,e]			4.82
(95% CI)			(0.56, 41.74)
p-value			0.15

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Infections and infestations			
Events - n (%)[a]	4 (7.8)	3 (5.6)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.83
p-value			0.53
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-0.85
p-value			0.51

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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	0.6, 1.8	
Unstratified hazard ratio[e]			0.62
(95% CI)			(0.14, 2.78)
p-value			0.53
Stratified hazard ratio[c,e]			0.61
(95% CI)			(0.13, 2.75)
p-value			0.52

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Gastrointestinal disorders			
Events - n (%)[a]	3 (5.9)	1 (1.9)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-0.95
p-value			0.34
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.11
p-value			0.27

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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, 3.35)
p-value			0.36
Stratified hazard ratio[c,e]			0.30
(95% CI)			(0.03, 2.87)
p-value			0.30

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
SOC: Blood and lymphatic system disorders			
Events - n (%)[a]	13 (25.5)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-7.01
p-value			<0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-6.89
p-value			<0.001

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
Time to event (KM) (months)[d]			
Median	NE	NE	
95% CI (median)	(NE, NE)	(NE, NE)	
Q1, Q3	0.49, NE	NE, NE	
Min, Max	0.3, 0.5		
Unstratified hazard ratio[e]			NE
(95% CI)			(NE, NE)
p-value			NE
Stratified hazard ratio[c,e]			NE
(95% CI)			(NE, NE)
p-value			NE

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Febrile neutropenia			
Events - n (%)[a]	9 (17.6)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-4.78
p-value			0.001
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-4.64
p-value			0.002

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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]			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. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	Blinatumomab (N=54)	Treatment Difference
PT: Neutropenia			
Events - n (%)[a]	3 (5.9)	0 (0.0)	
Unstratified log-rank test			
n	51	54	
Normal score[b]			-1.54
p-value			0.075
Stratified log-rank test[c]			
n	51	54	
Normal score[b]			-1.52
p-value			0.077

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N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

	HC3 (N=51)	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		
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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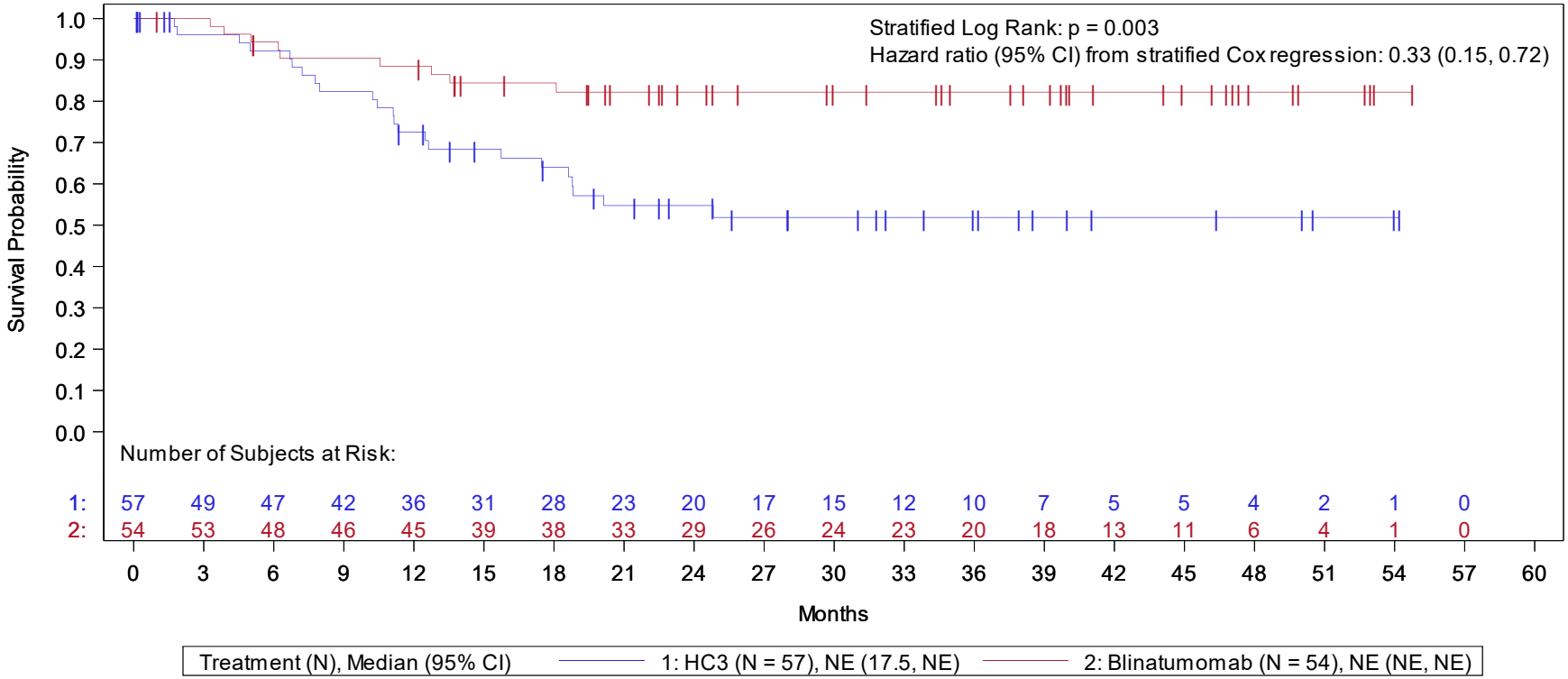
N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.
[a] Events are first onset of treatment emergent adverse event.
[b] A normal score < 0 indicates fewer 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.
The results are exploratory and can not be used for interpretation.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/tables/t-sae-tte-ont-ge5-soc-pref-saf.sas
Output: t14-06-015-003-sae-tte-ont-ge5-soc-pref-saf.rtf (Date generated: 18JAN2021:23:27) Source data: adampc.adsl, adampc.adae, adampc.adatpt, sdtmpc.sv

G.2: Ergänzende Kaplan-Meier-Kurven

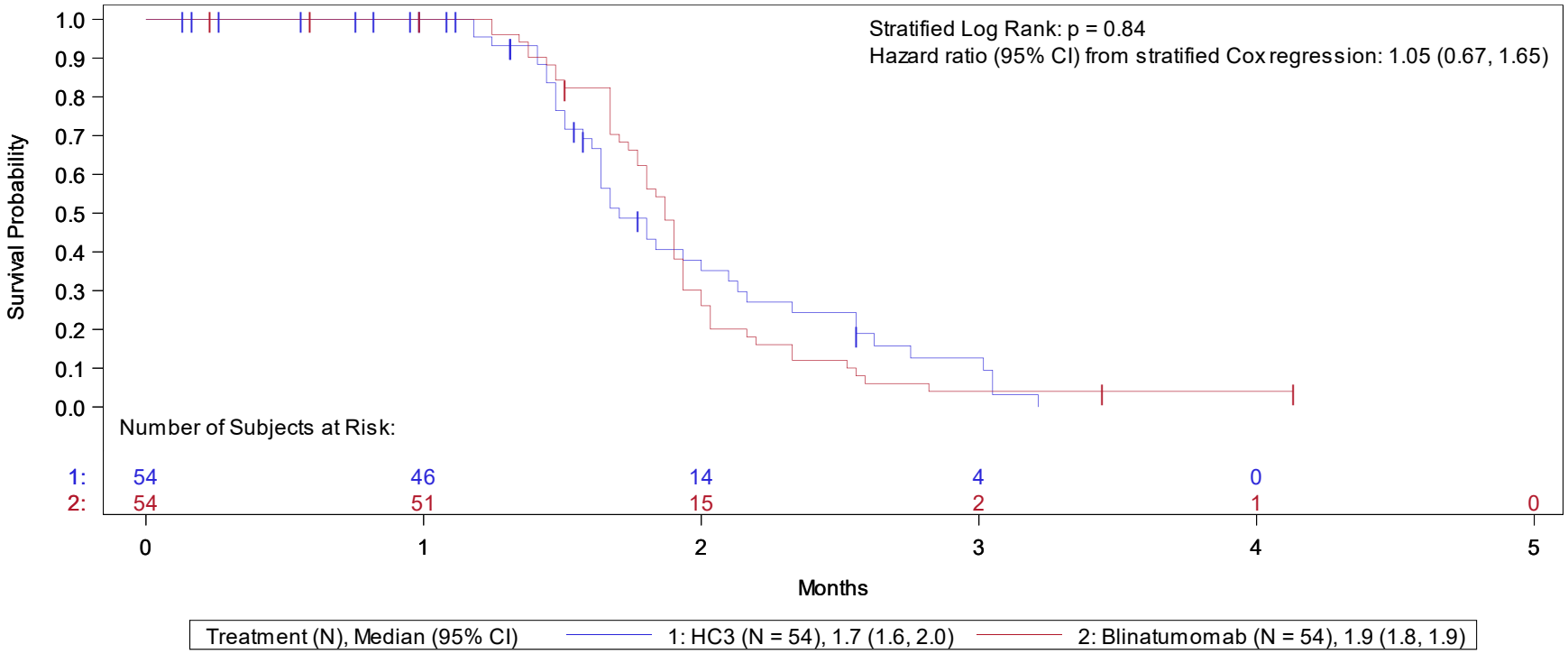
Figure 14-4.1.1. Kaplan-Meier for Overall Survival (Full Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Snapshot date: 14SEP2020

Program: /userdata/stat/amg103/onc/20120215/analysis/ema_202009/figures/program/f-km-os-fas.sas
Output: f14-04-001-001-km-os-fas.rtf (Date Generated: 17SEP2020:00:11) Source Data: adam.adsl, adam.adtteeff

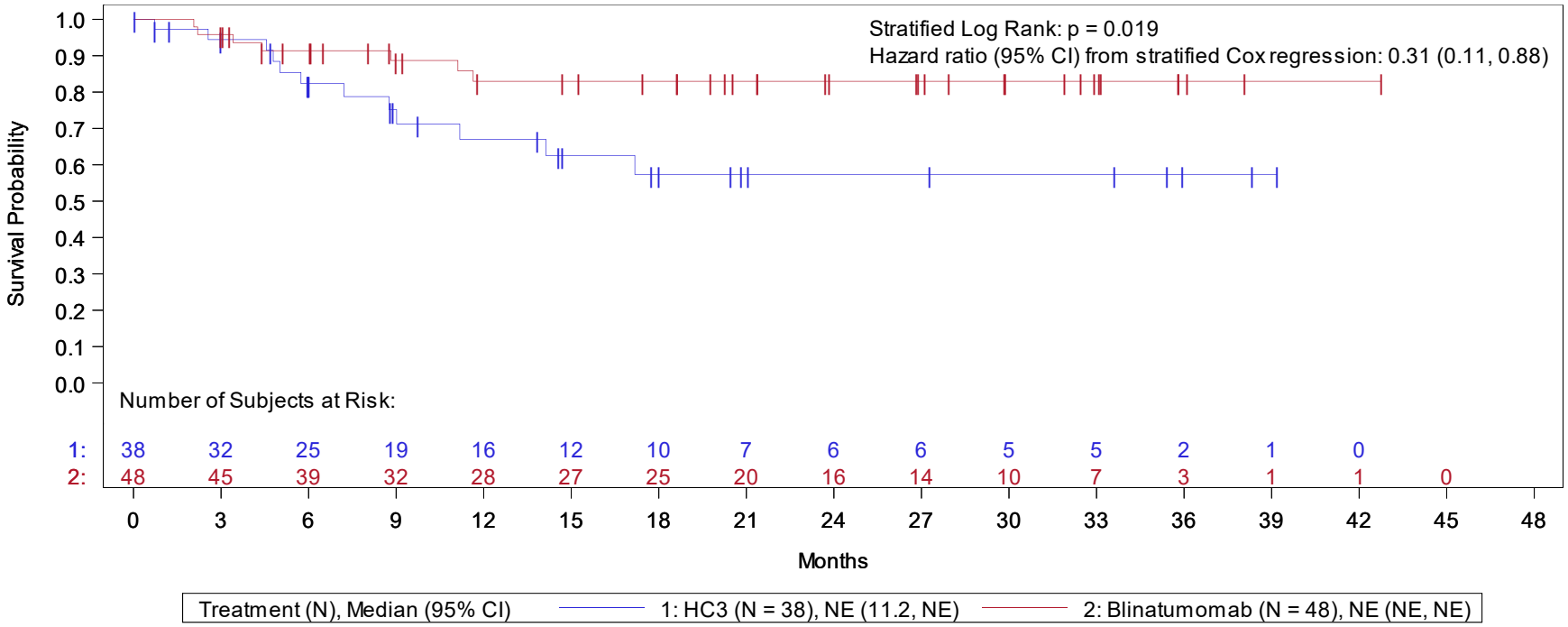
Figure 14-4.6.1. Kaplan-Meier Plot for Allogeneic HSCT Time to Event Analysis (Full Analysis Set)



CI = Confidence Interval.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-allohsct-tte-fas.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-04-006-001-km-allohsct-tte-fas.rtf
(Date Generated: 04JAN2021 : 00:35) Source Data: adampc.adsl, adampc.adtteeff

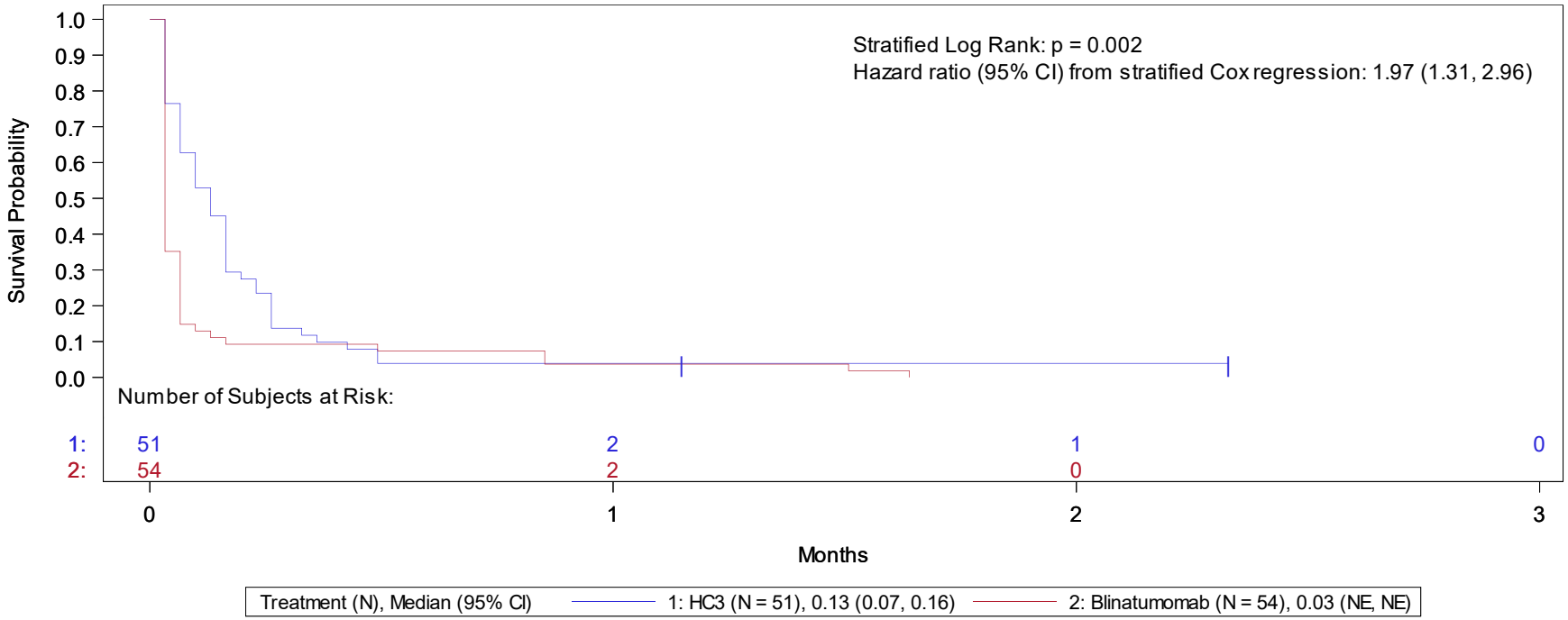
Figure 14-4.6.2. Kaplan-Meier Plot for Survival Status Following Allogeneic HSCT (HSCT Analysis Set)



Months are calculated from alloHSCT date to death/censor date
CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ss-allohsct-has.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-04-006-002-km-ss-allohsct-has.rtf
(Date Generated: 09DEC2020 : 22:09) Source Data: adampc.adsl, adampc.adtteeff

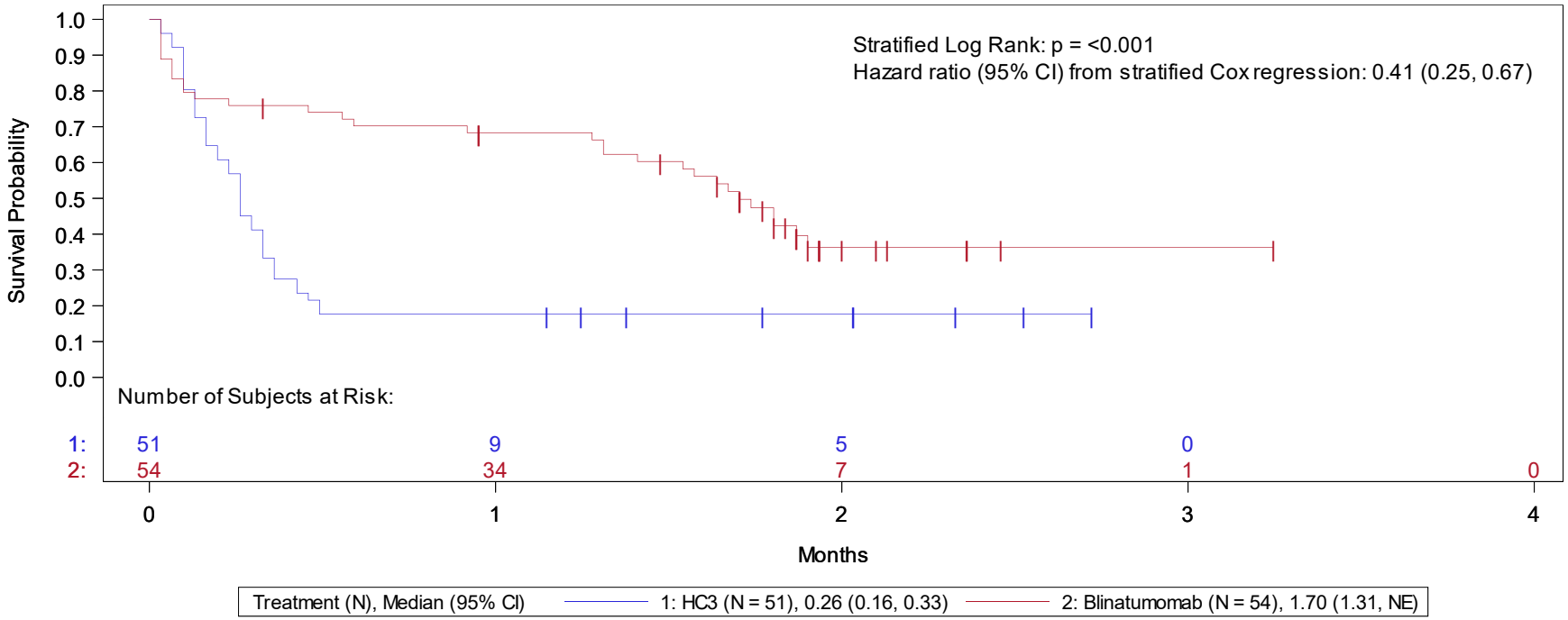
Figure 14-6.11.6. Kaplan-Meier Plot for Time to First Onset of Treatment Emergent Adverse Event (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-011-006-km-ae-ont-teae-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

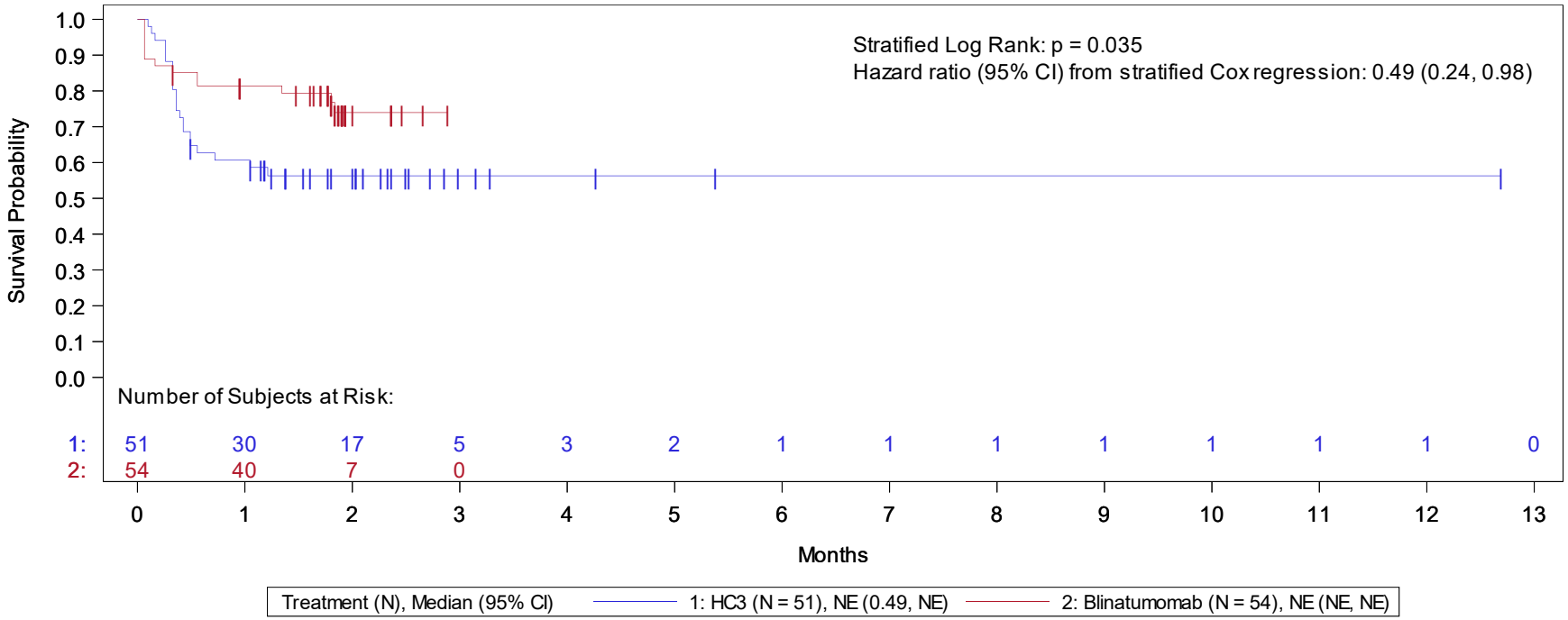
Figure 14-6.11.7. Kaplan-Meier Plot for Time to First Onset of Grade 3 and Above Treatment Emergent Adverse Event (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-011-007-km-ae-ont-teae-grade3-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

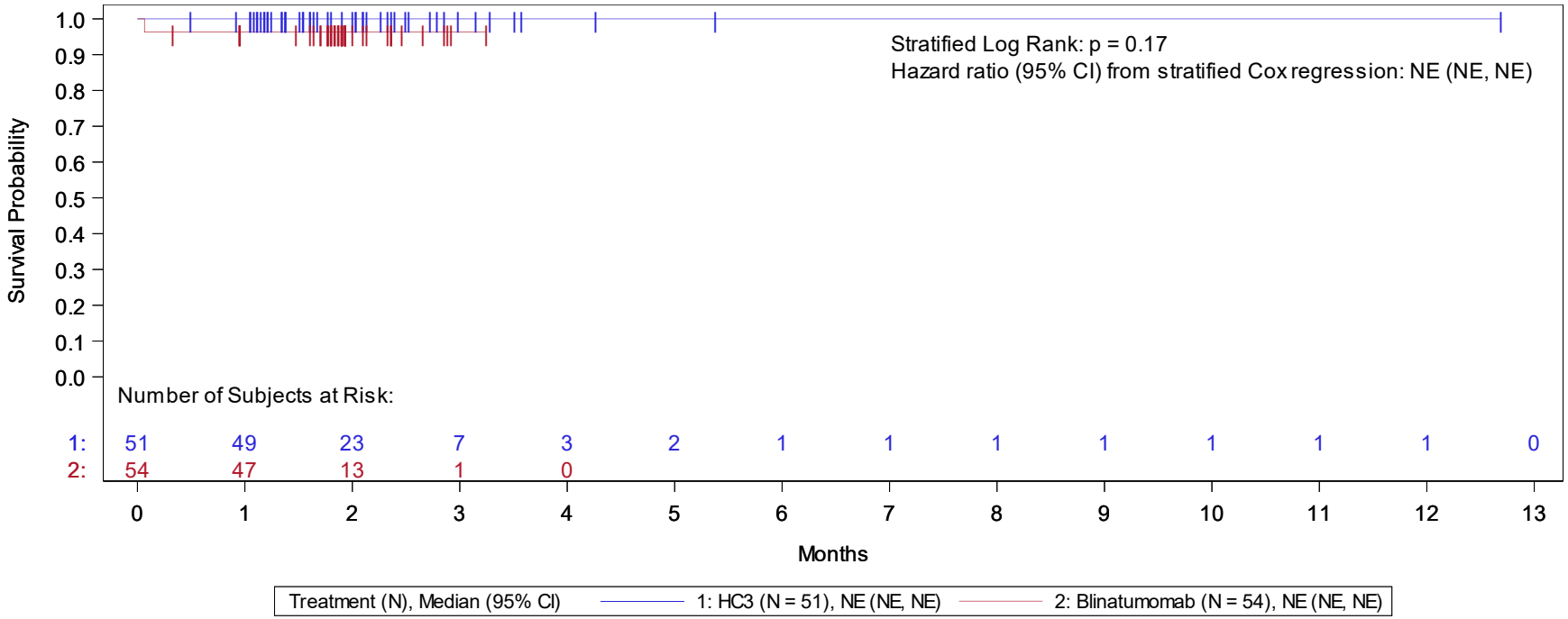
Figure 14-6.11.8. Kaplan-Meier Plot for Time to First Onset of Serious Treatment Emergent Adverse Event (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-011-008-km-sae-ont-teae-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

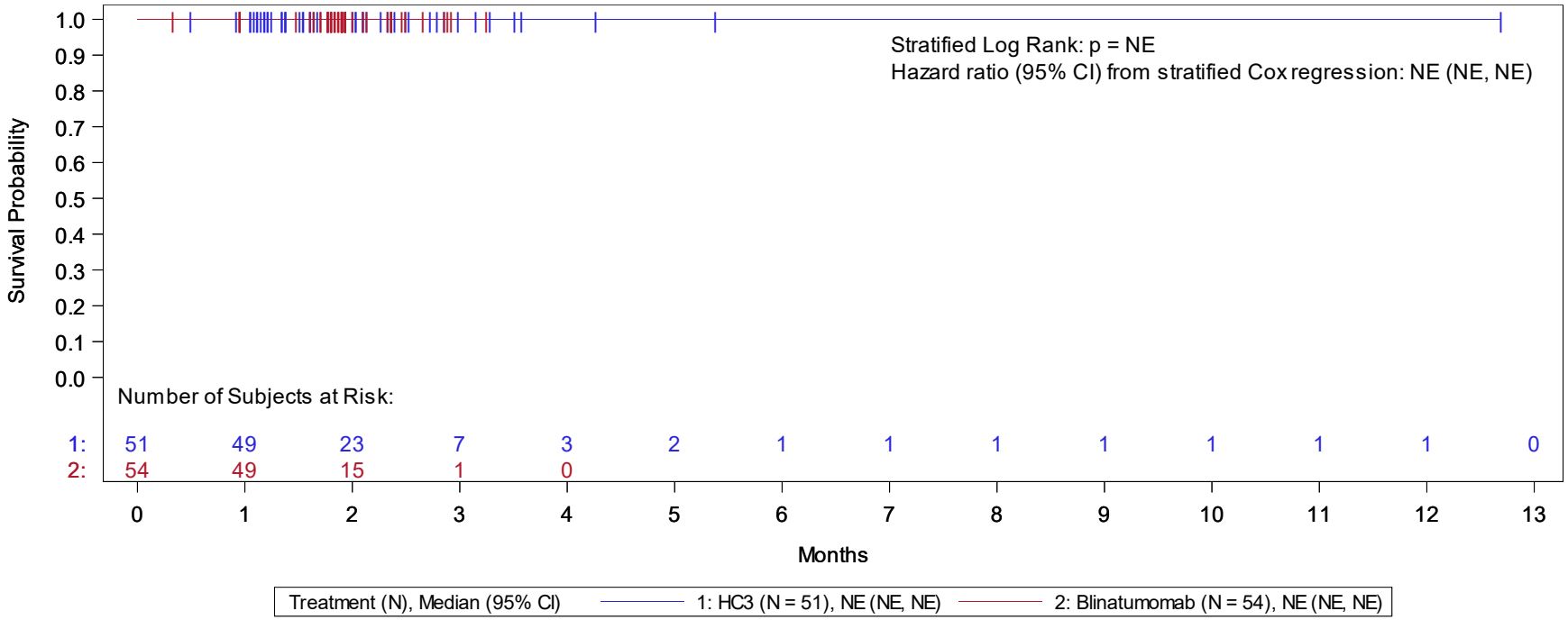
Figure 14-6.11.9. Kaplan-Meier Plot for Time to First Onset of Treatment Emergent Adverse Event Leading to Any Study Treatment Discontinuation (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-011-009-km-ae-ont-teae-trtdisc-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

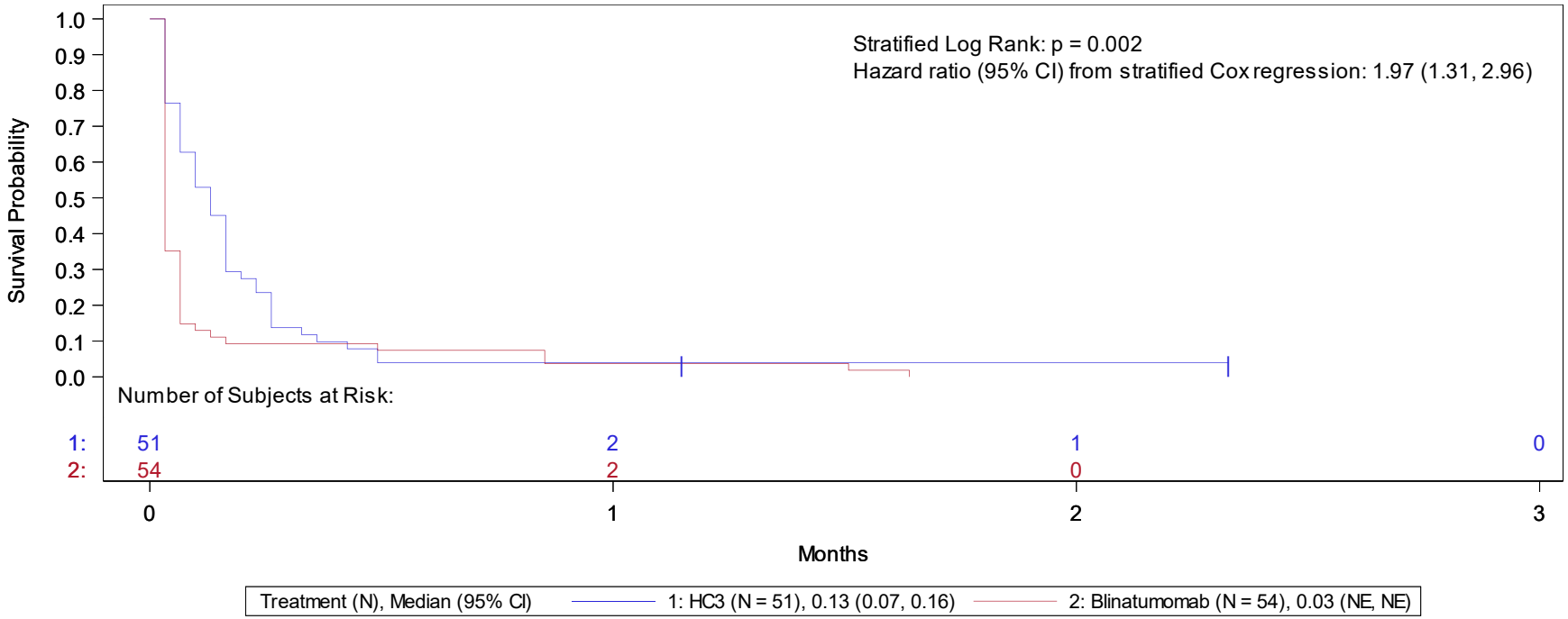
Figure 14-6.11.10. Kaplan-Meier Plot for Time to First Onset of Fatal Treatment Emergent Adverse Event (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-011-010-km-ae-ont-teae-fatal-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

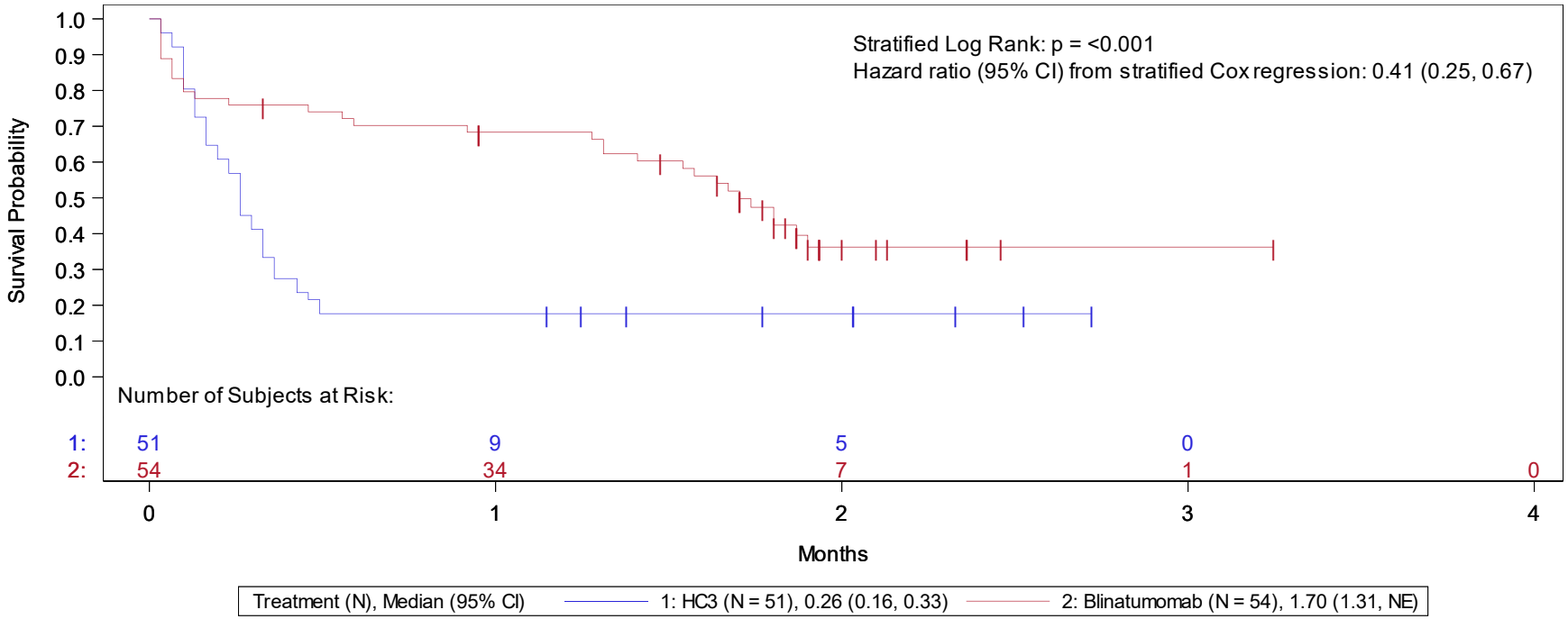
Figure 14-6.13.4. Kaplan-Meier Plot for Time to First Onset of Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-013-004-km-ae-ont-teae-edp-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

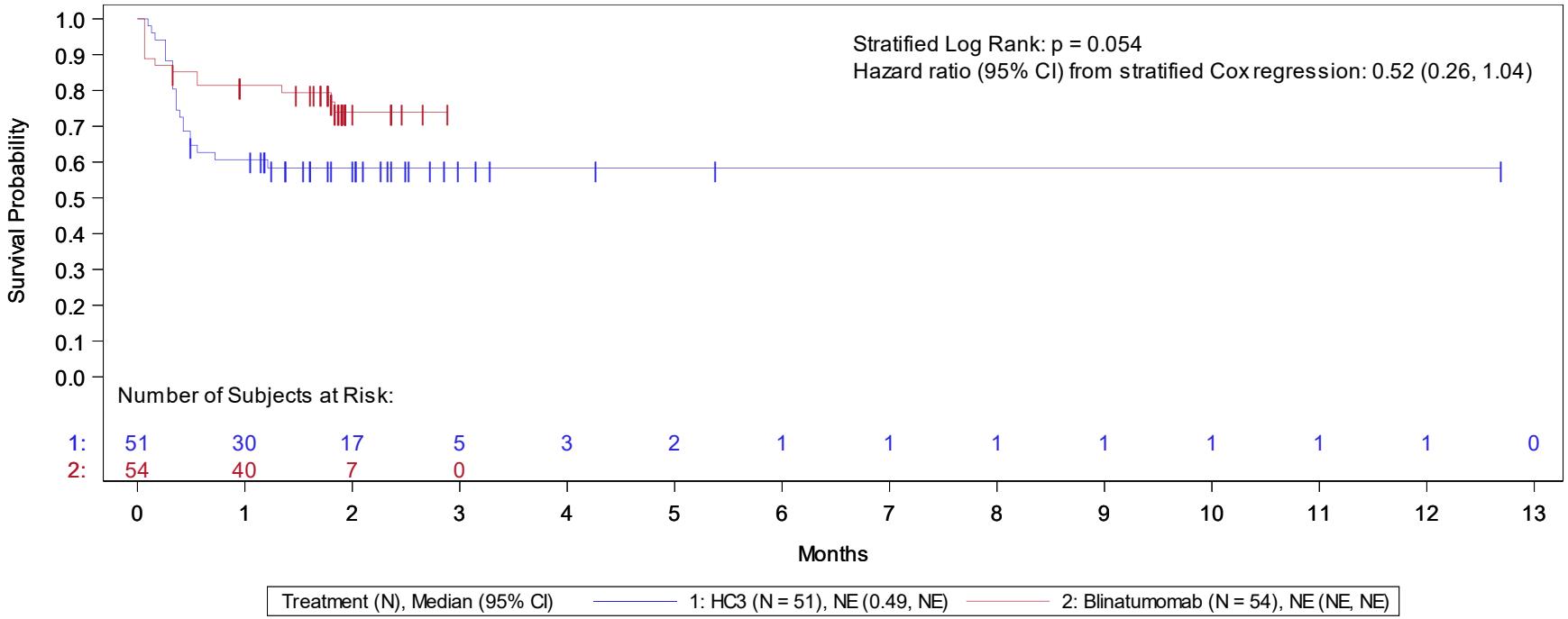
Figure 14-6.13.5. Kaplan-Meier Plot for Time to First Onset of Grade 3 and Above Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-013-005-km-ae-ont-teae-grade3-edp-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

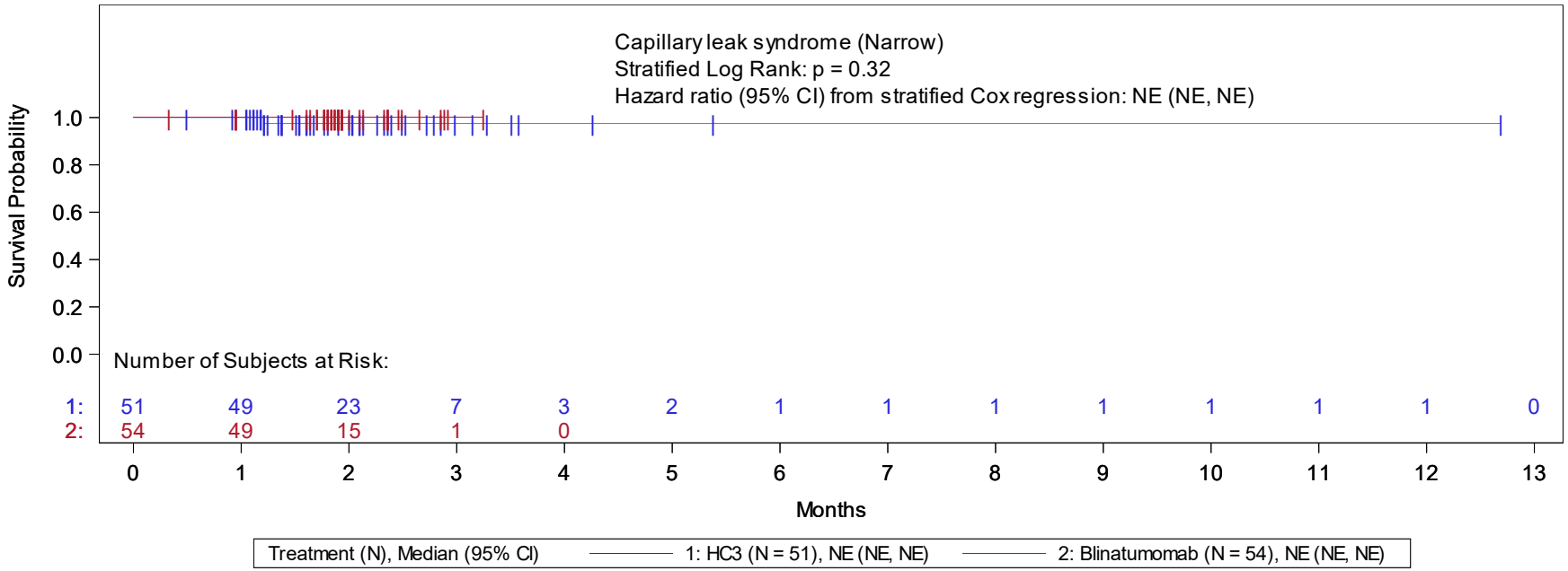
Figure 14-6.13.6. Kaplan-Meier Plot for Time to First Onset of Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Data cut-off date: 17JUL2019

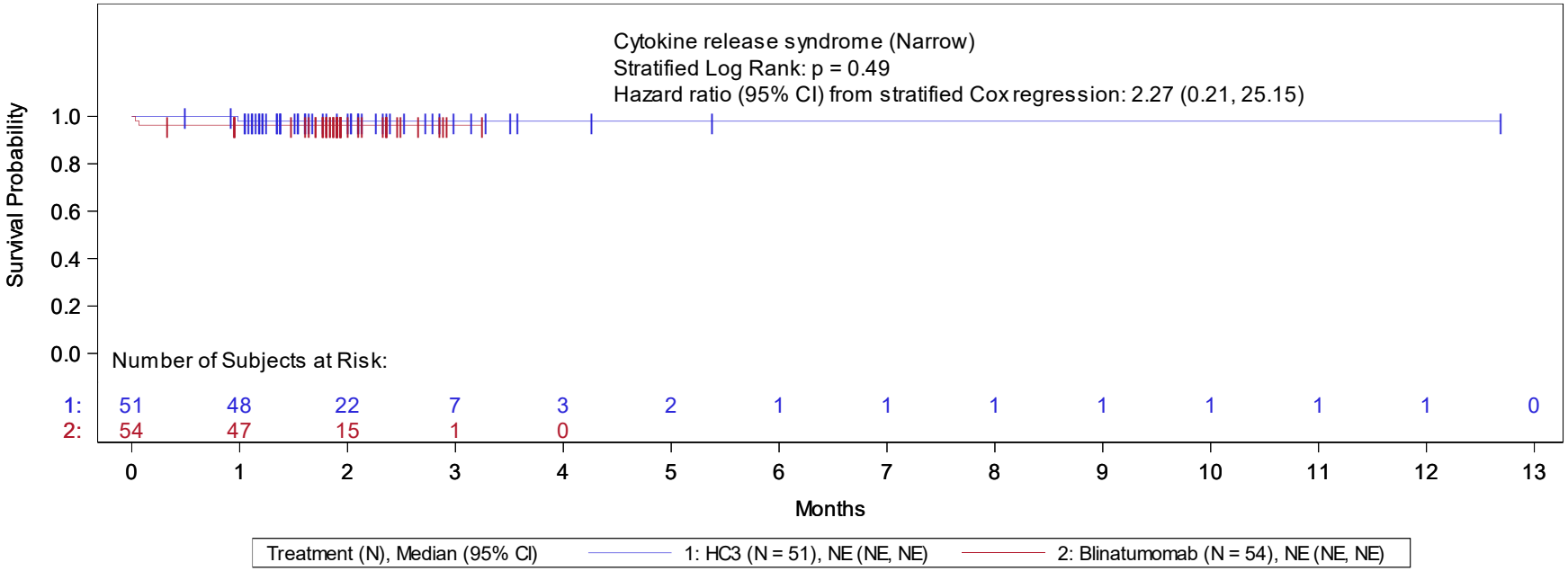
Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-013-006-km-sae-ont-teae-edp-saf.rtf (Date Generated: 05JAN2021 : 04:52) Source Data: adampc.adsl, adam.adtteae

Figure 14-6.12.16. Kaplan-Meier Plot for Time to First Onset of Treatment Emergent Adverse Event of Interest (Safety Analysis Set)



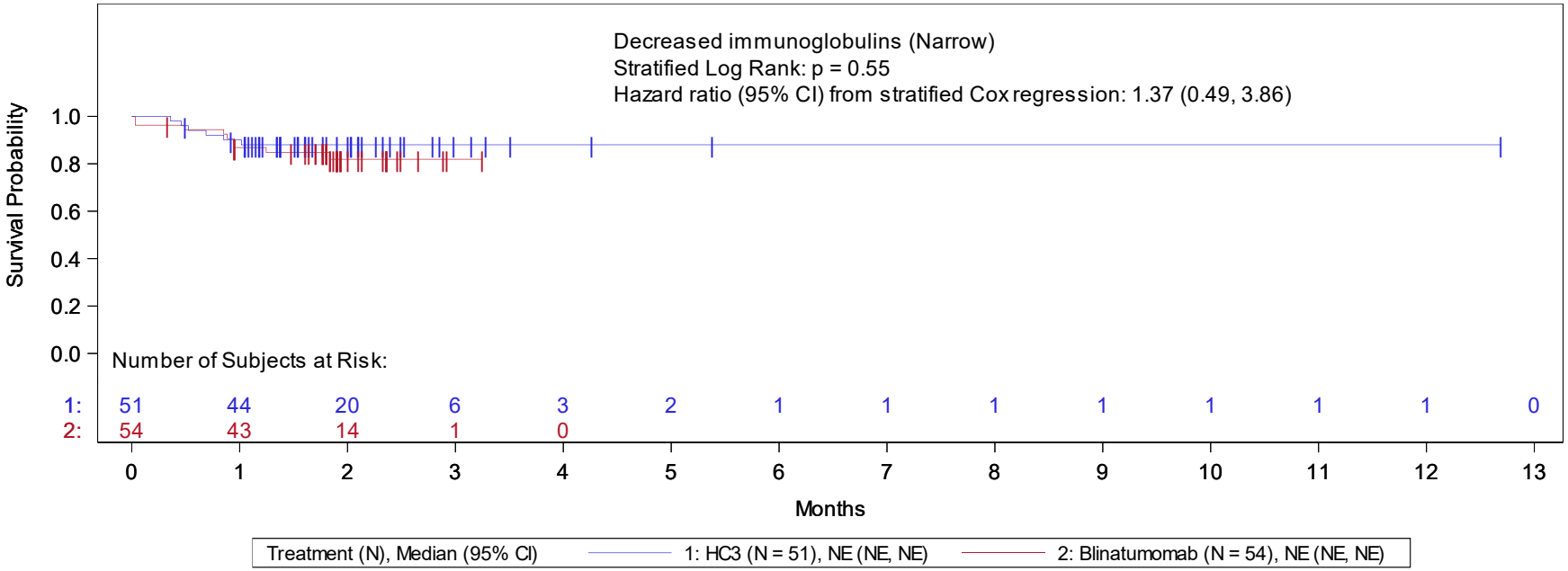
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



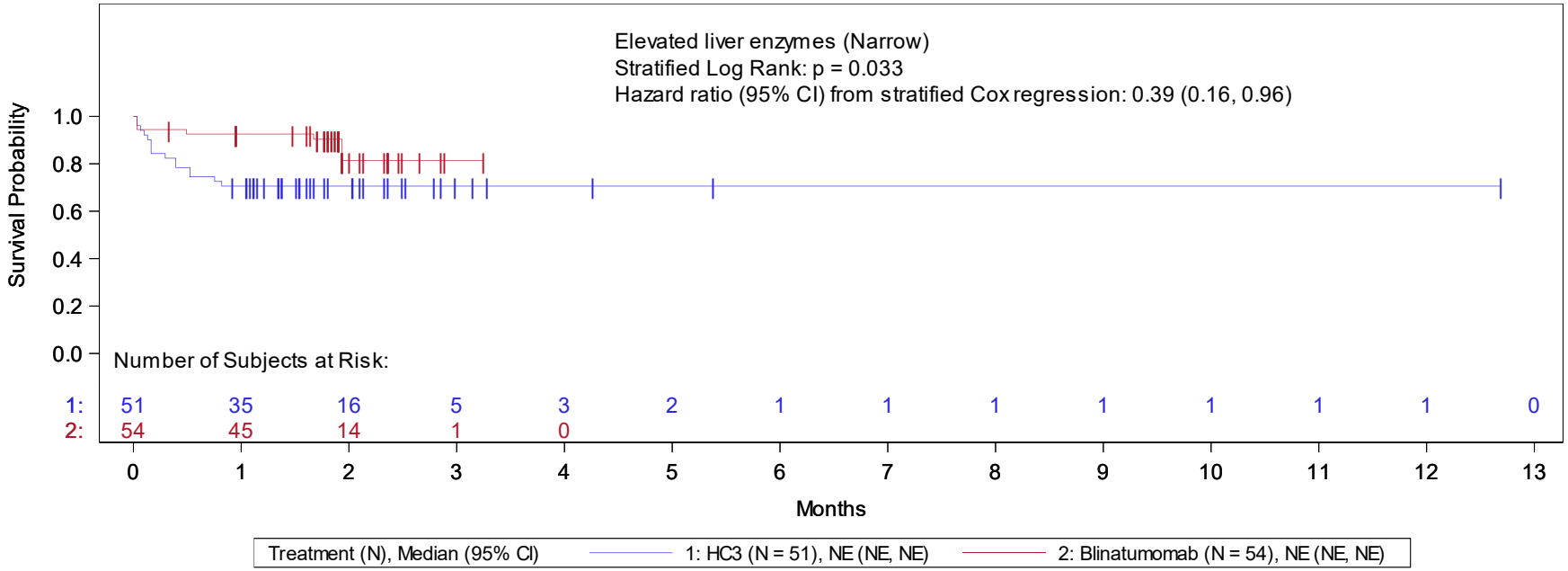
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



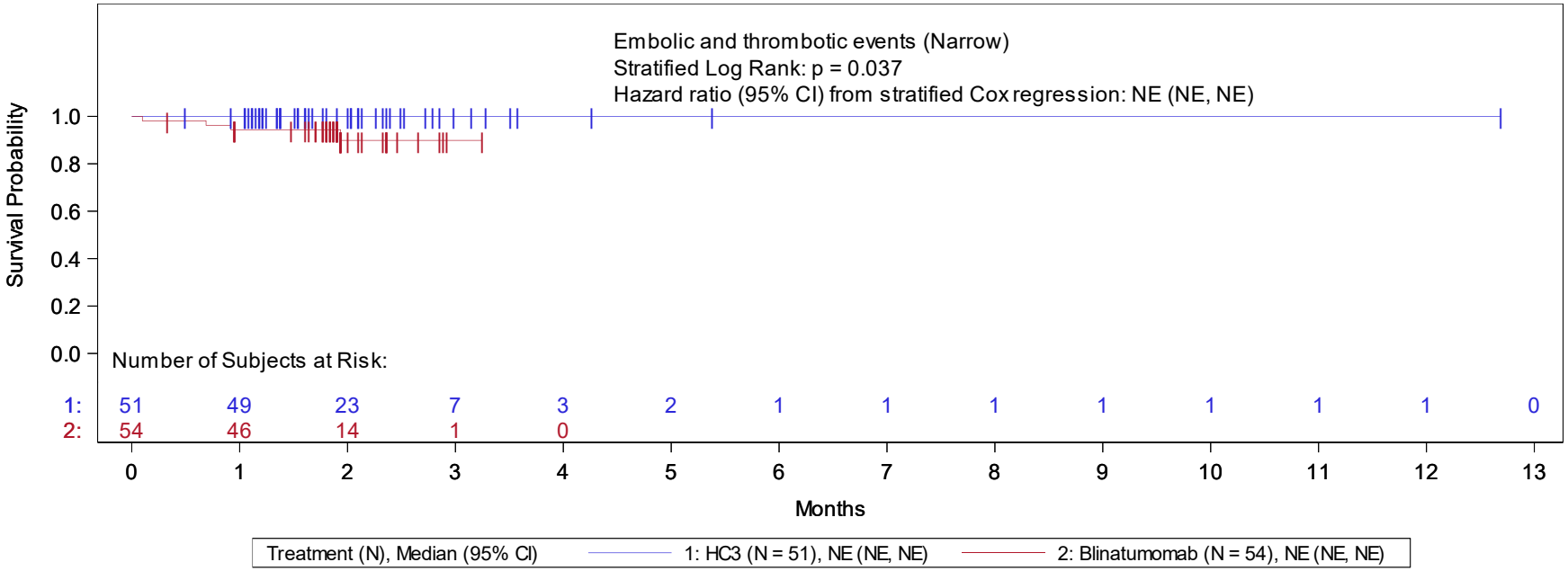
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



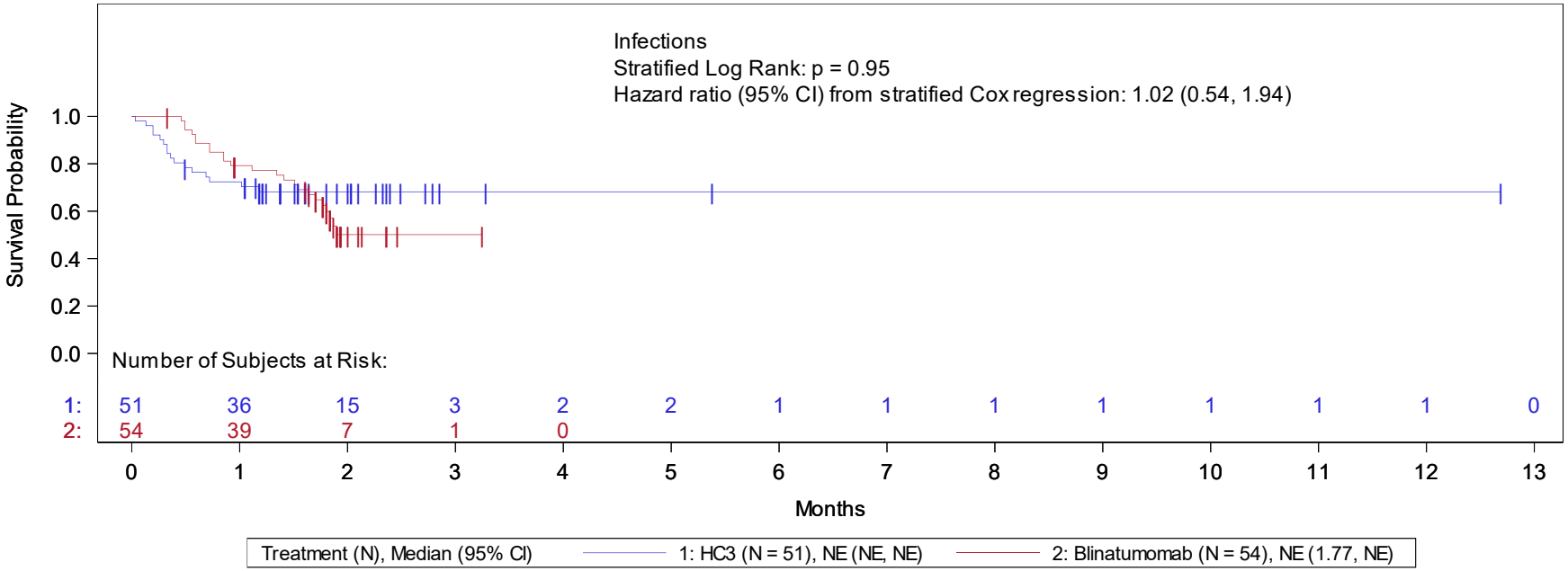
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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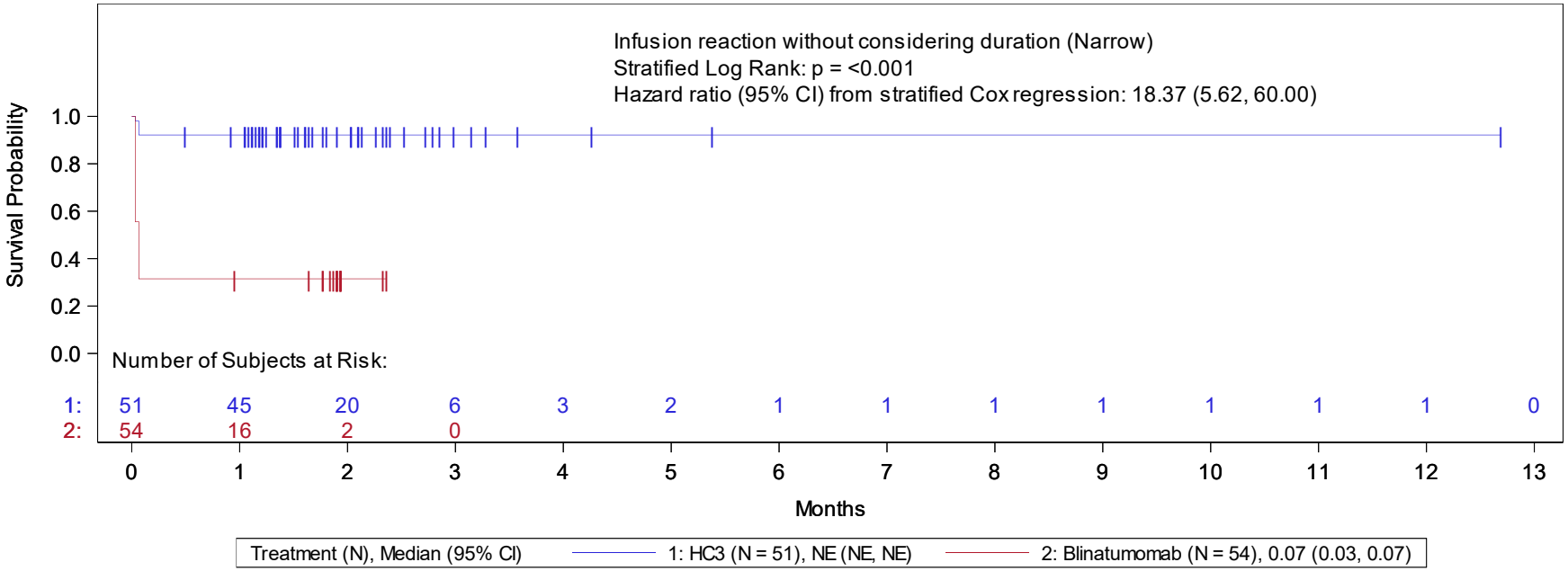
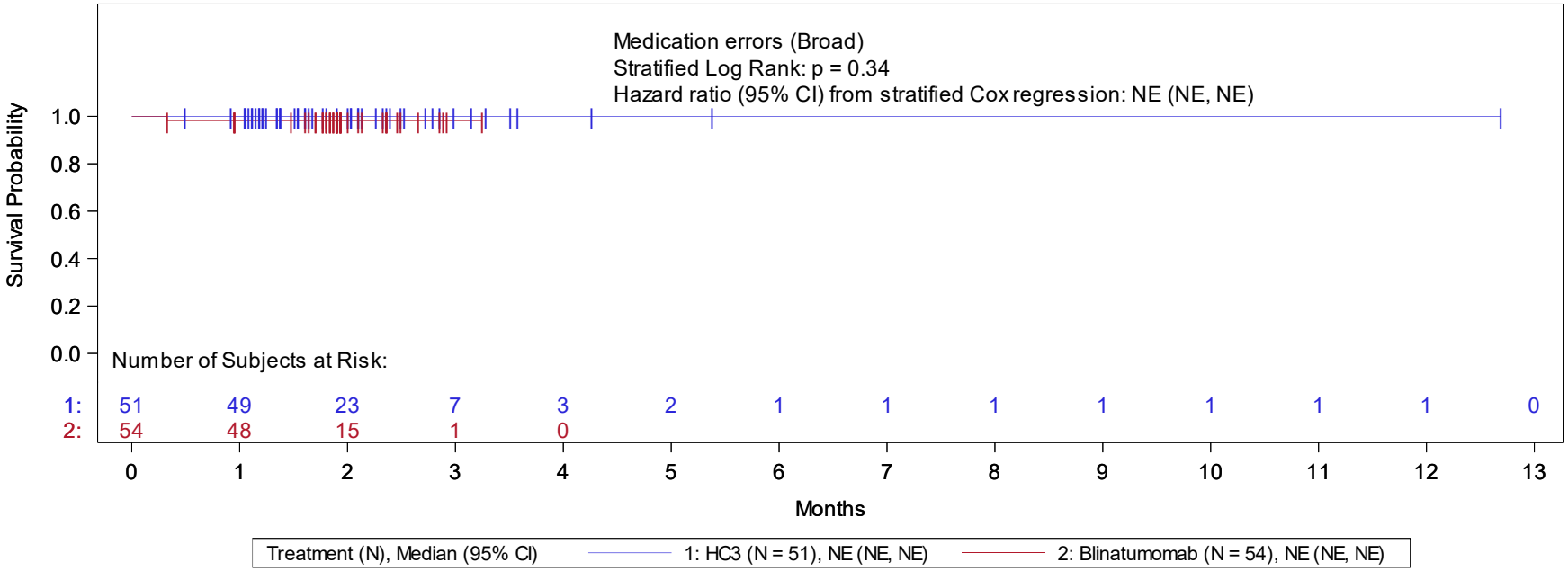
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



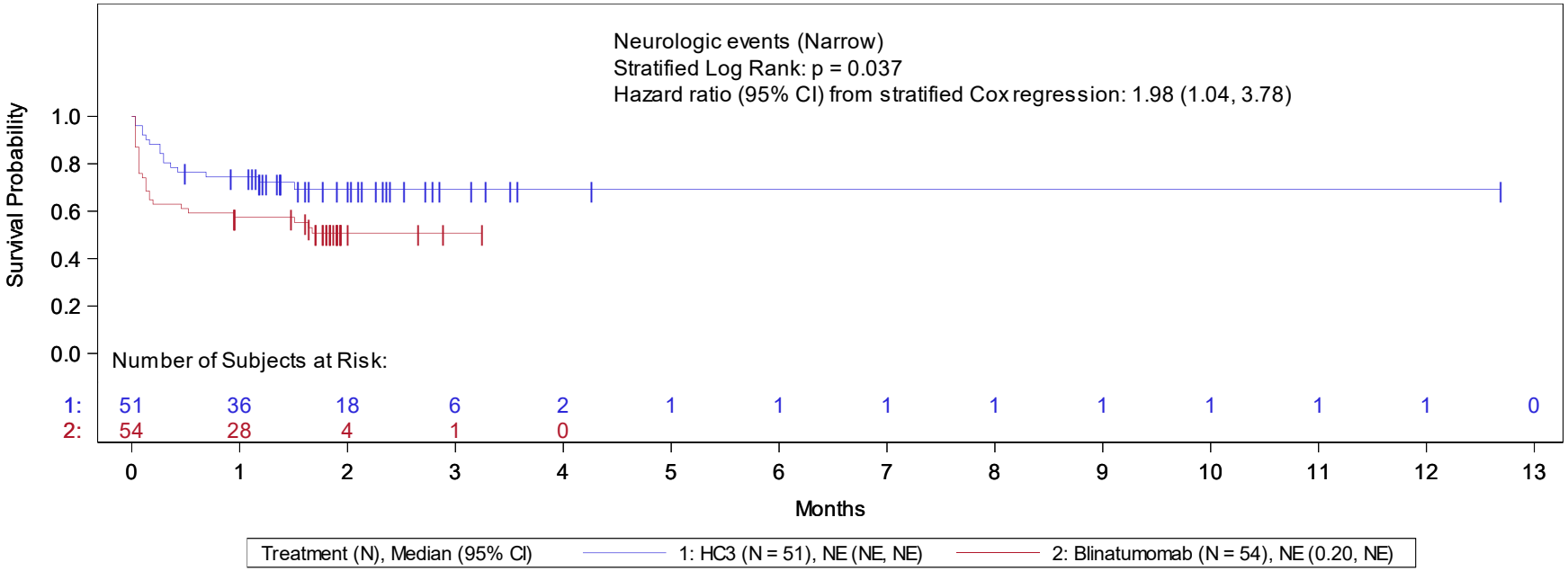
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



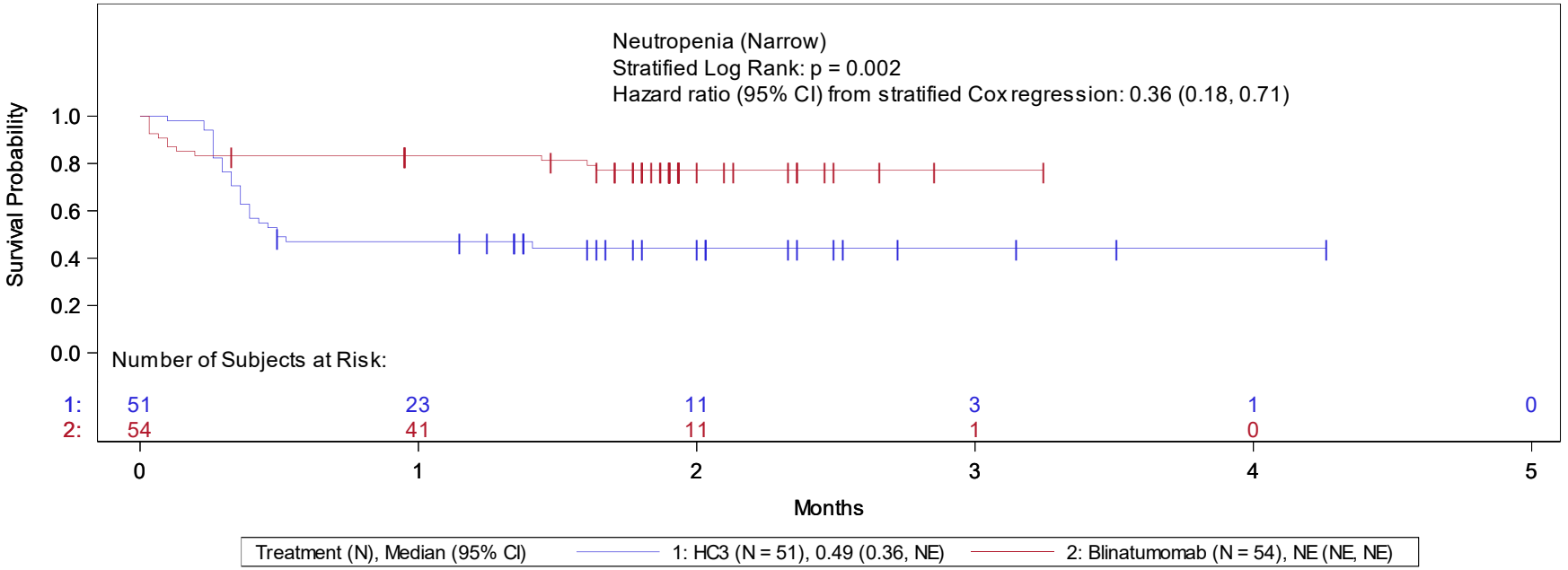
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



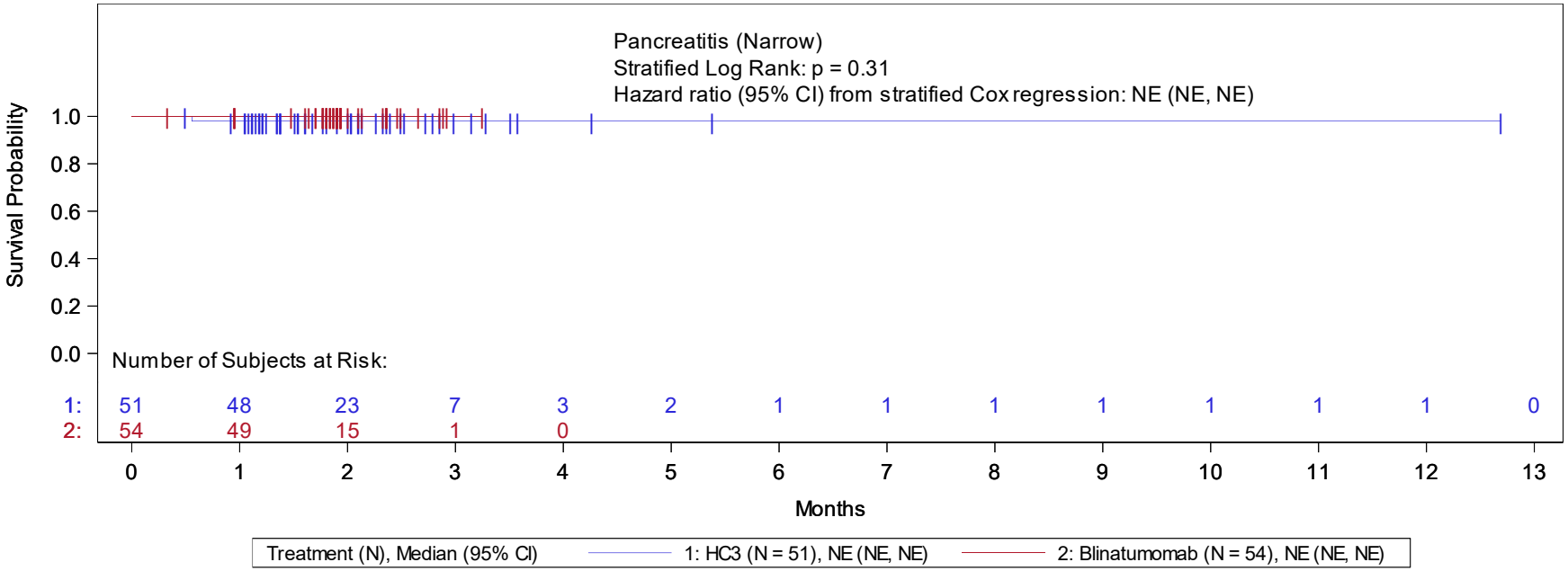
CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

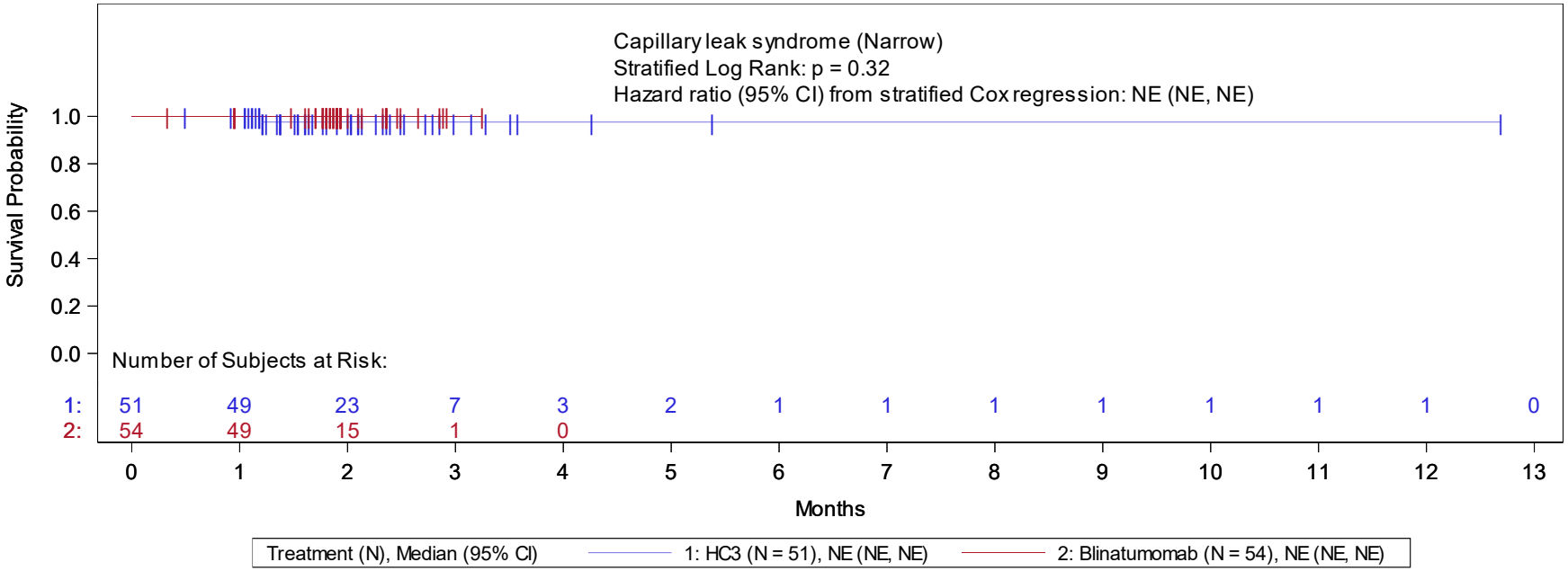
Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

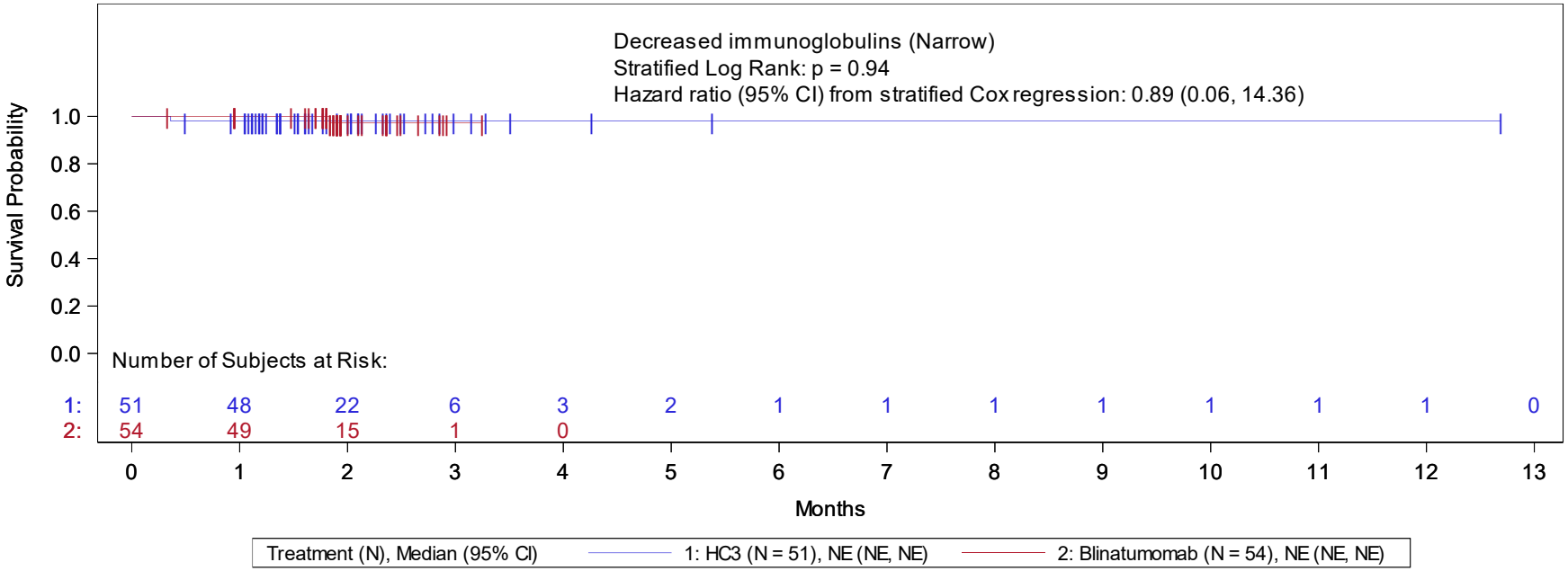
Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-016-km-ae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae

Figure 14-6.12.17. Kaplan-Meier Plot for Time to First Onset of Grade 3 and Above Treatment Emergent Adverse Event of Interest (Safety Analysis Set)



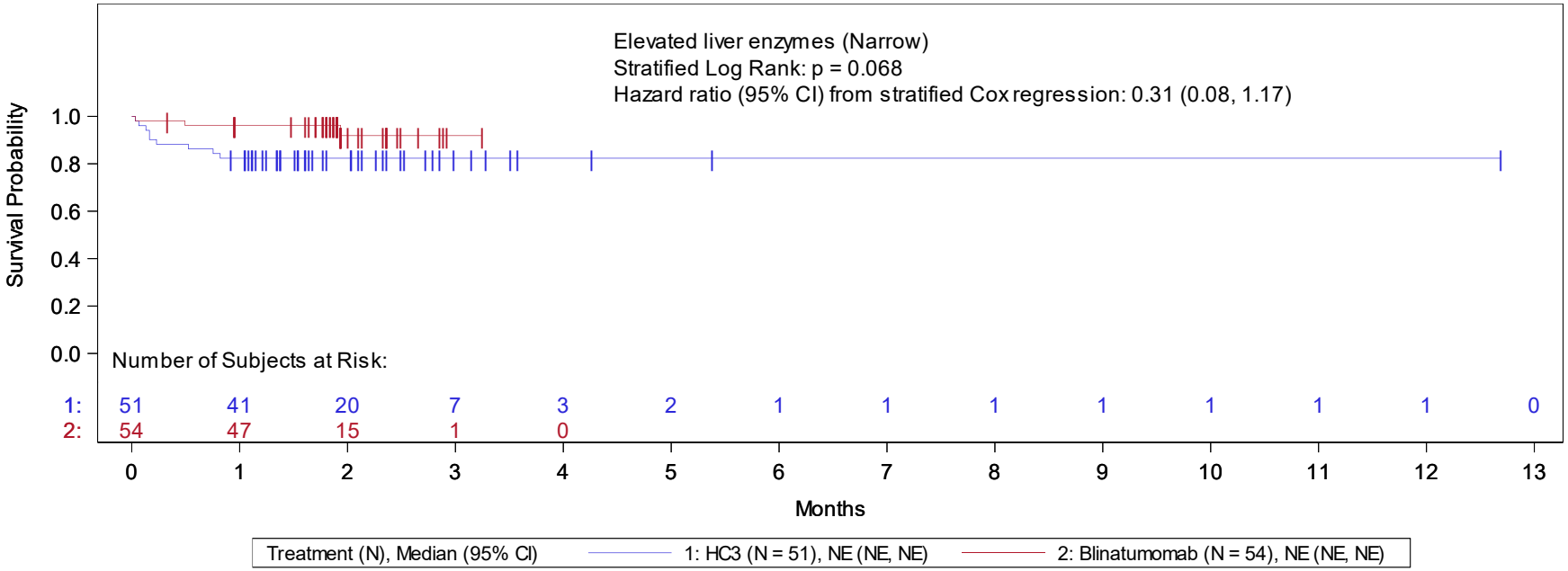
CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
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Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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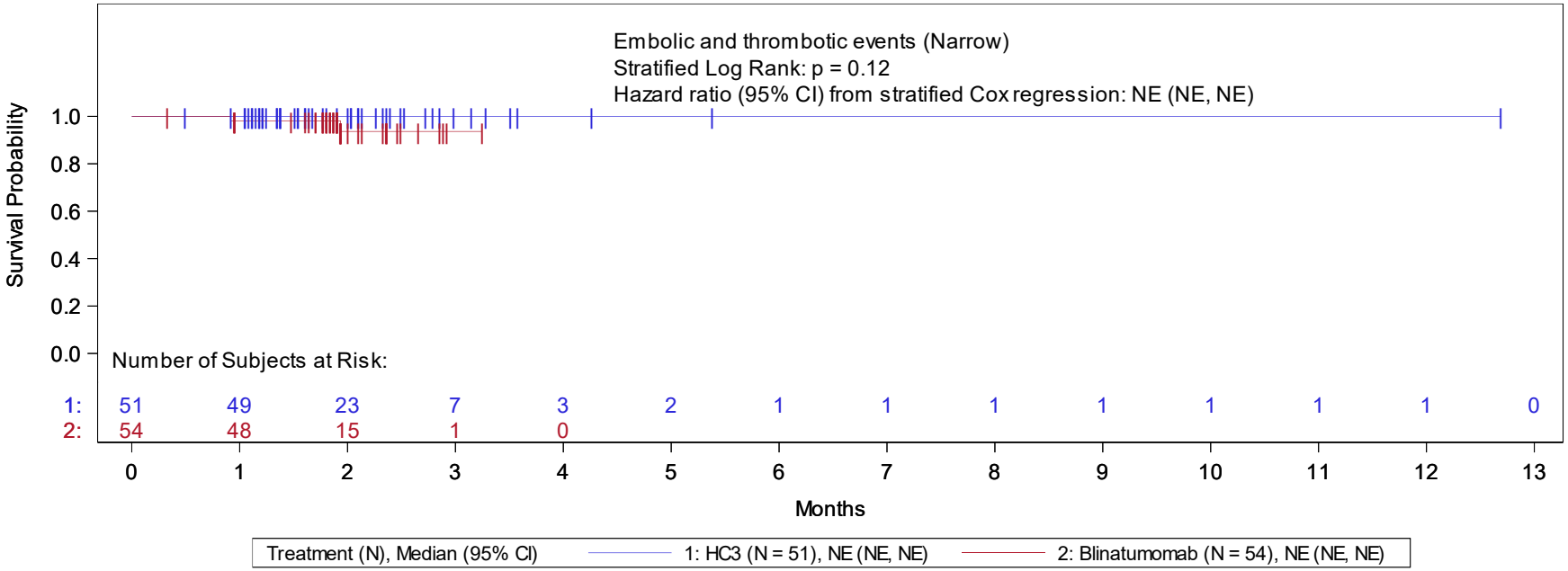

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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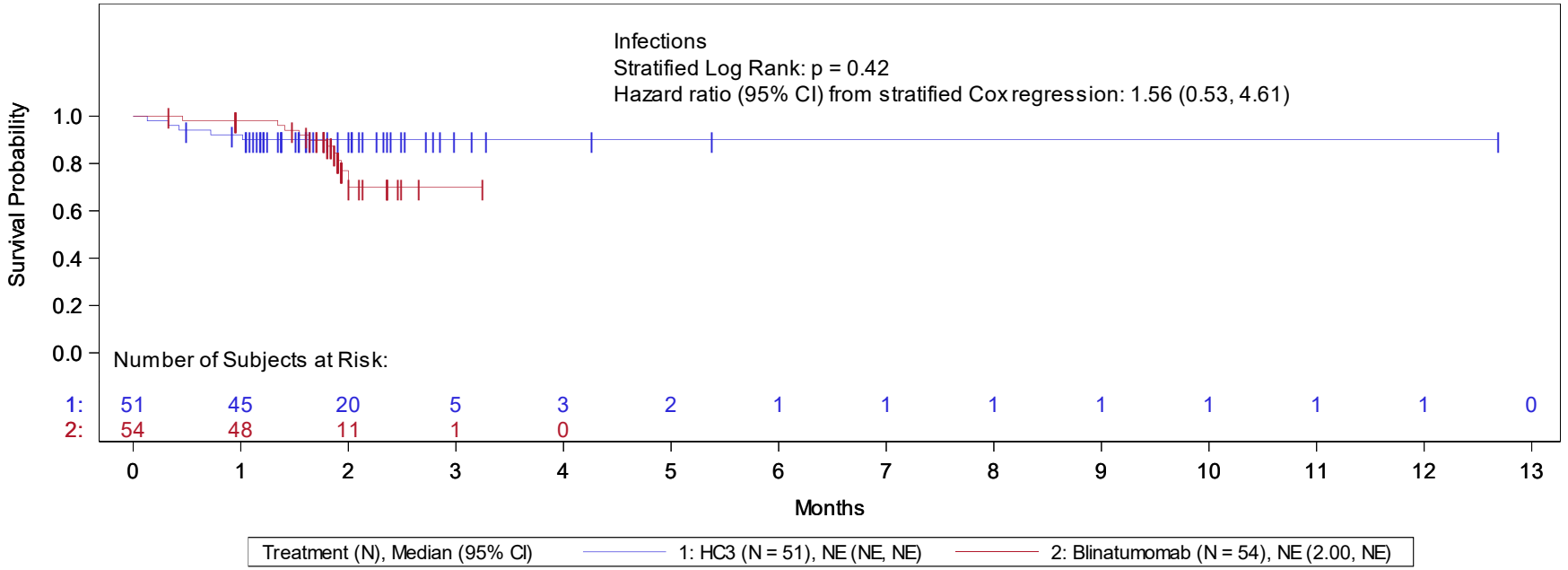
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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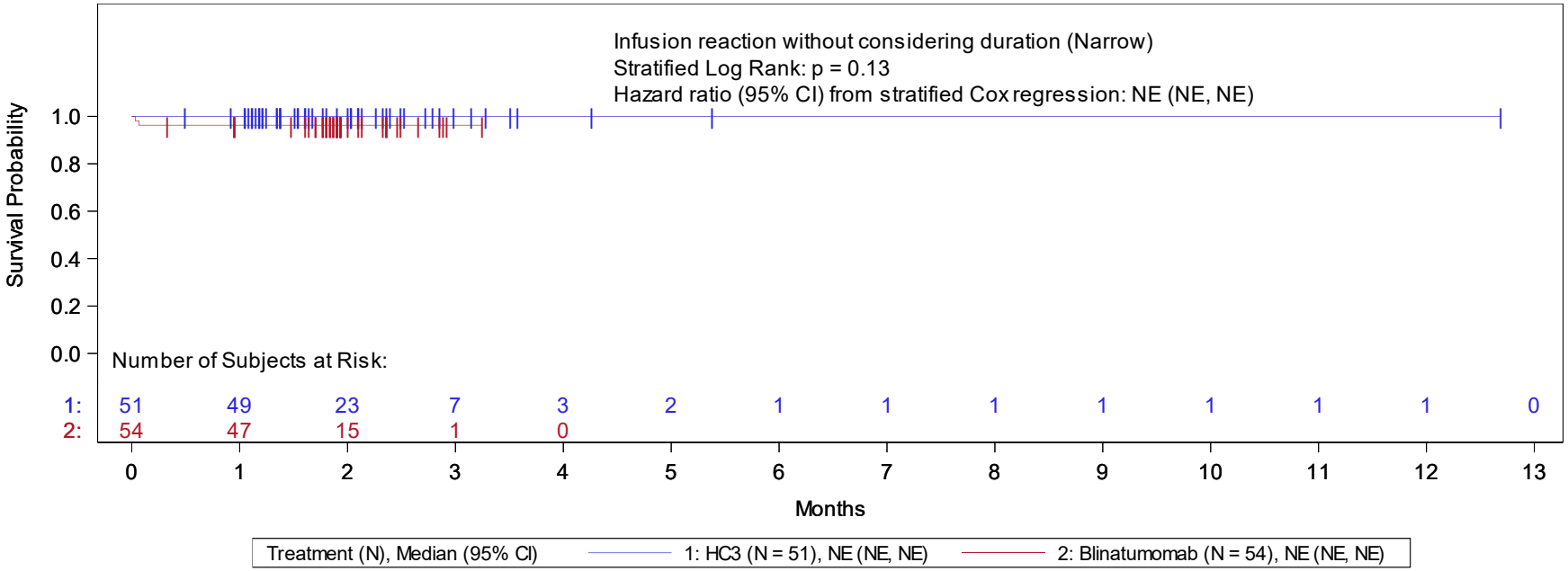
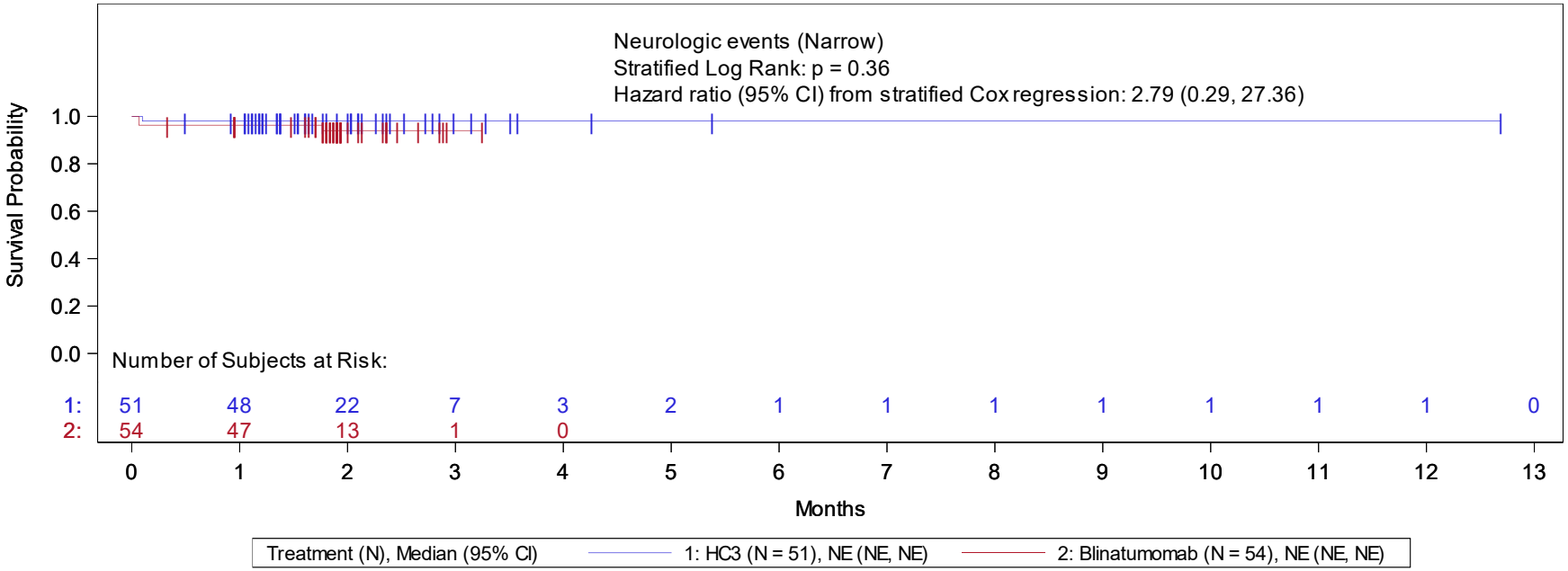
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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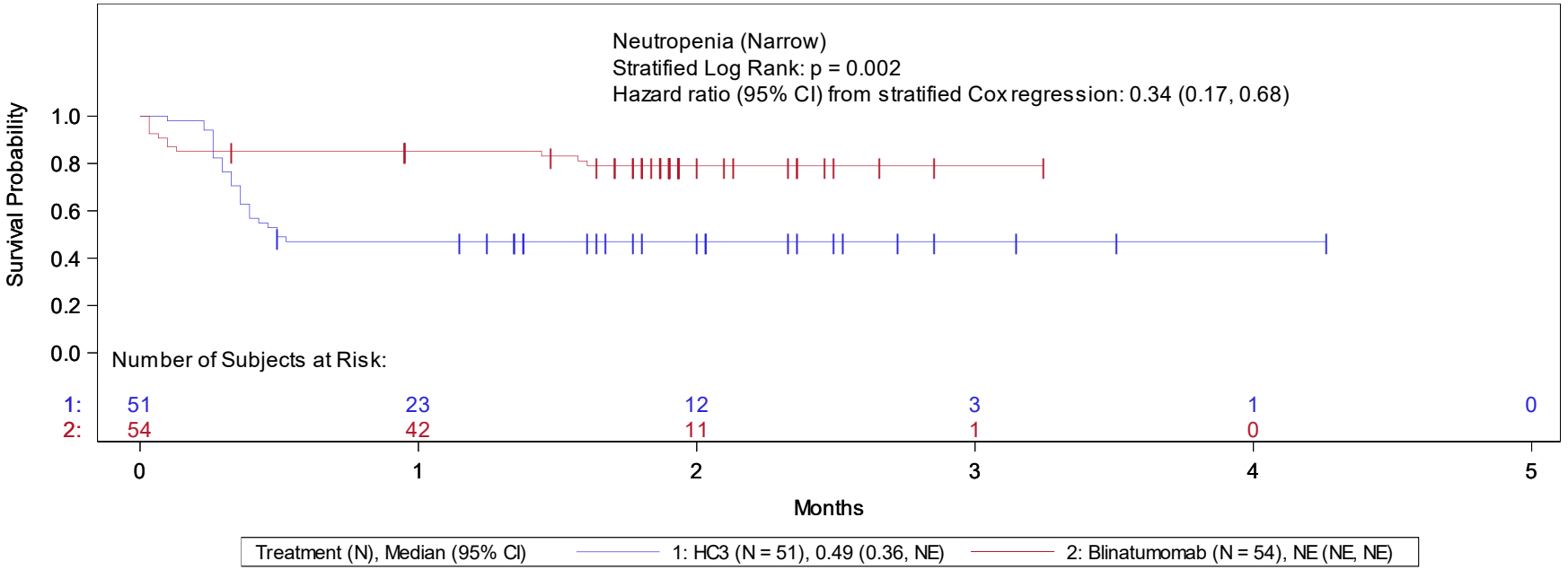
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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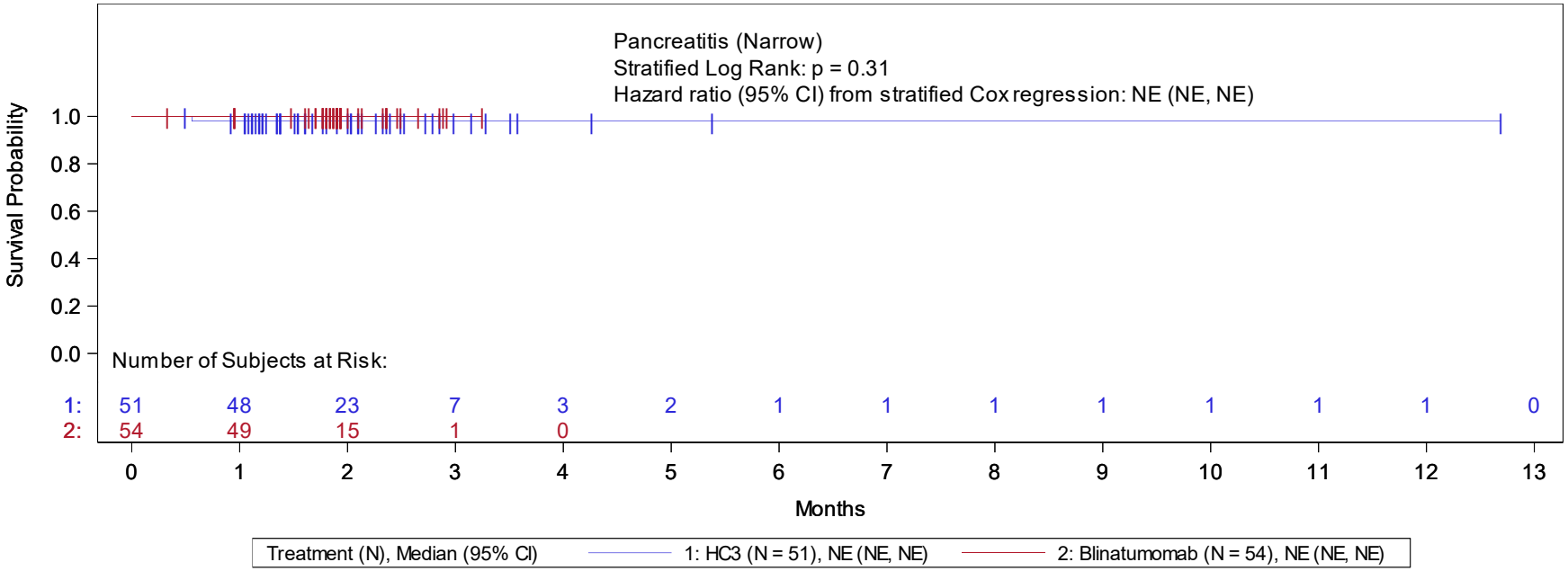
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-017-km-ae-ont-teae-by-eoi-grade3-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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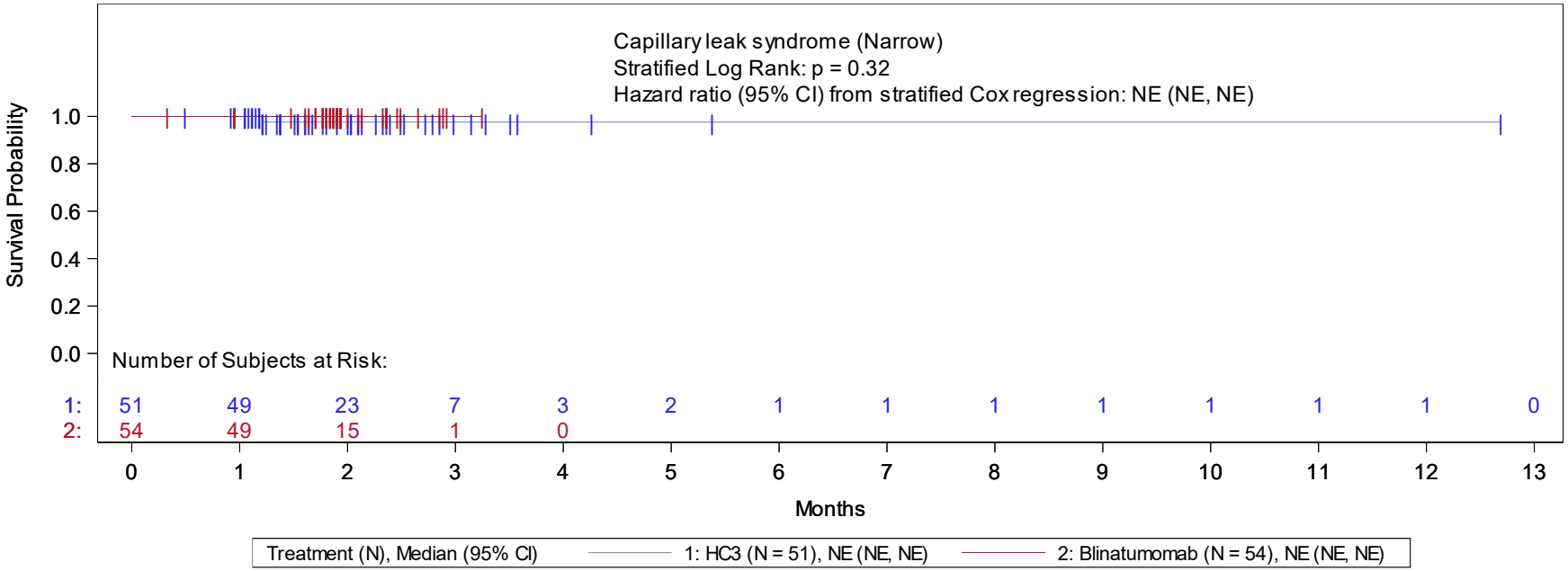
Figure 14-6.12.18. Kaplan-Meier Plot for Time to First Onset of Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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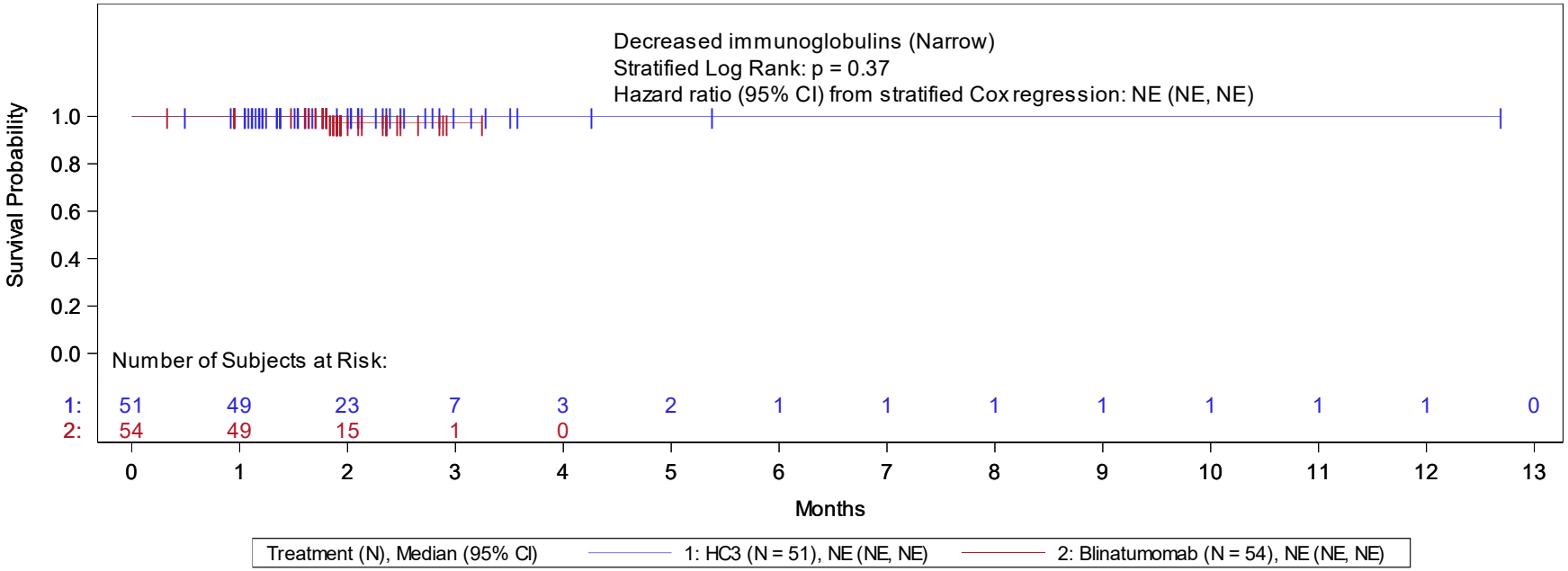

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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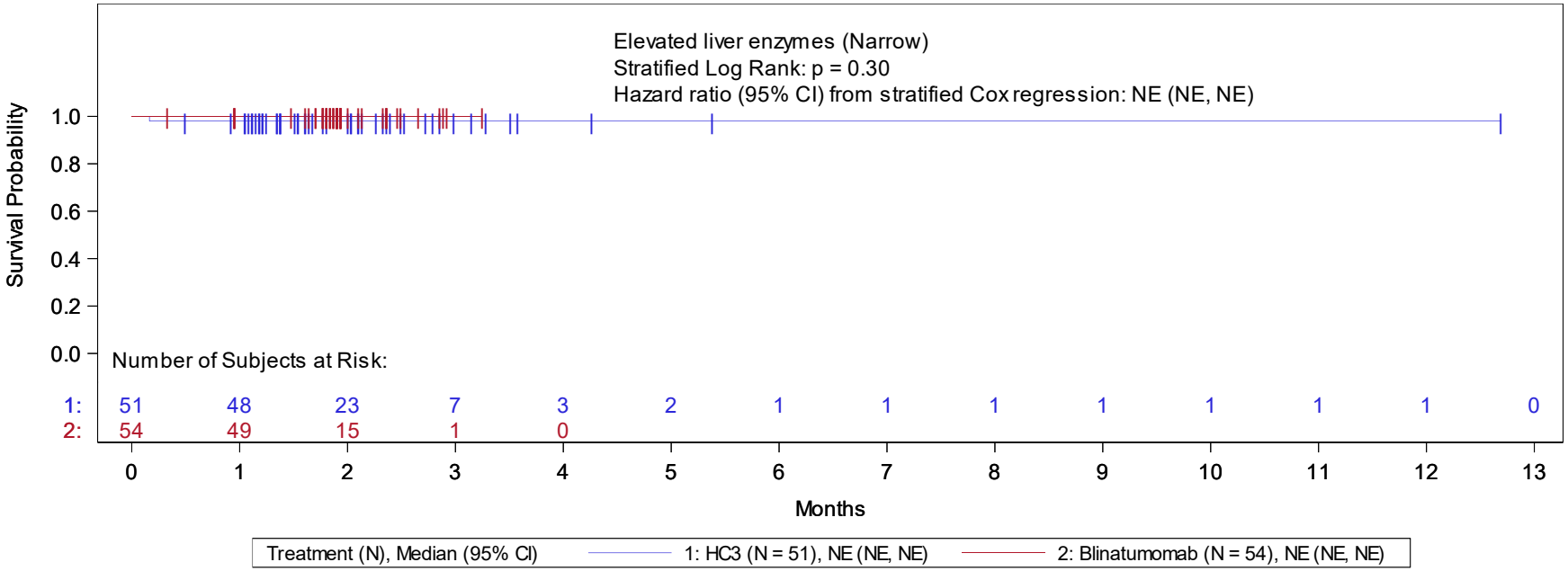
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-012-018-km-sae-ont-teae-by-eoi-saf.rtf (Date Generated: 07MAR2021 : 21:20) Source Data: adampc.adsl, adam.adtteae



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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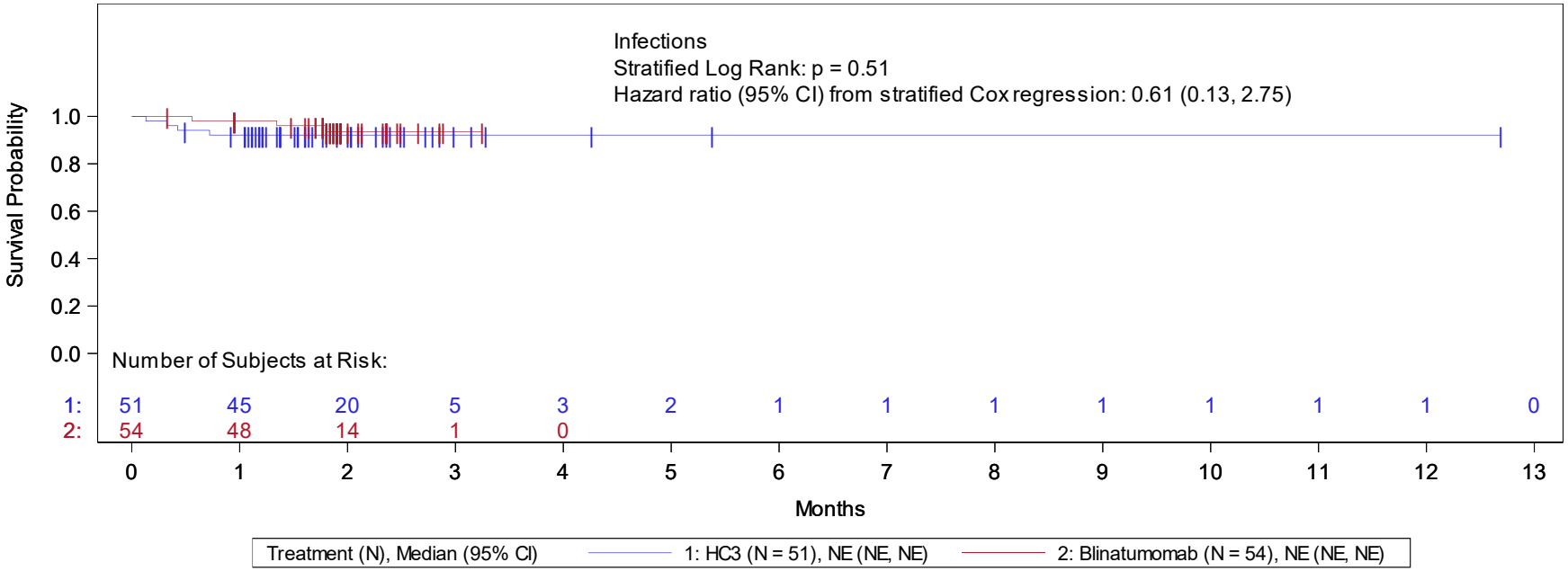

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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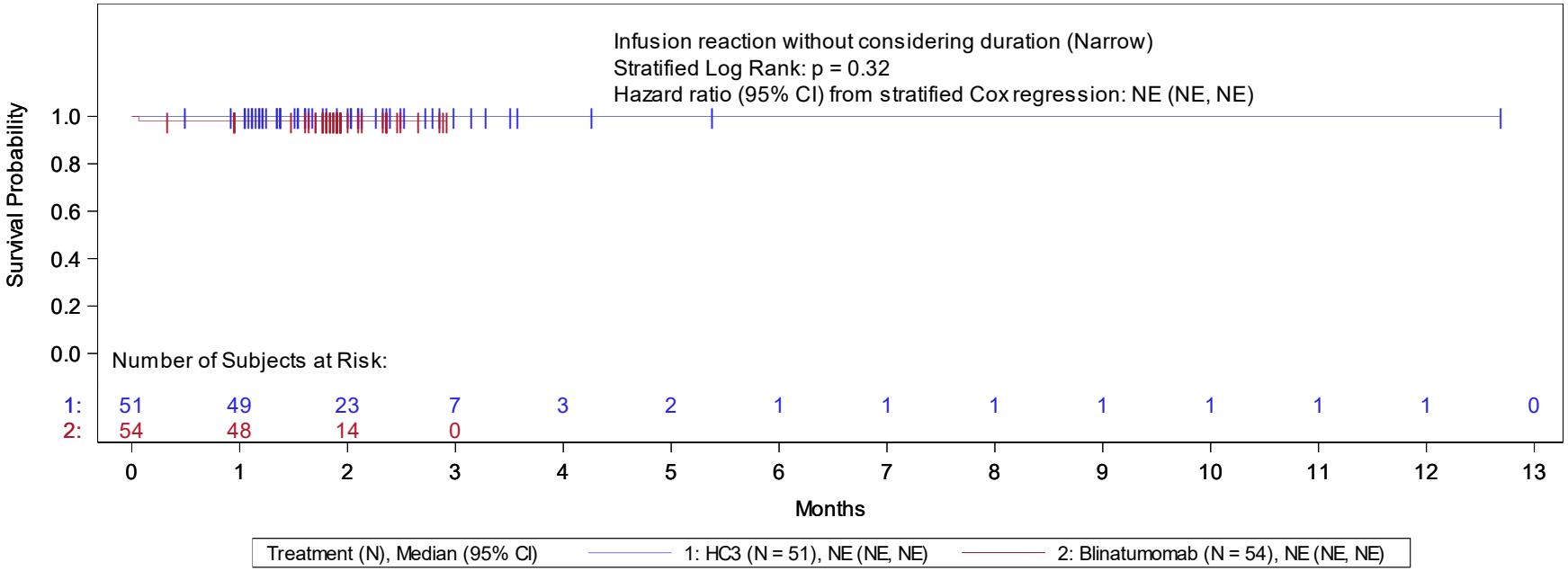

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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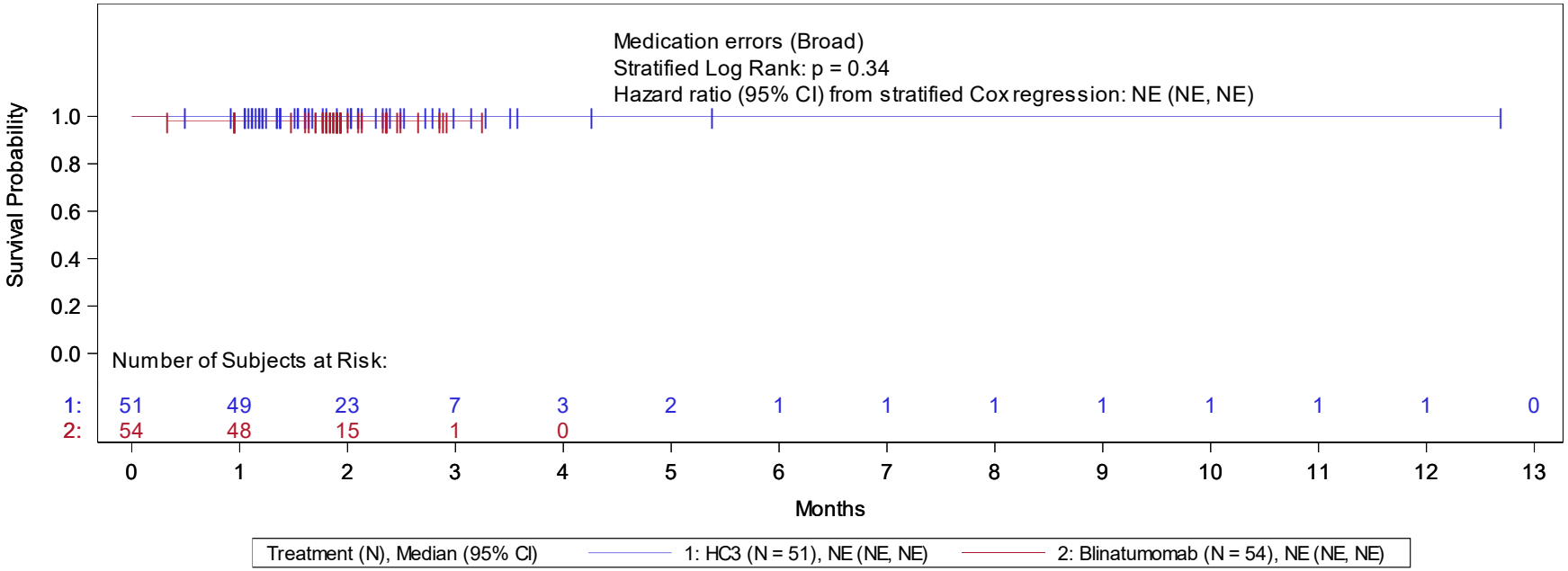

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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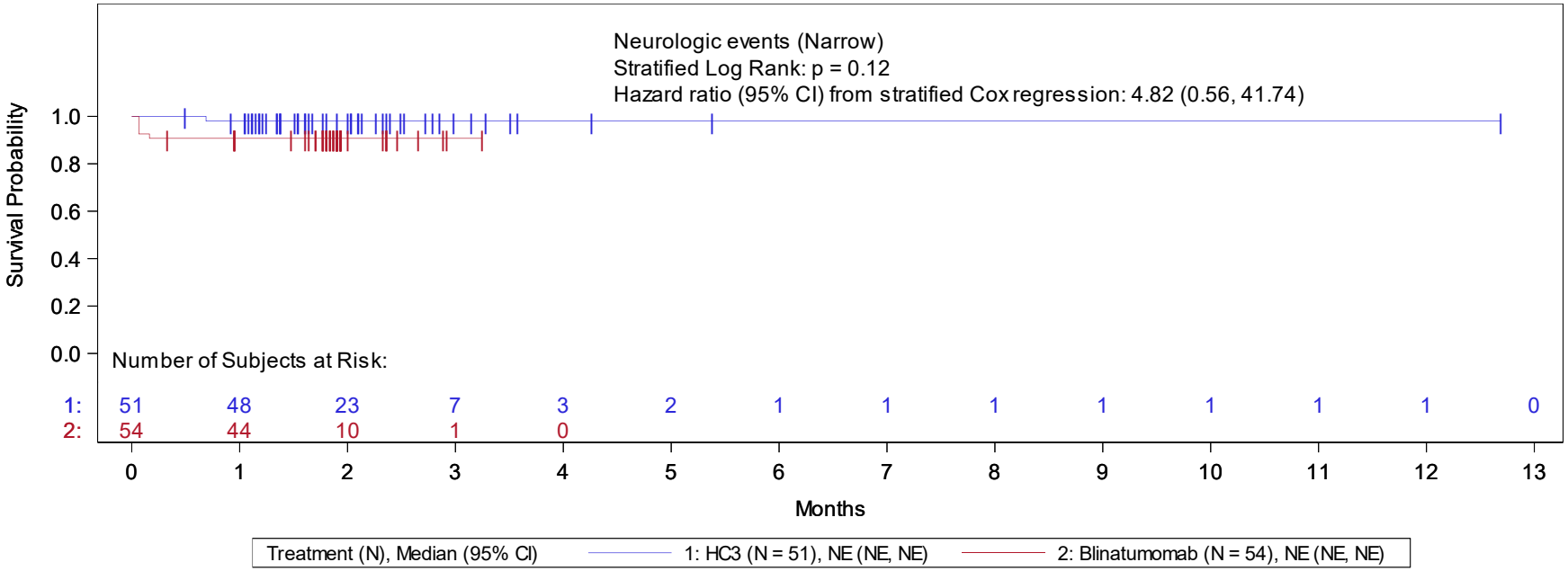

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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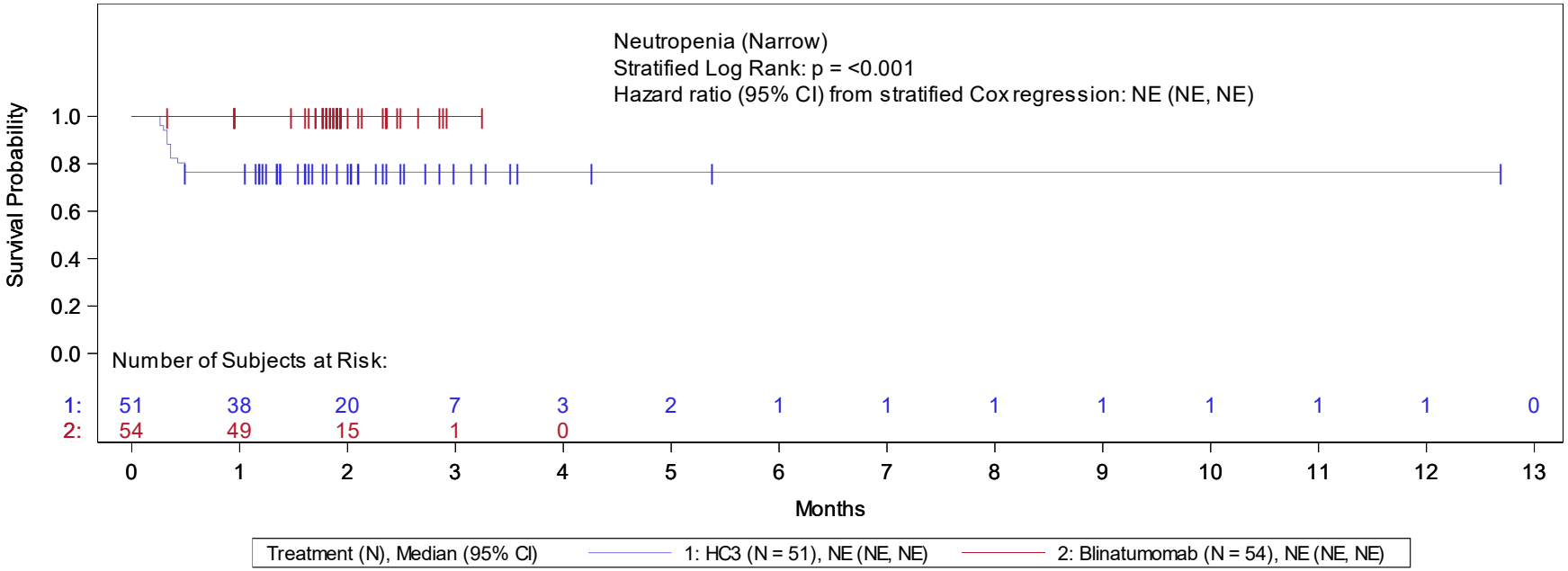

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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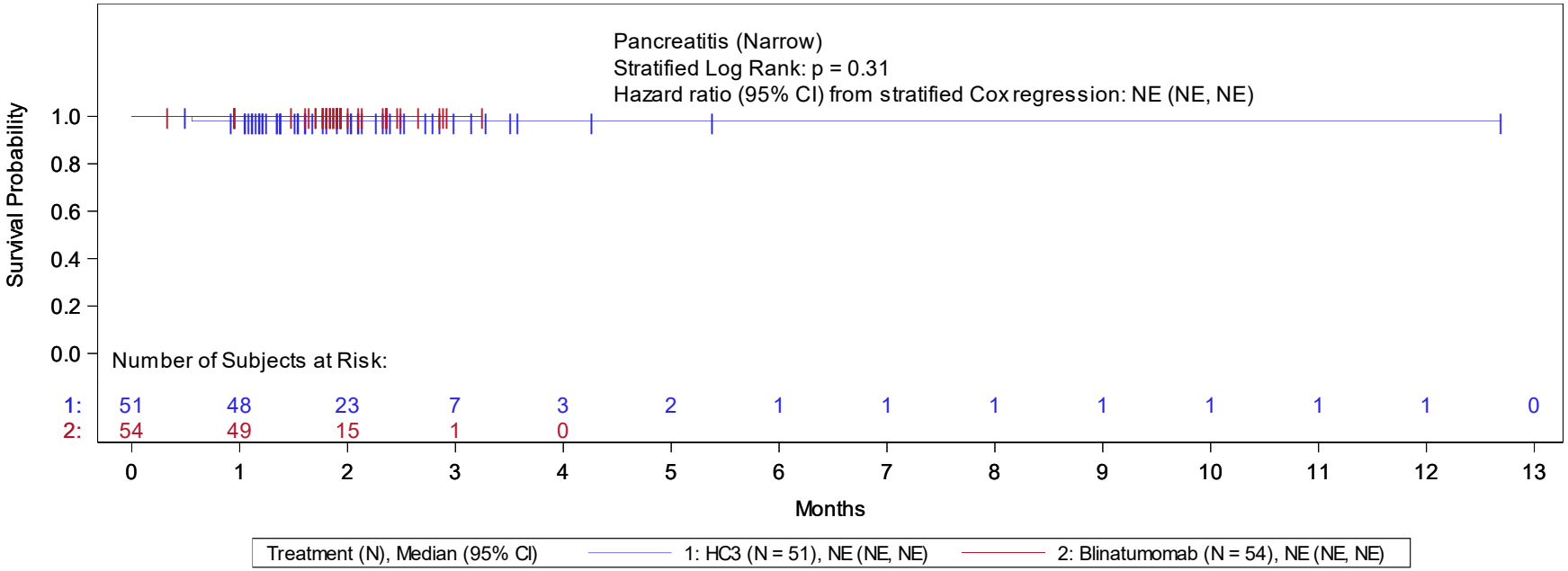

CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

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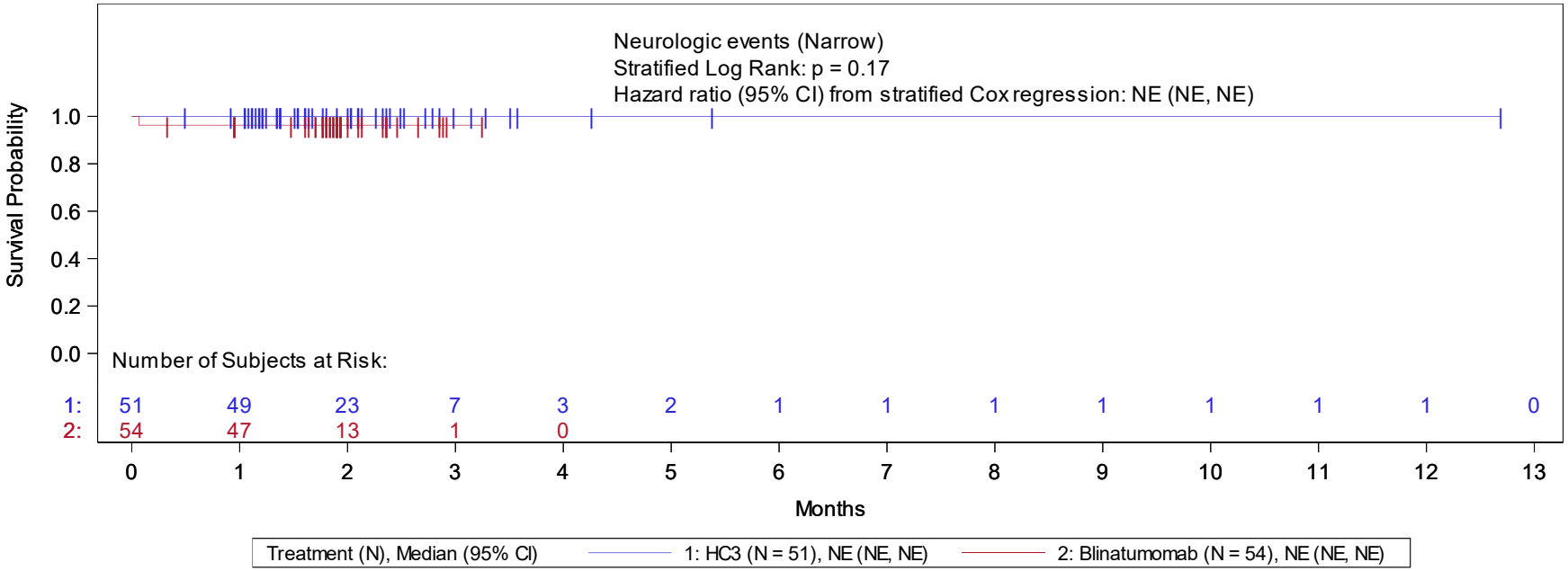
Figure 14-6.12.19. Kaplan-Meier Plot for Time to First Onset of Treatment Emergent Adverse Event of Interest Leading to Any Study Treatment Discontinuation (Safety Analysis Set)



CI = Confidence Interval. NE = Not estimable.
Censor indicated by vertical bar |.
Events of Interest with 0 events are not displayed.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
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Figure 14-6.12.20. Kaplan-Meier Plot for Time to First Onset of Fatal Treatment Emergent Adverse Event of Interest (Safety Analysis Set)

--- No event observed. ---

No fatal event observed in any event of interest.
Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-eoi-saf.sas
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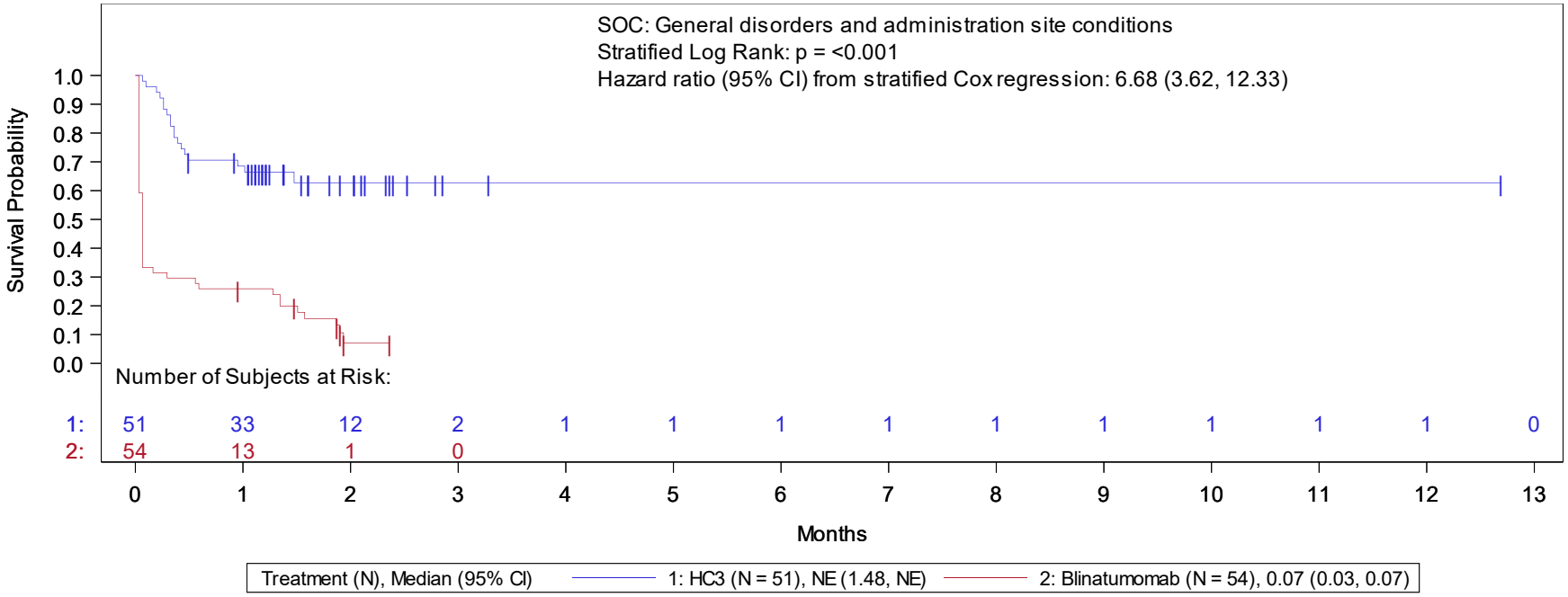
Source Data: adampc.adsl, adam.adtteae

Figure 14-6.15.4. Kaplan-Meier Plot for Time to First Onset of Treatment-Emergent Adverse Events (at least 10 % in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)



N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-ge10-soc-pref-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-015-004-km-ae-ont-ge10-soc-pref-saf.rtf
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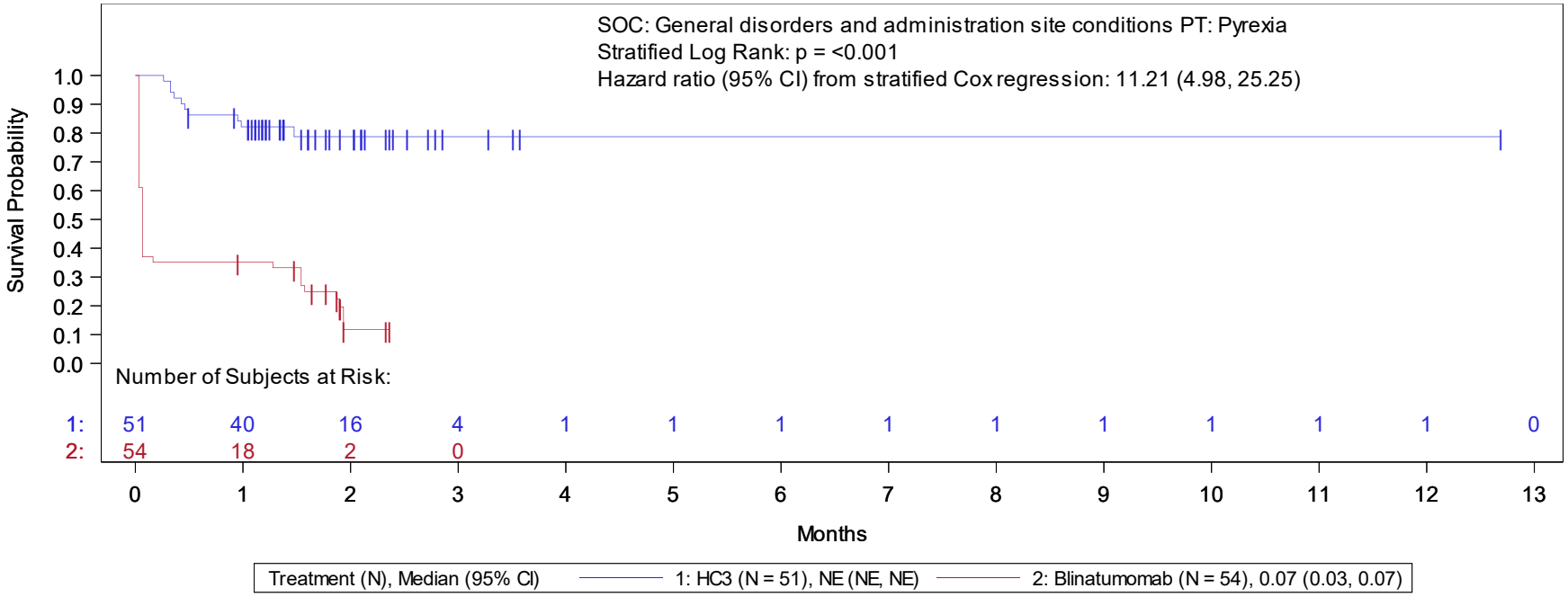
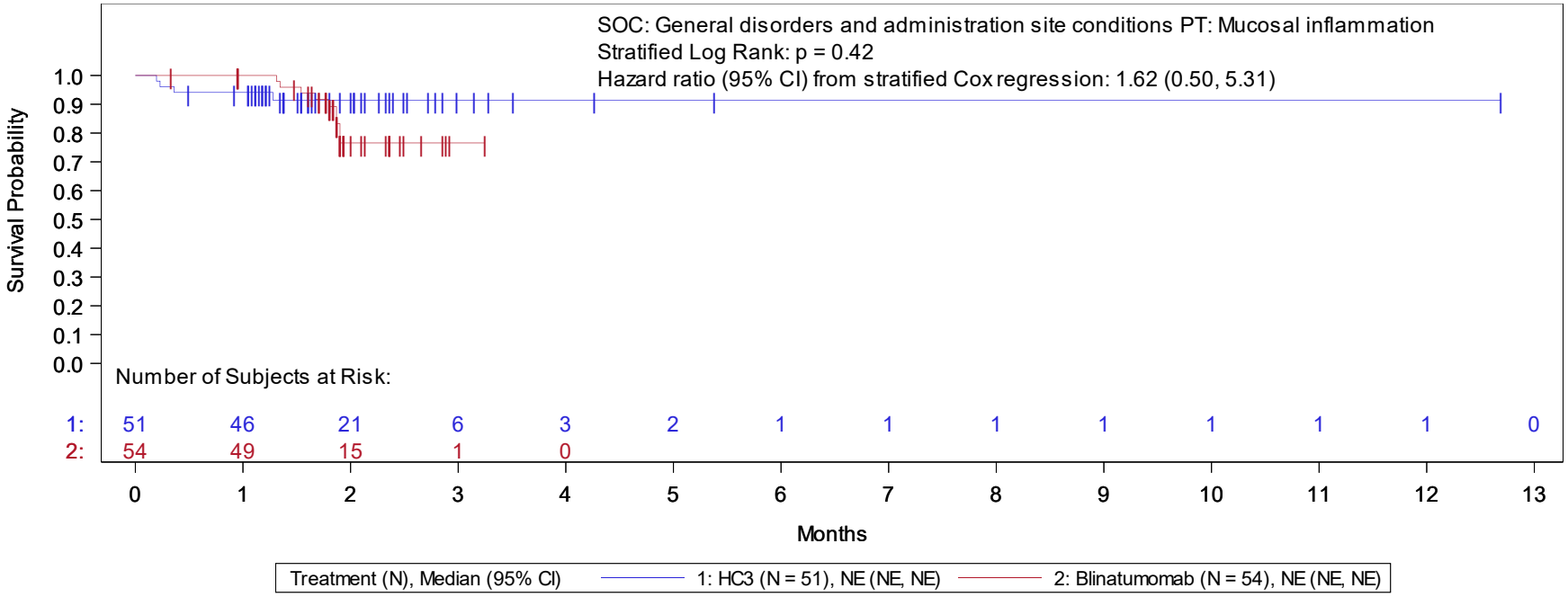


N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

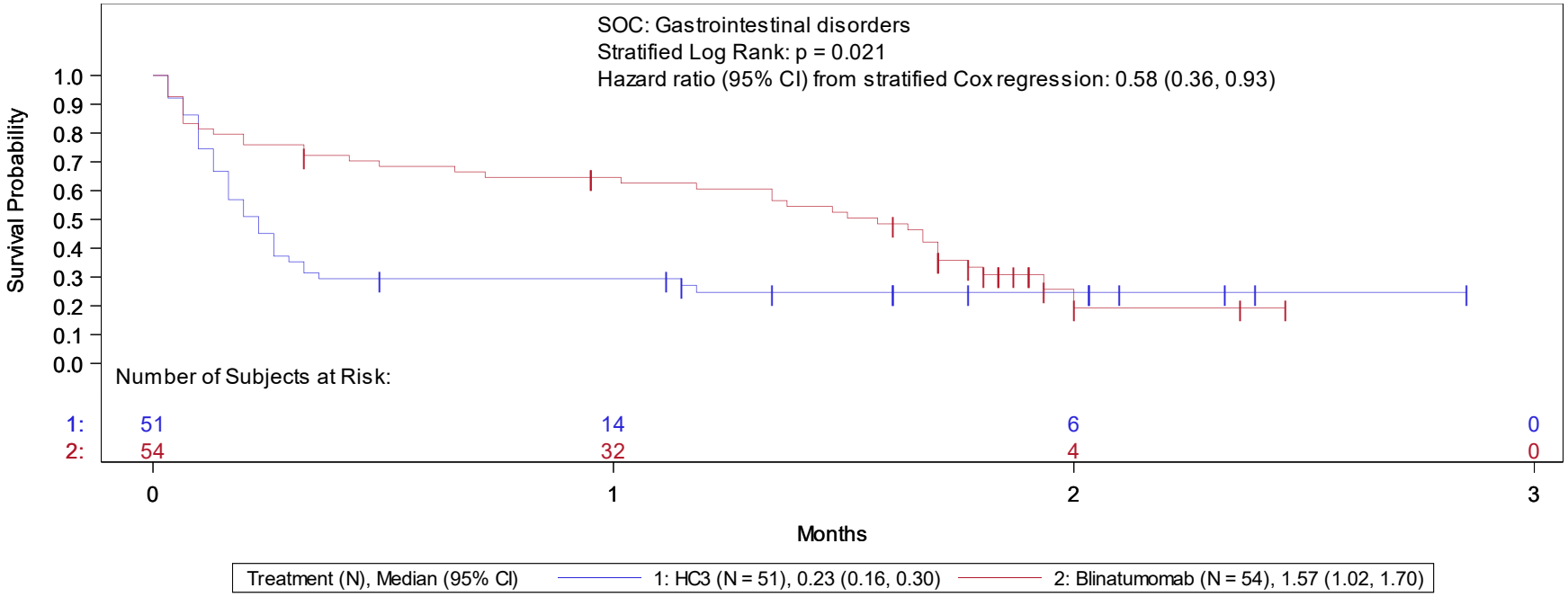
Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-ge10-soc-pref-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-015-004-km-ae-ont-ge10-soc-pref-saf.rtf
(Date Generated: 19JAN2021 : 01:47) Source Data: adampc.adsl, outtab.t_aette_socpref



N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

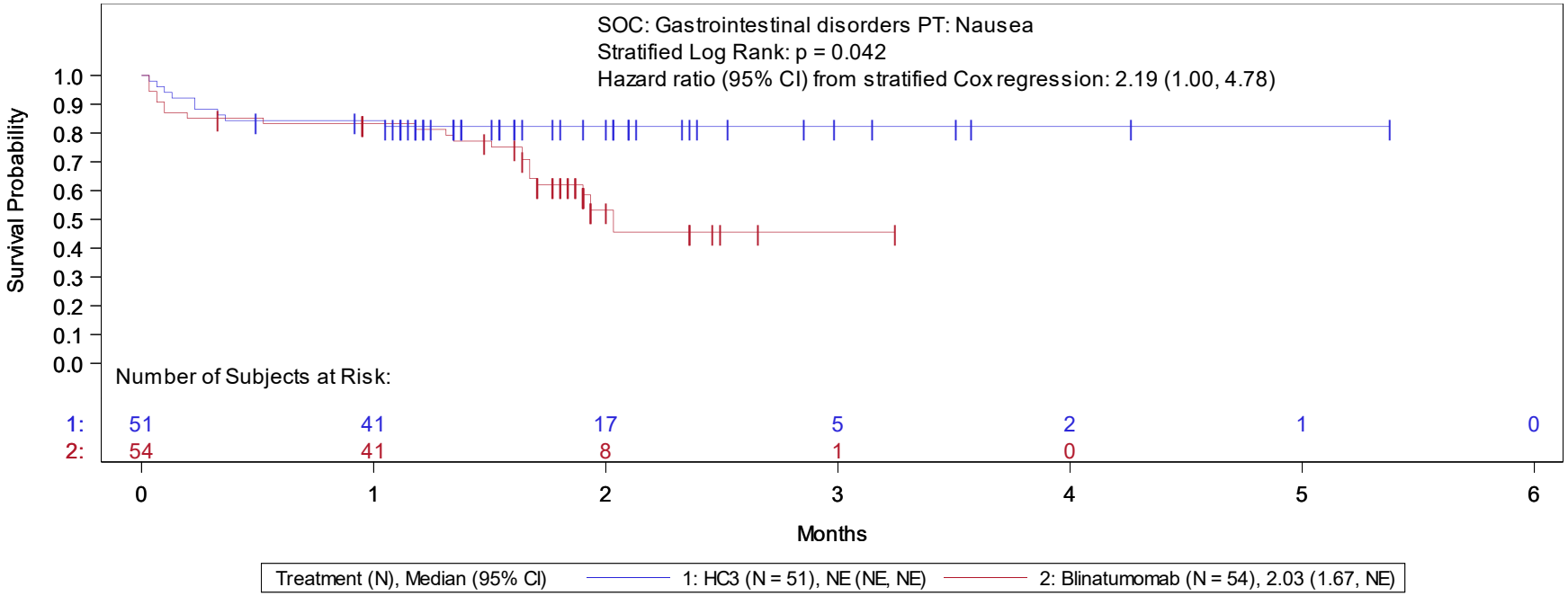
Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-ge10-soc-pref-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-015-004-km-ae-ont-ge10-soc-pref-saf.rtf
(Date Generated: 19JAN2021 : 01:47) Source Data: adampc.adsl, outtab.t_aette_socpref



N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

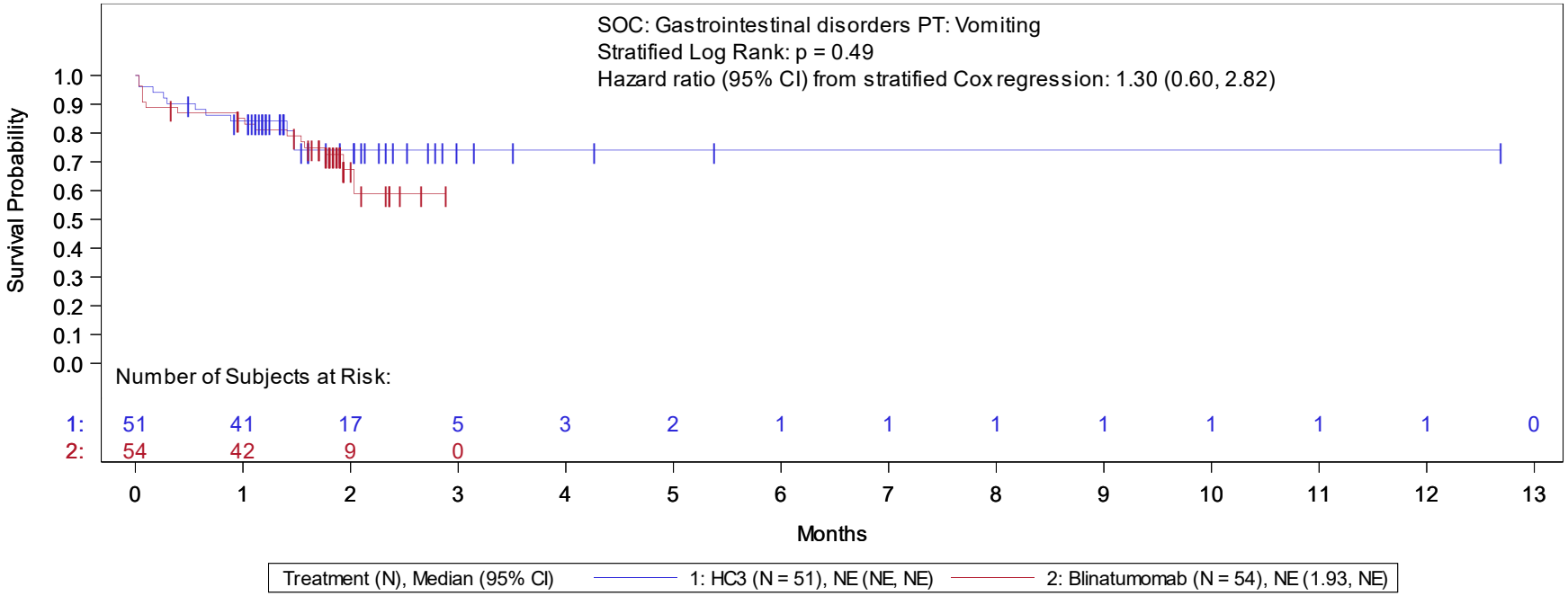
Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-ge10-soc-pref-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-015-004-km-ae-ont-ge10-soc-pref-saf.rtf
(Date Generated: 19JAN2021 : 01:47) Source Data: adampc.adsl, outtab.t_aette_socpref



N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-ge10-soc-pref-saf.sas
Output: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/output/f14-06-015-004-km-ae-ont-ge10-soc-pref-saf.rtf
(Date Generated: 19JAN2021 : 01:47) Source Data: adampc.adsl, outtab.t_aette_socpref



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Data cut-off date: 17JUL2019

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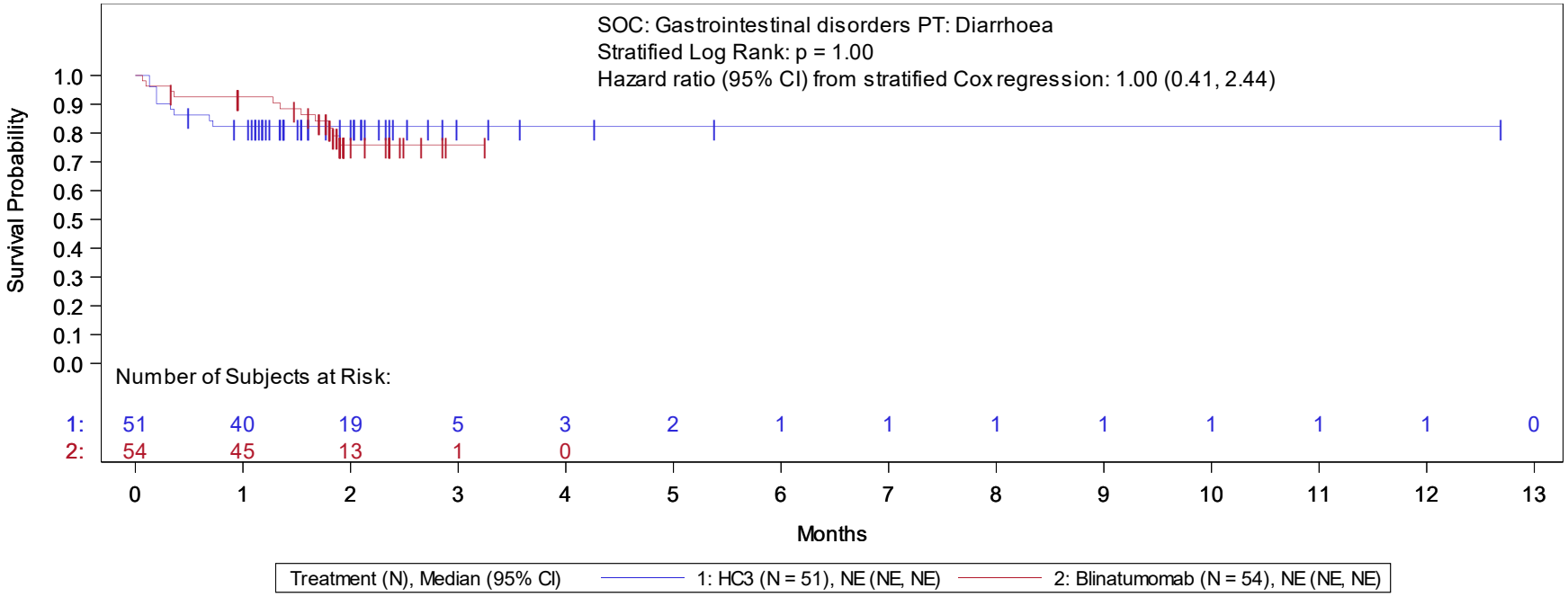

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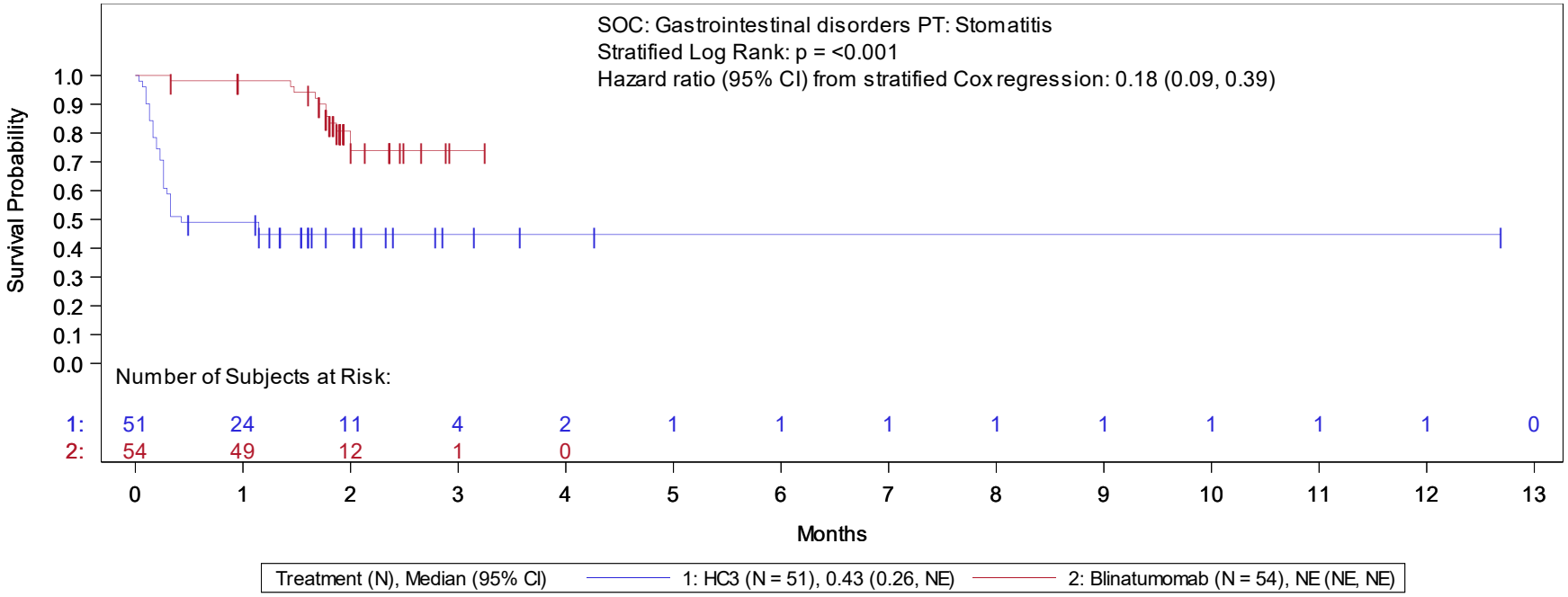

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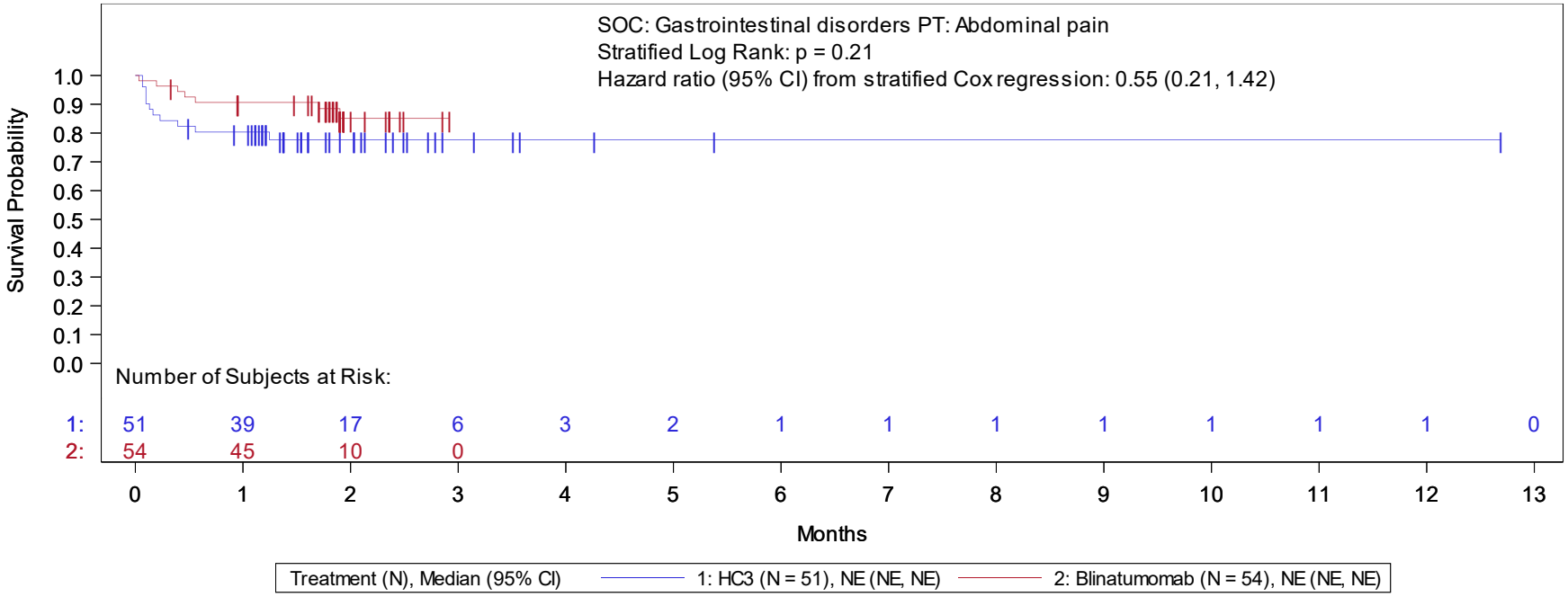

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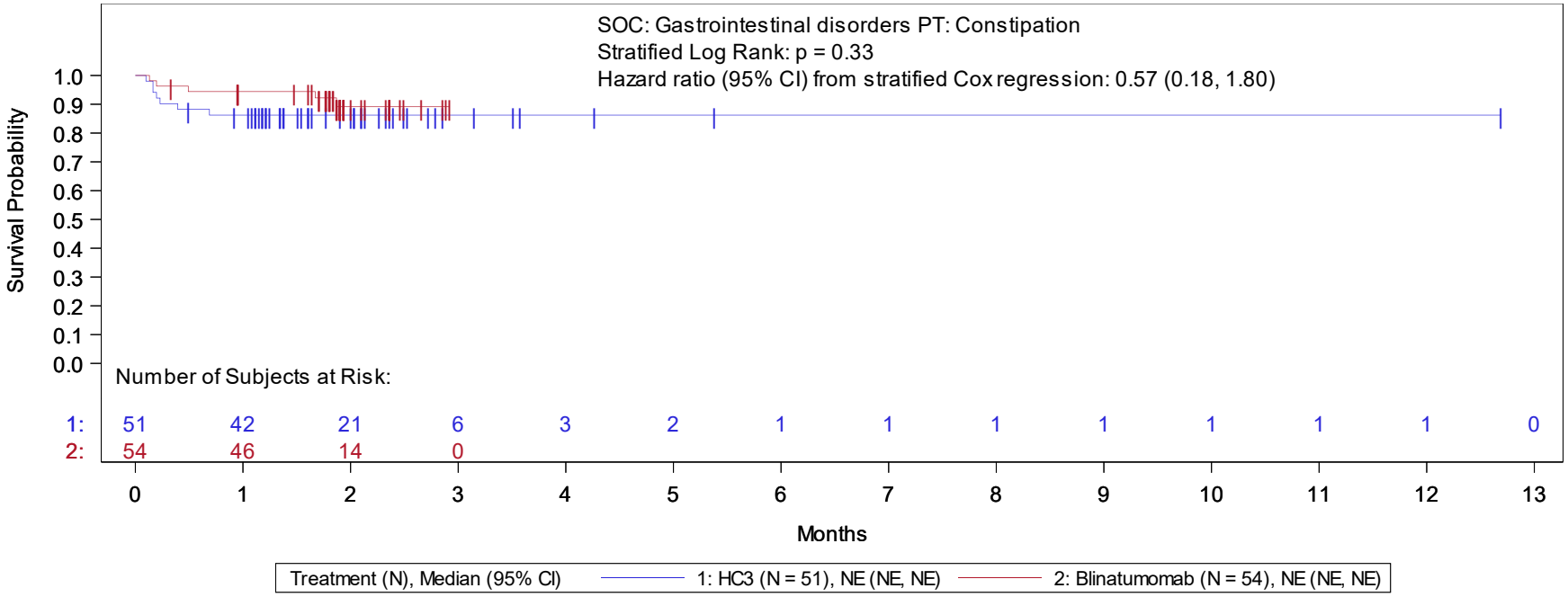

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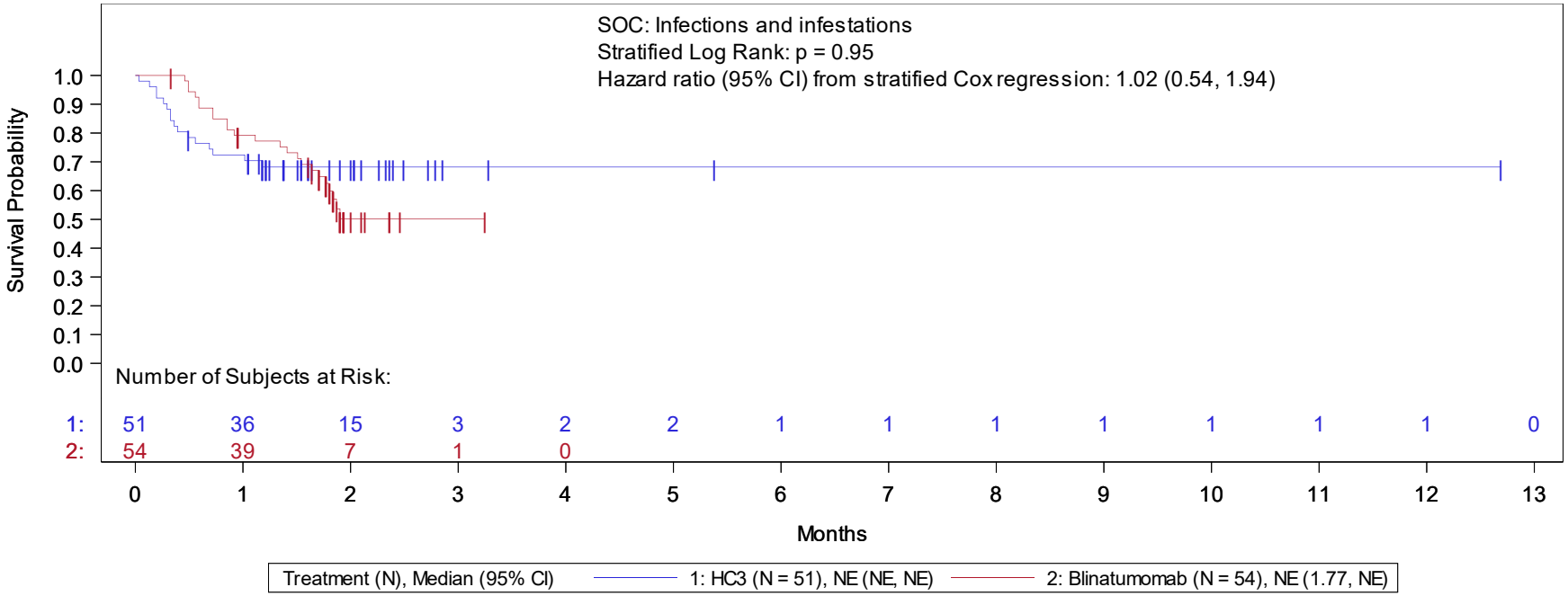

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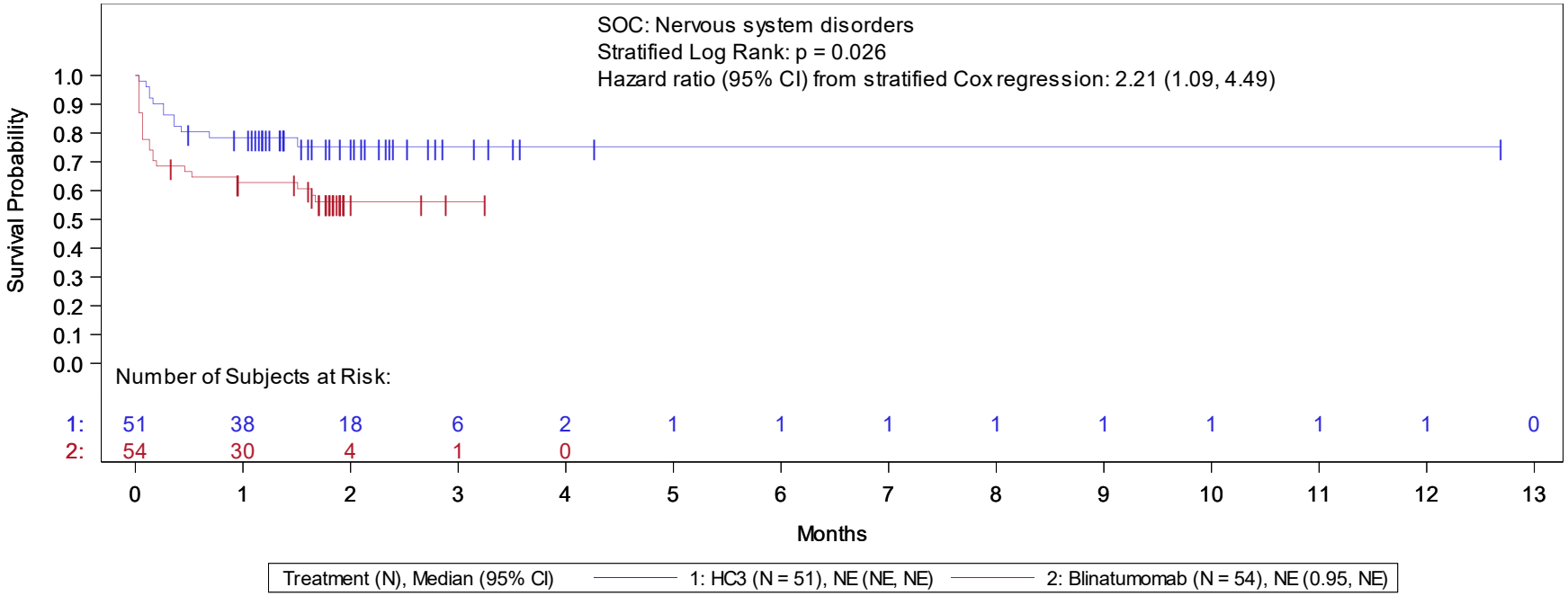

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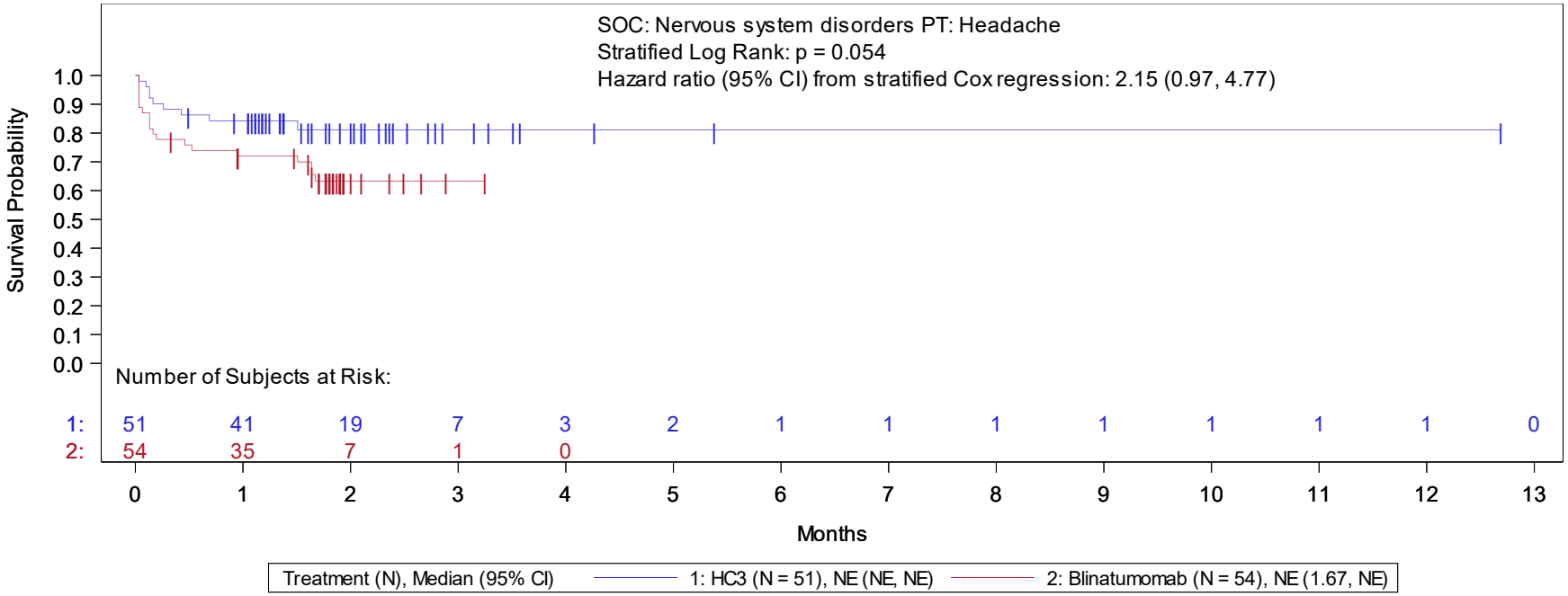

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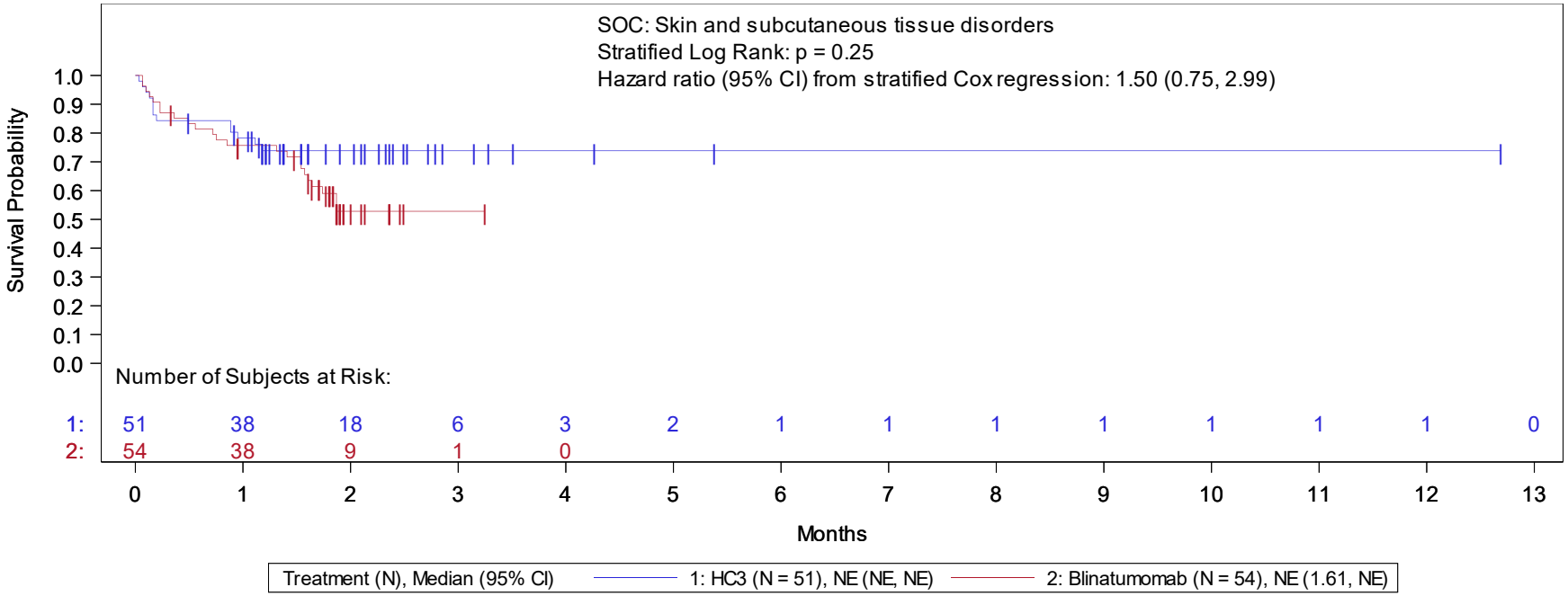

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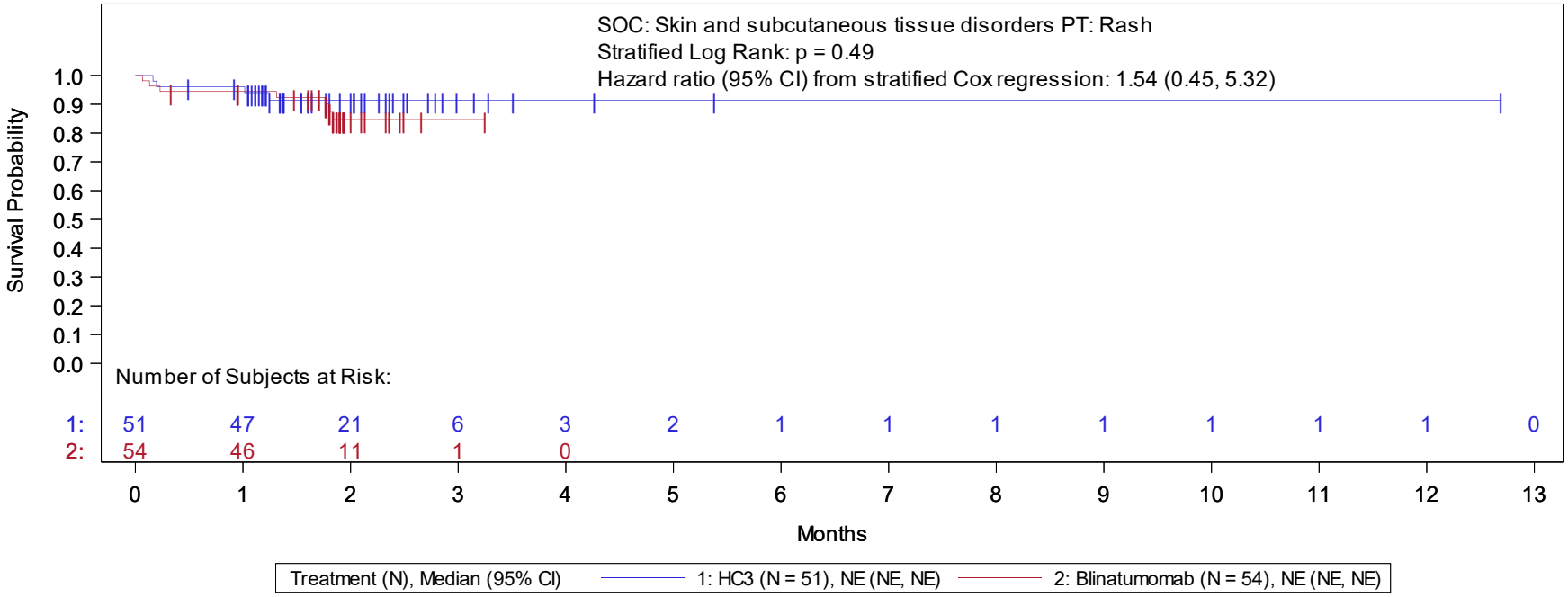

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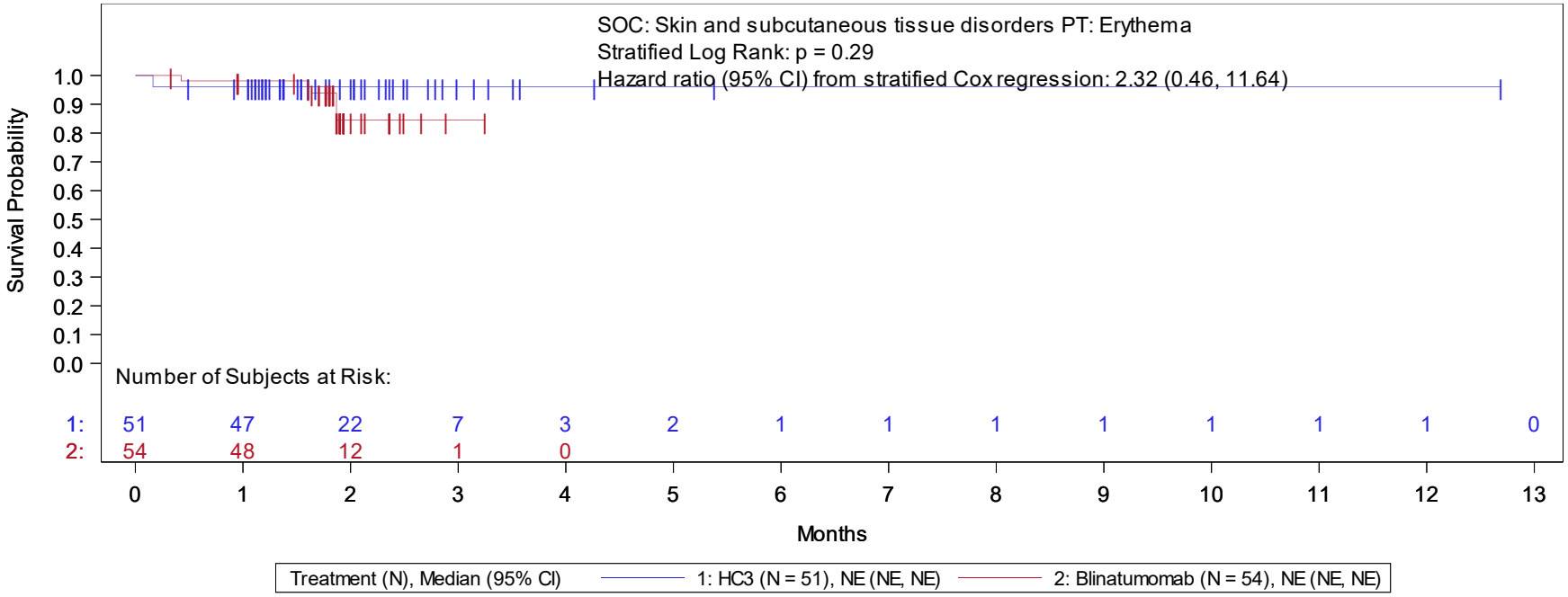

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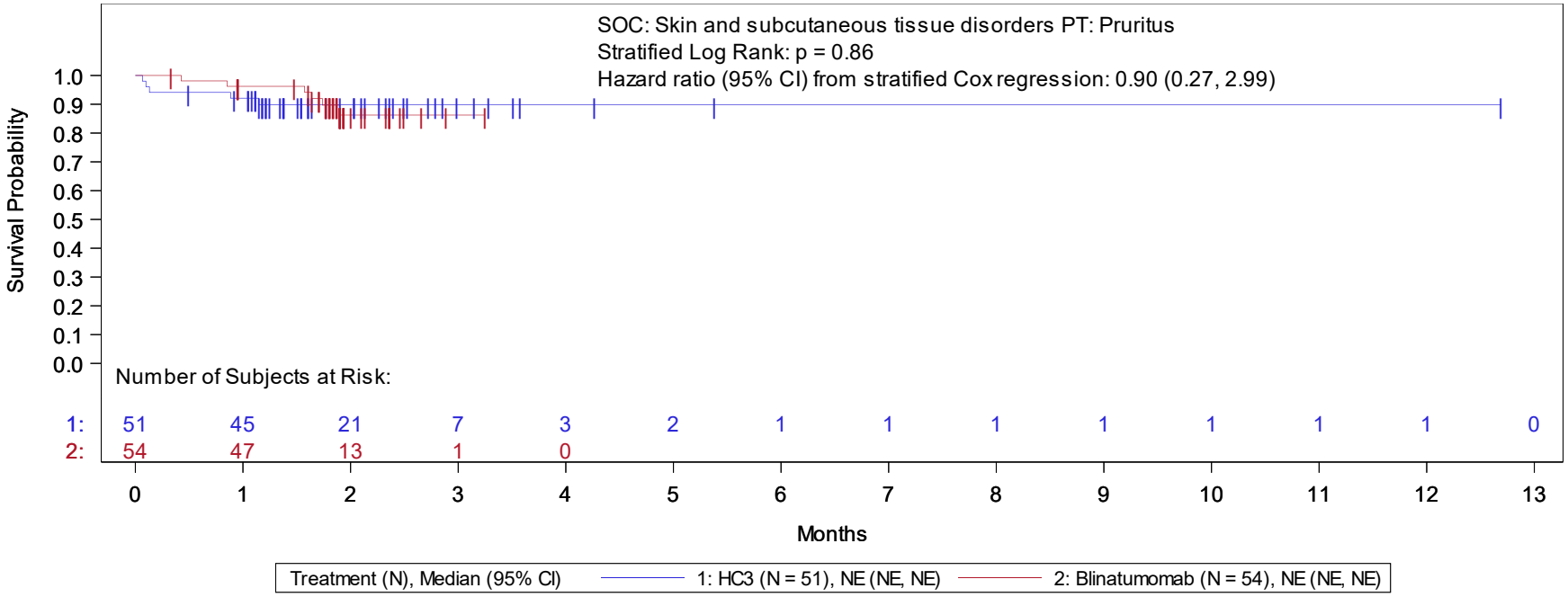

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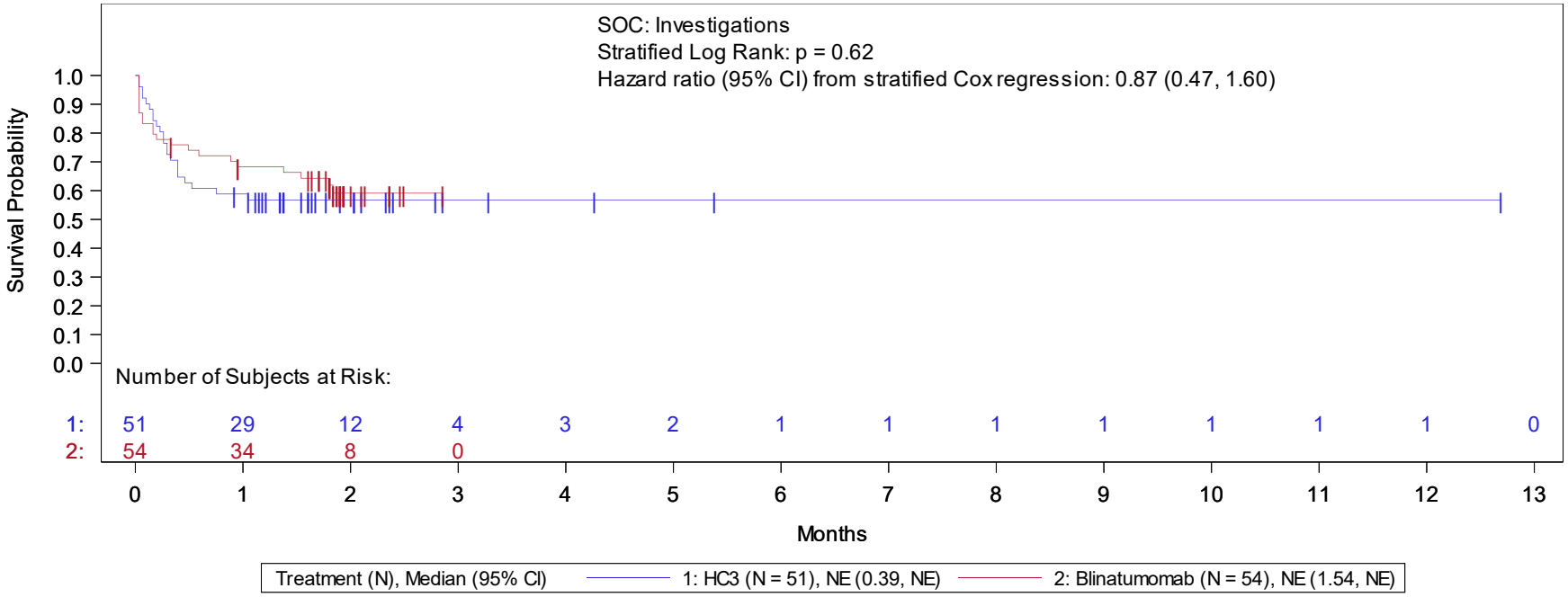

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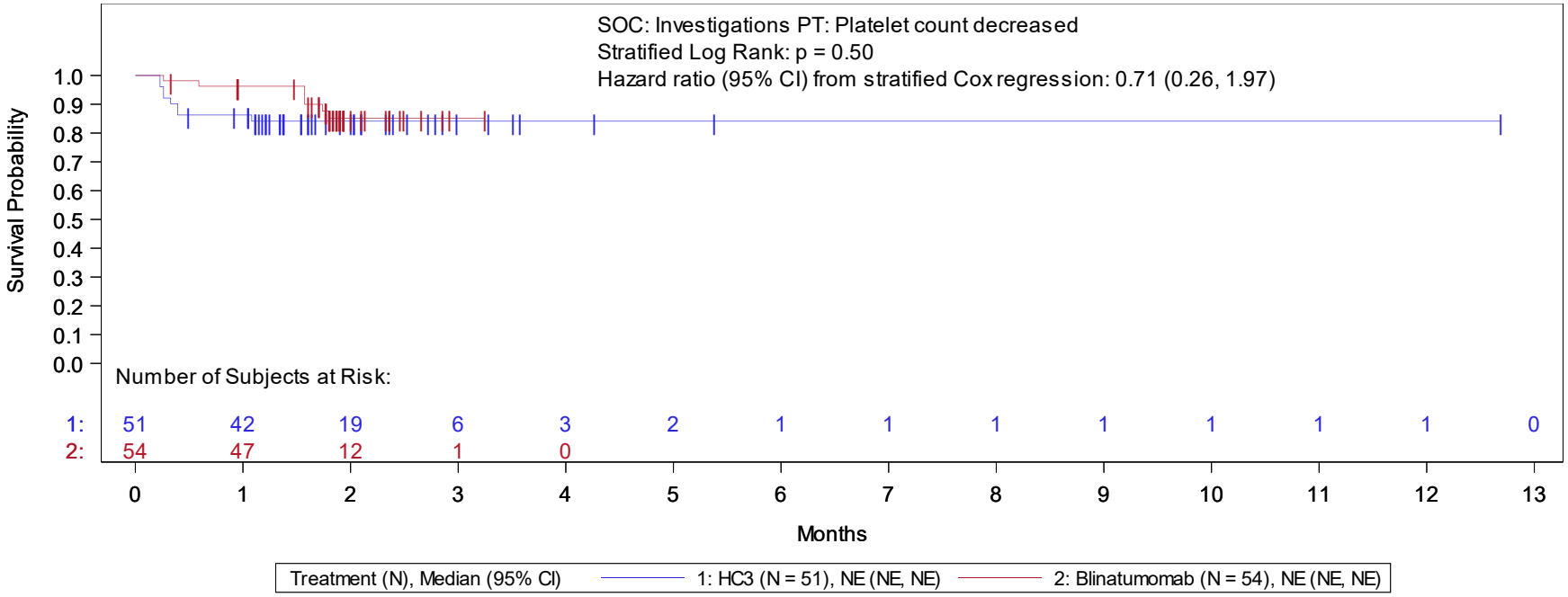

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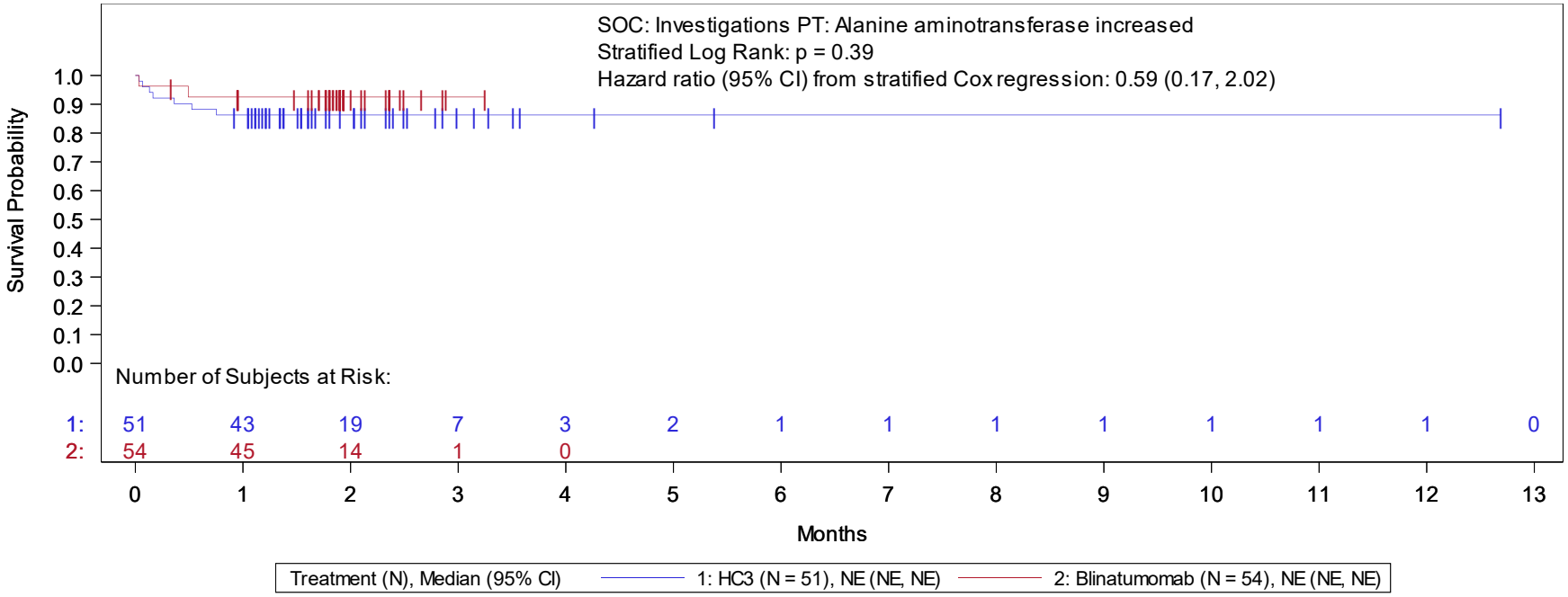

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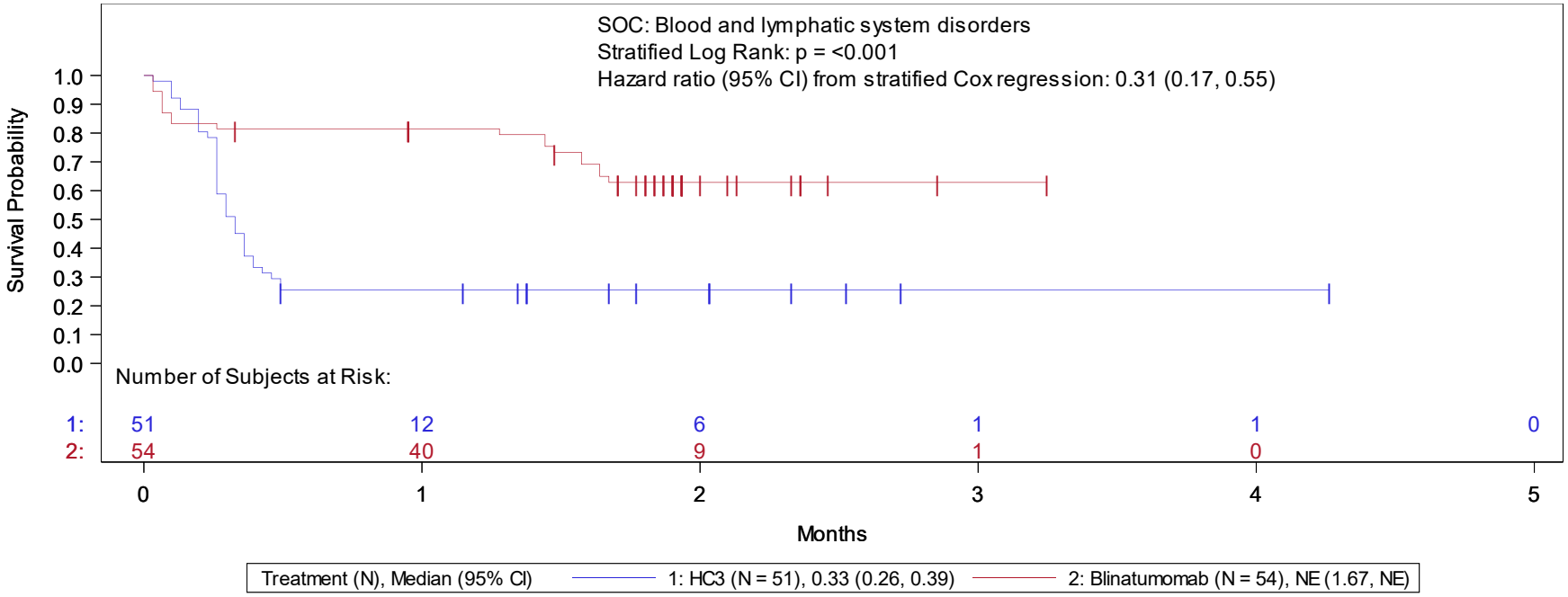

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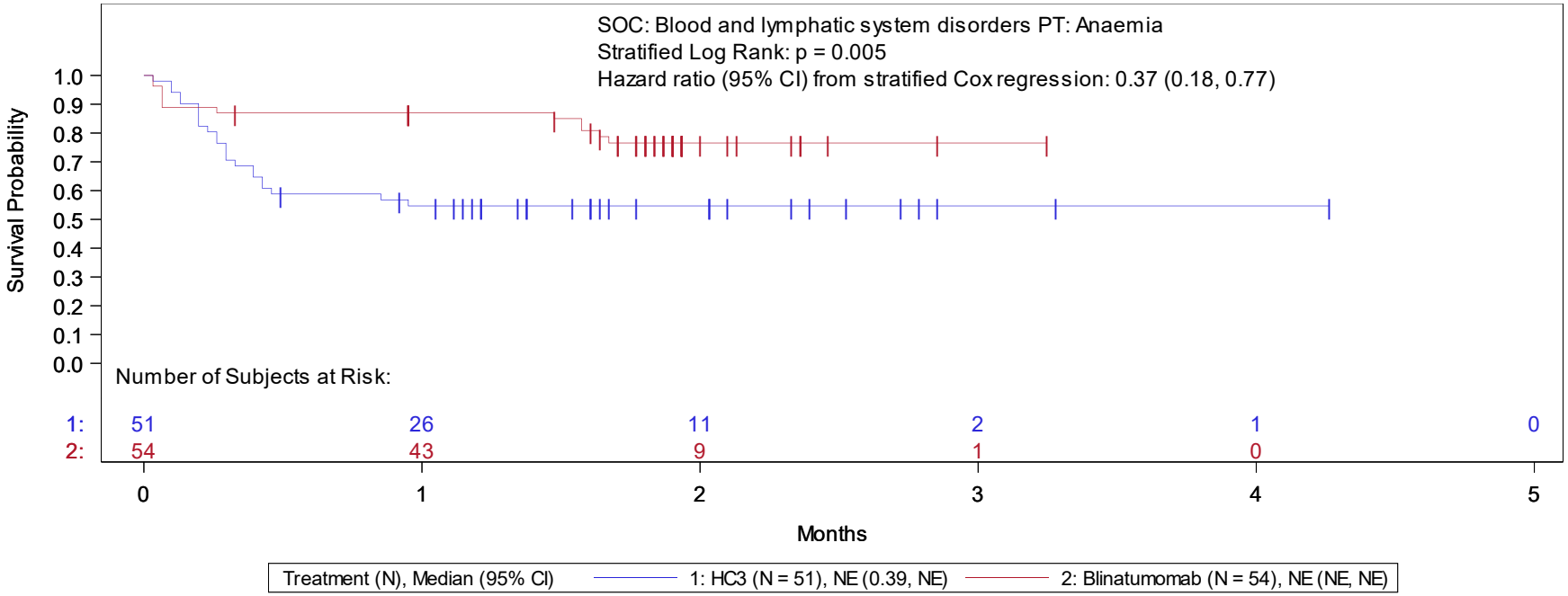

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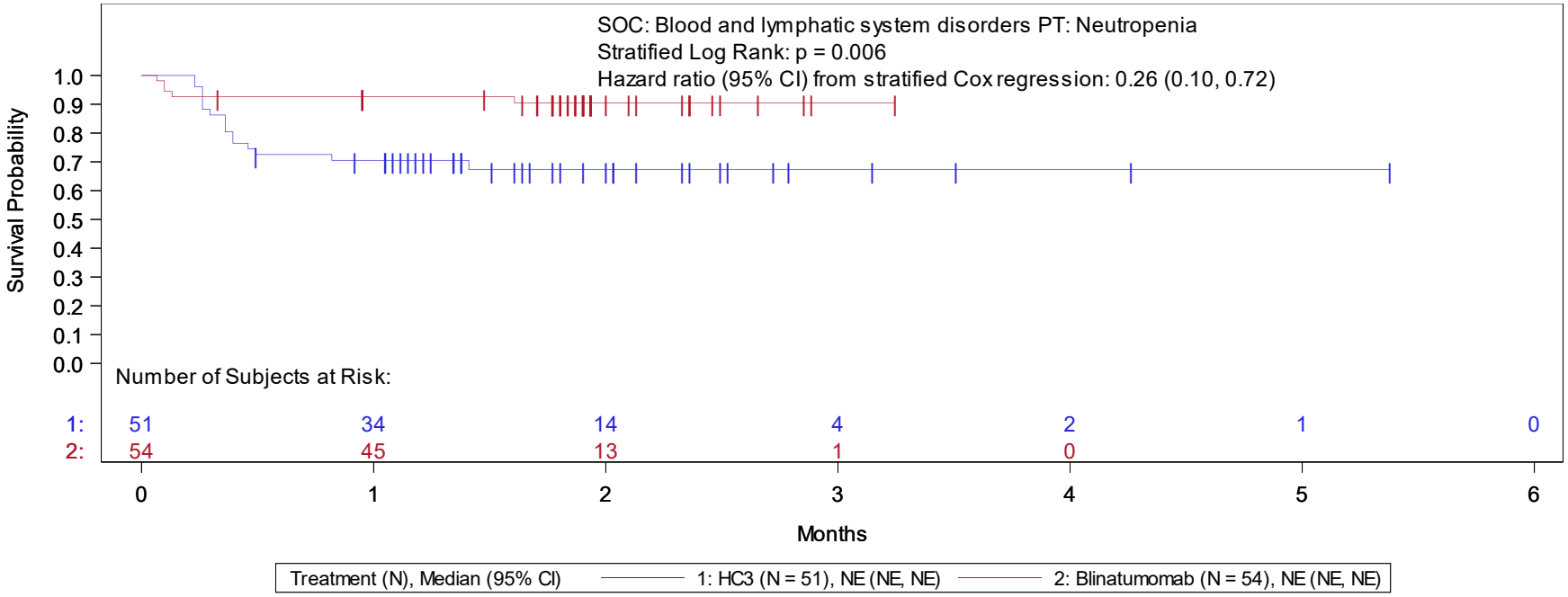

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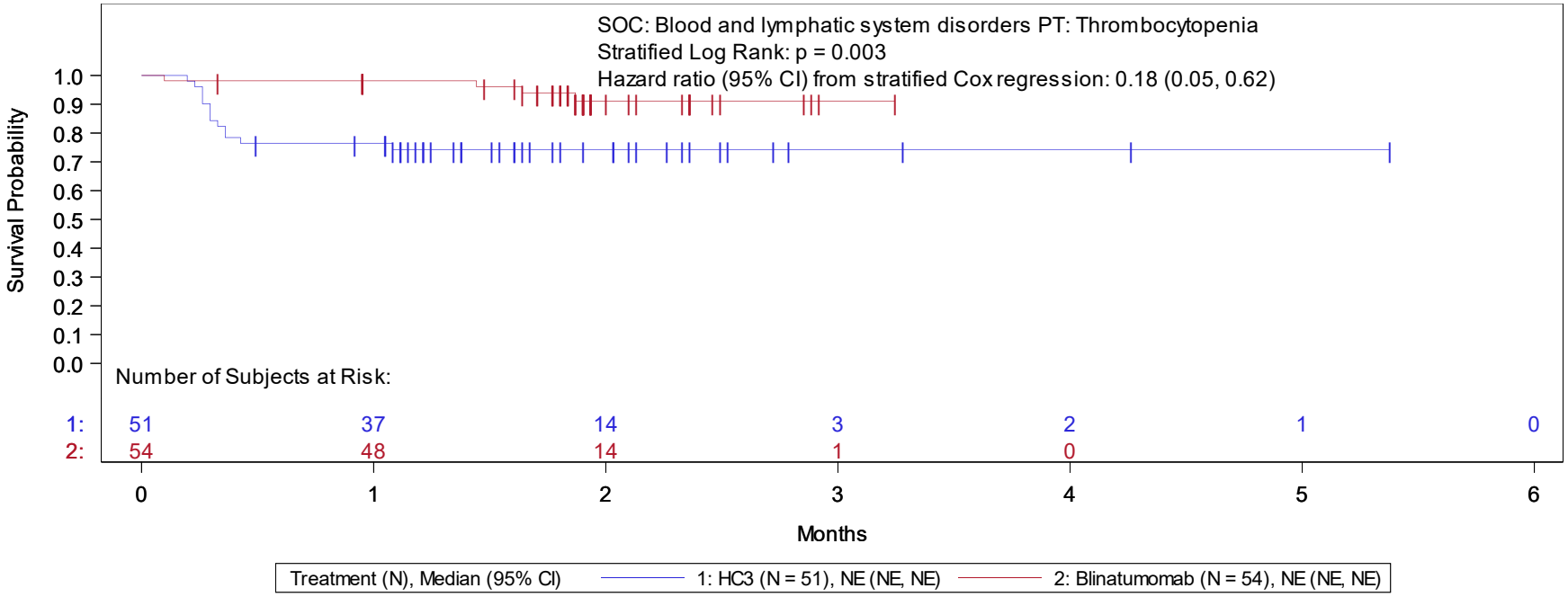

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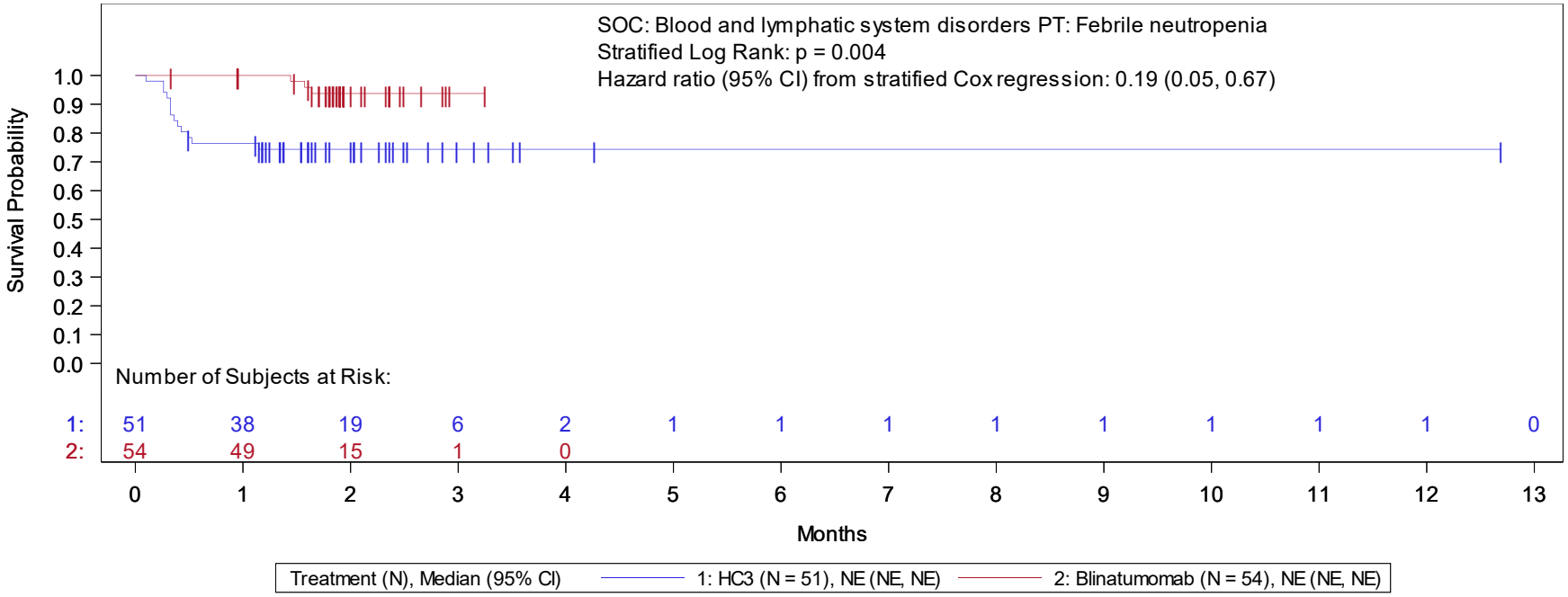

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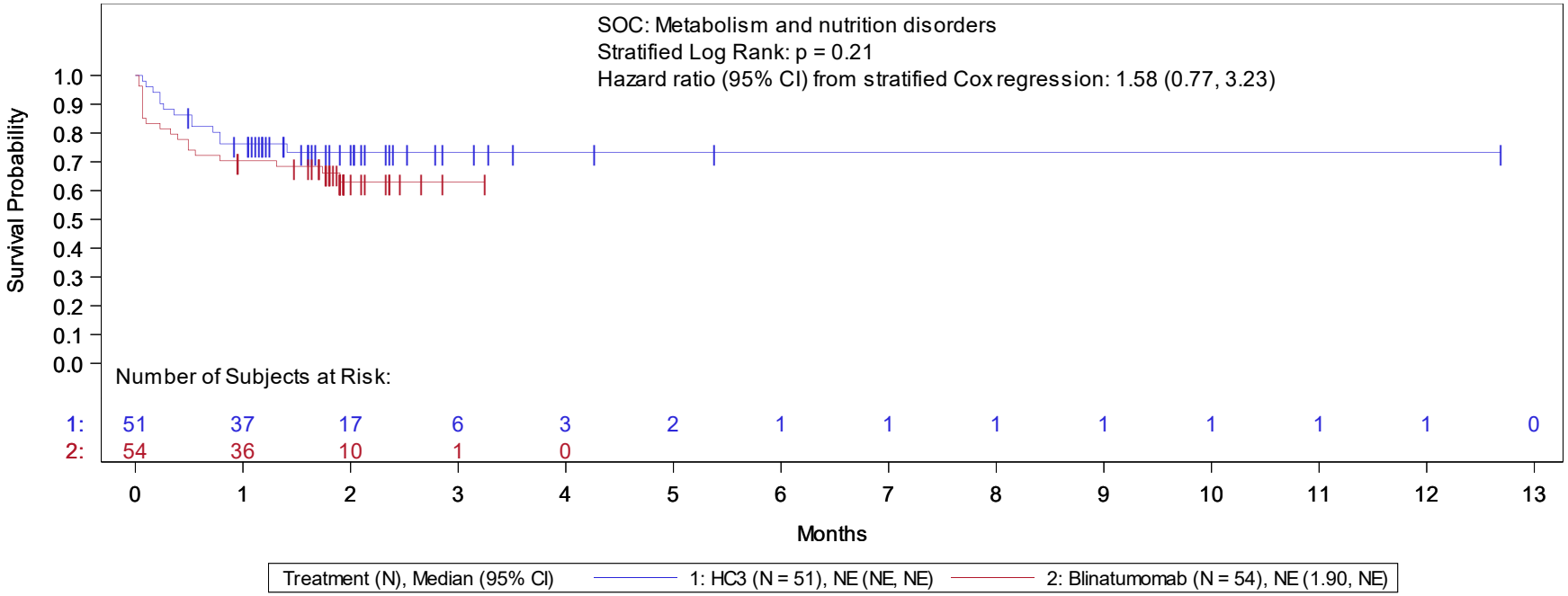

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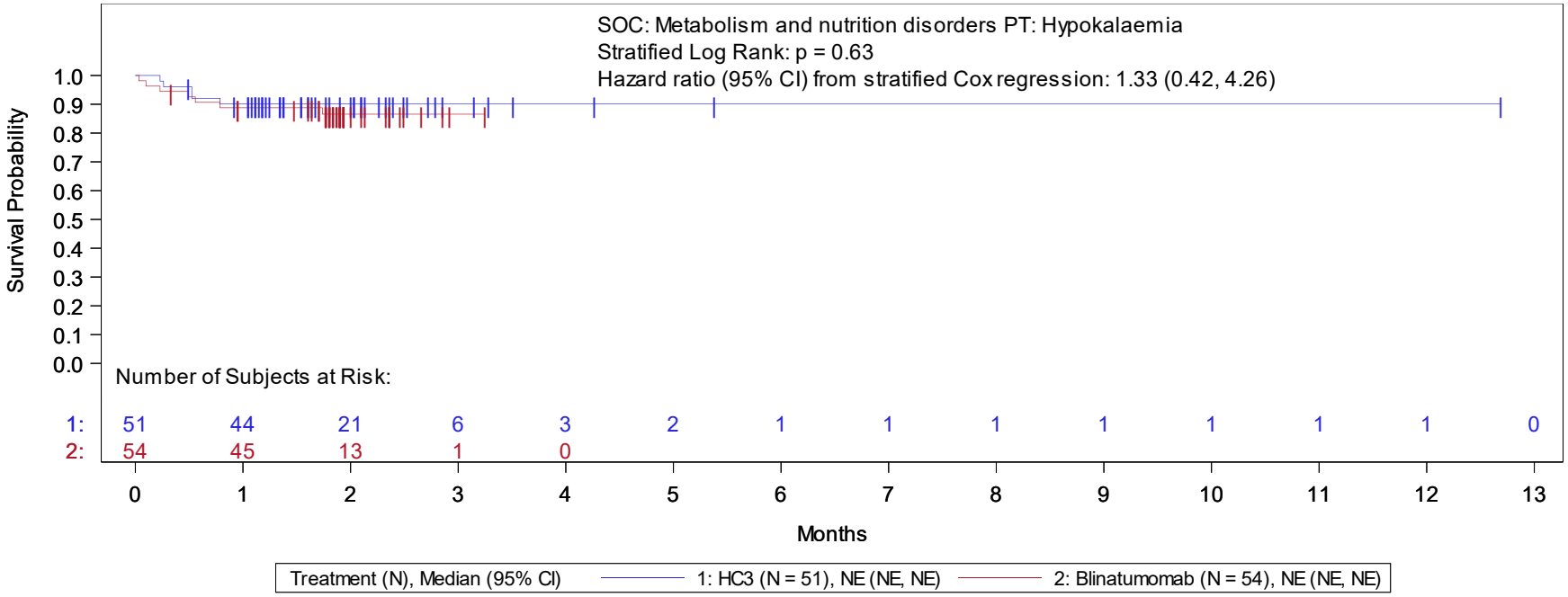

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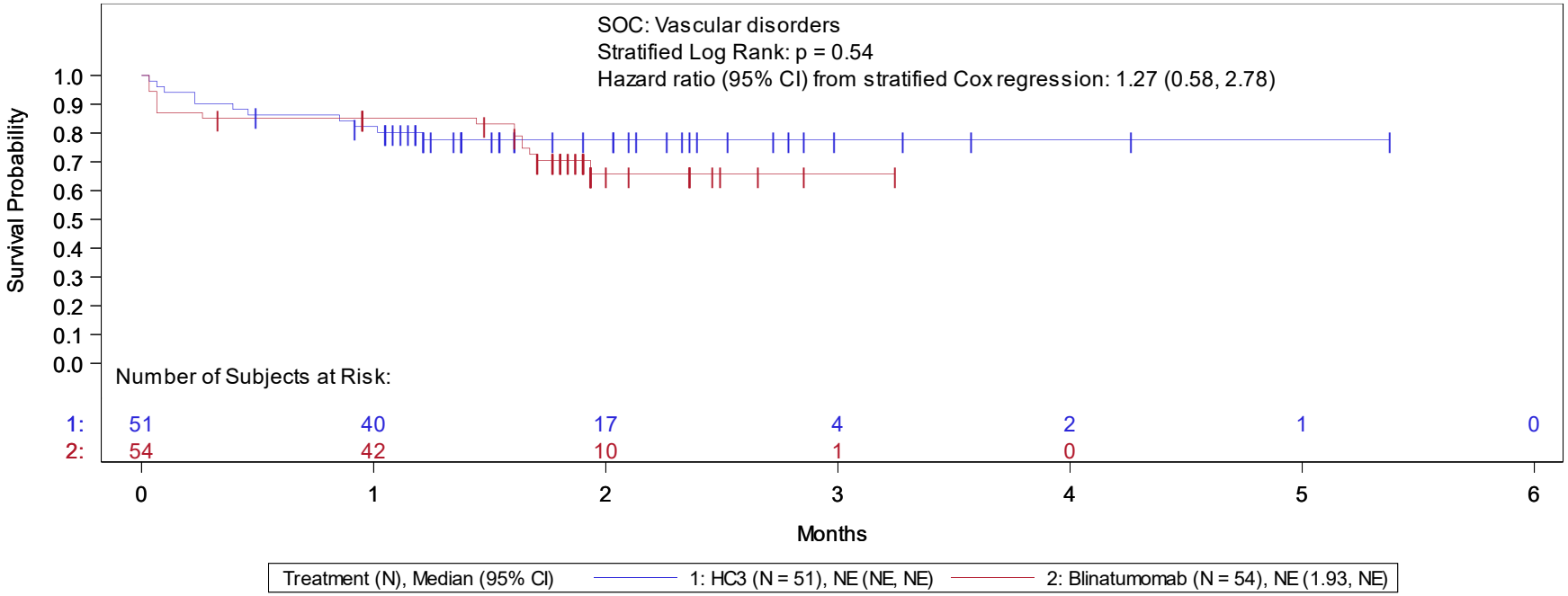

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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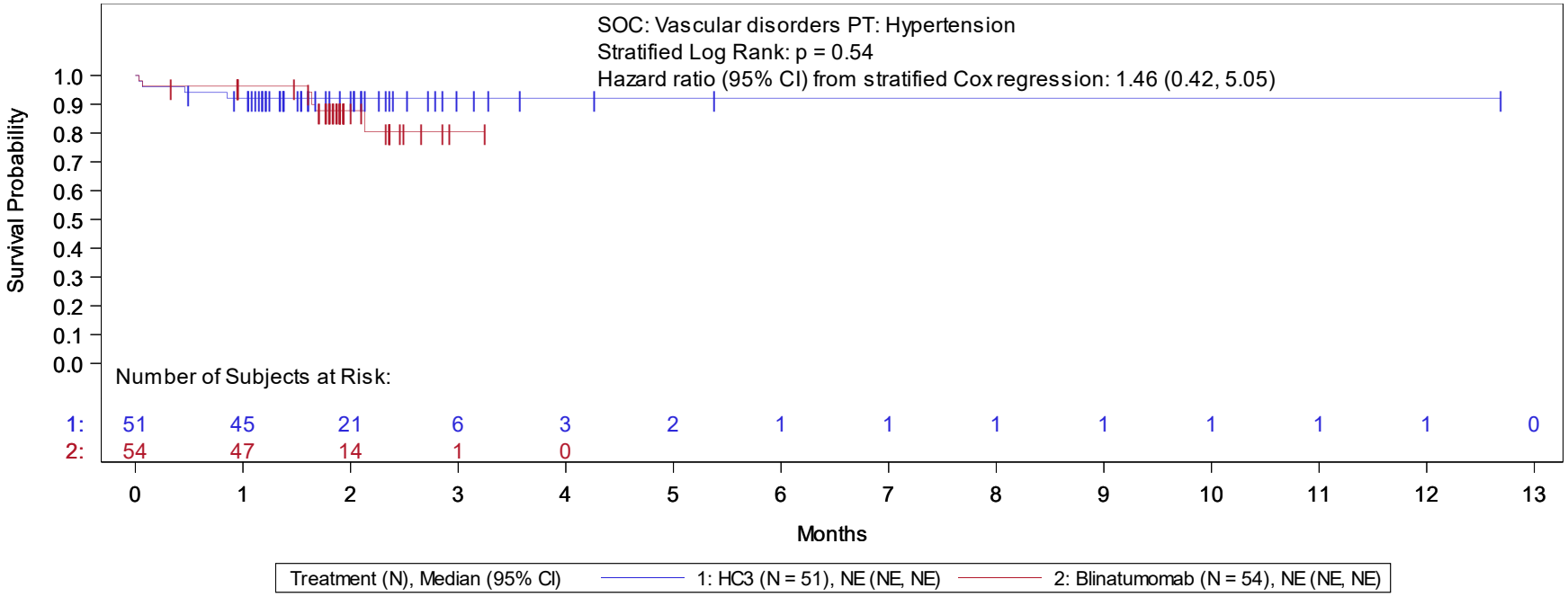

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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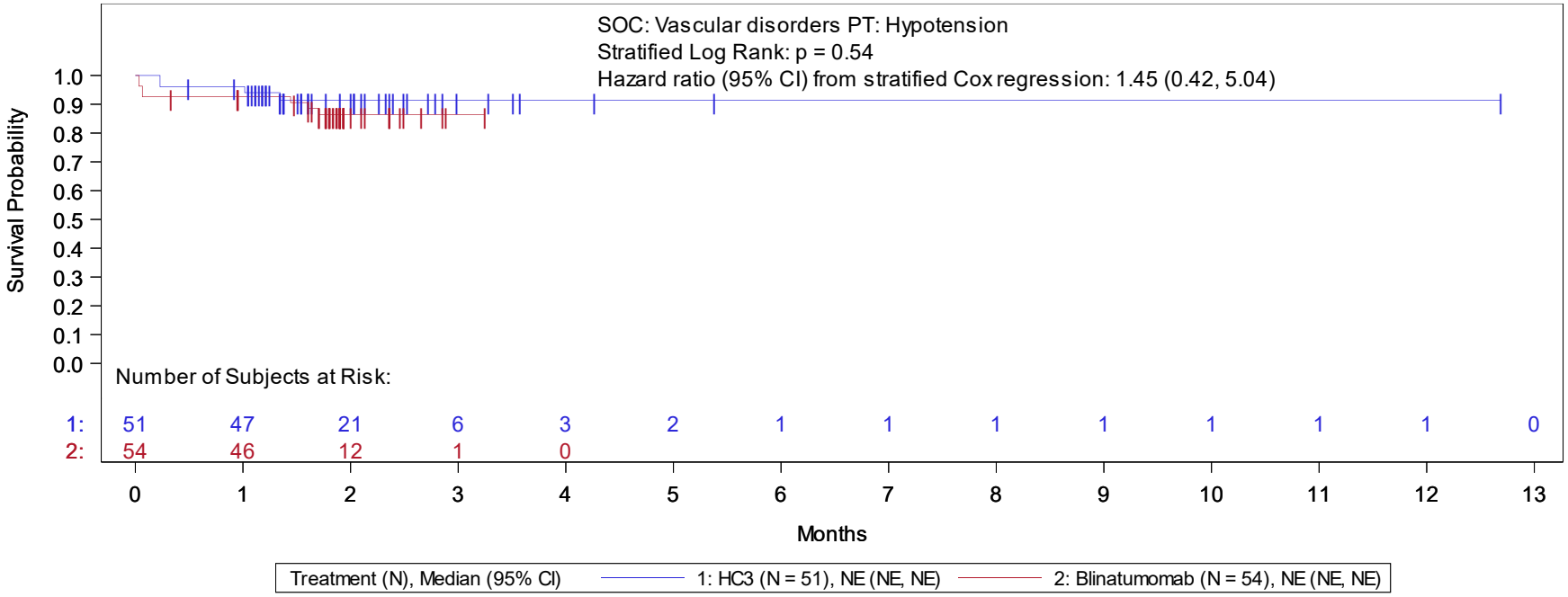

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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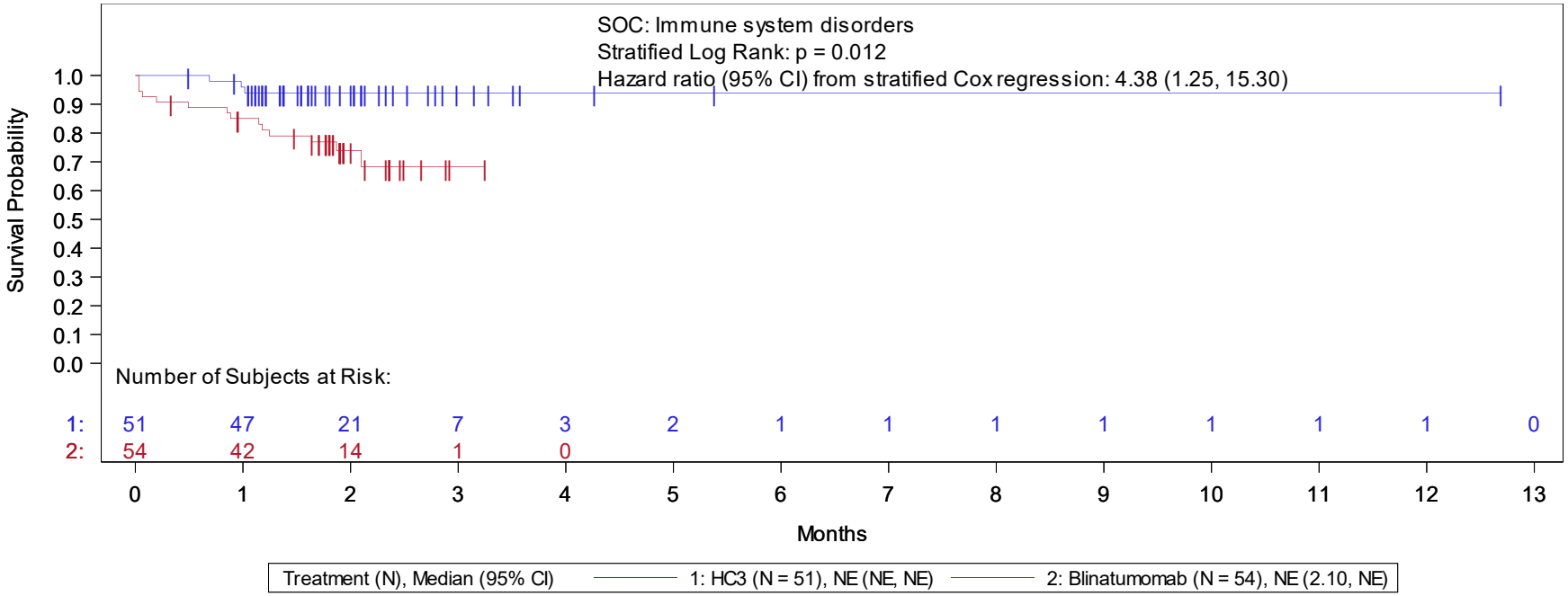

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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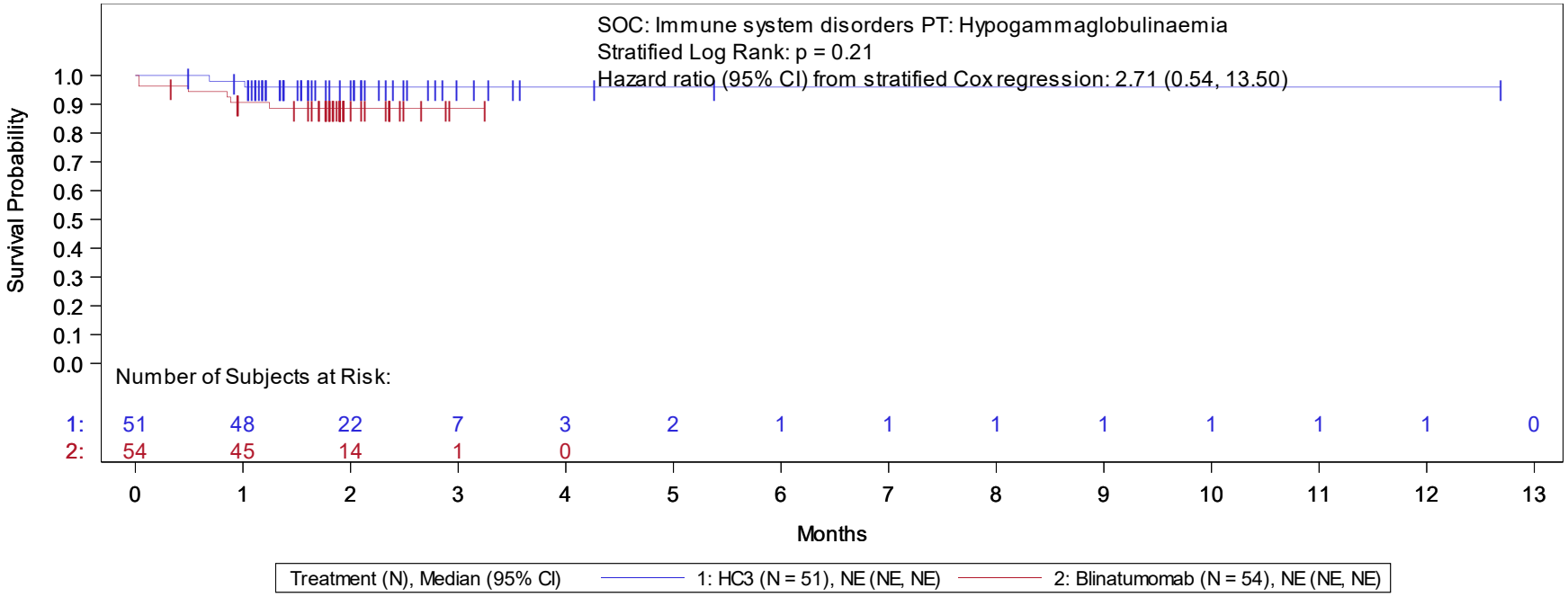

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

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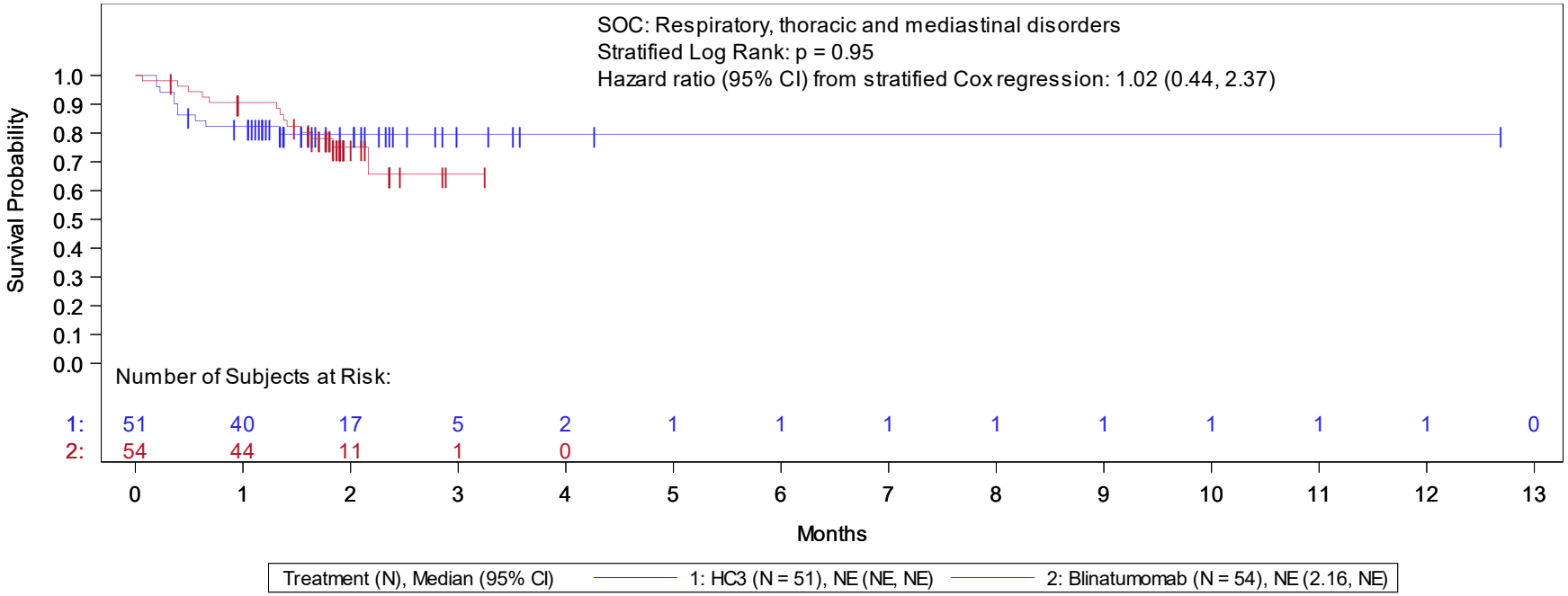

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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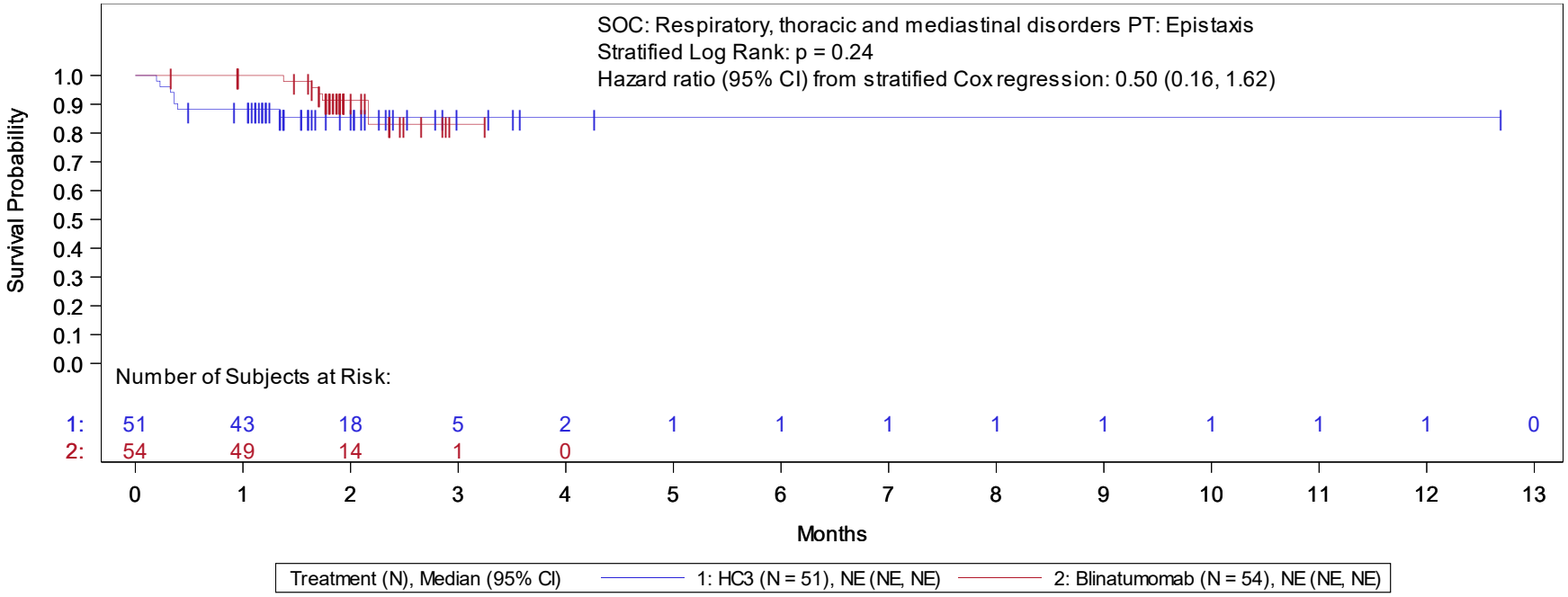

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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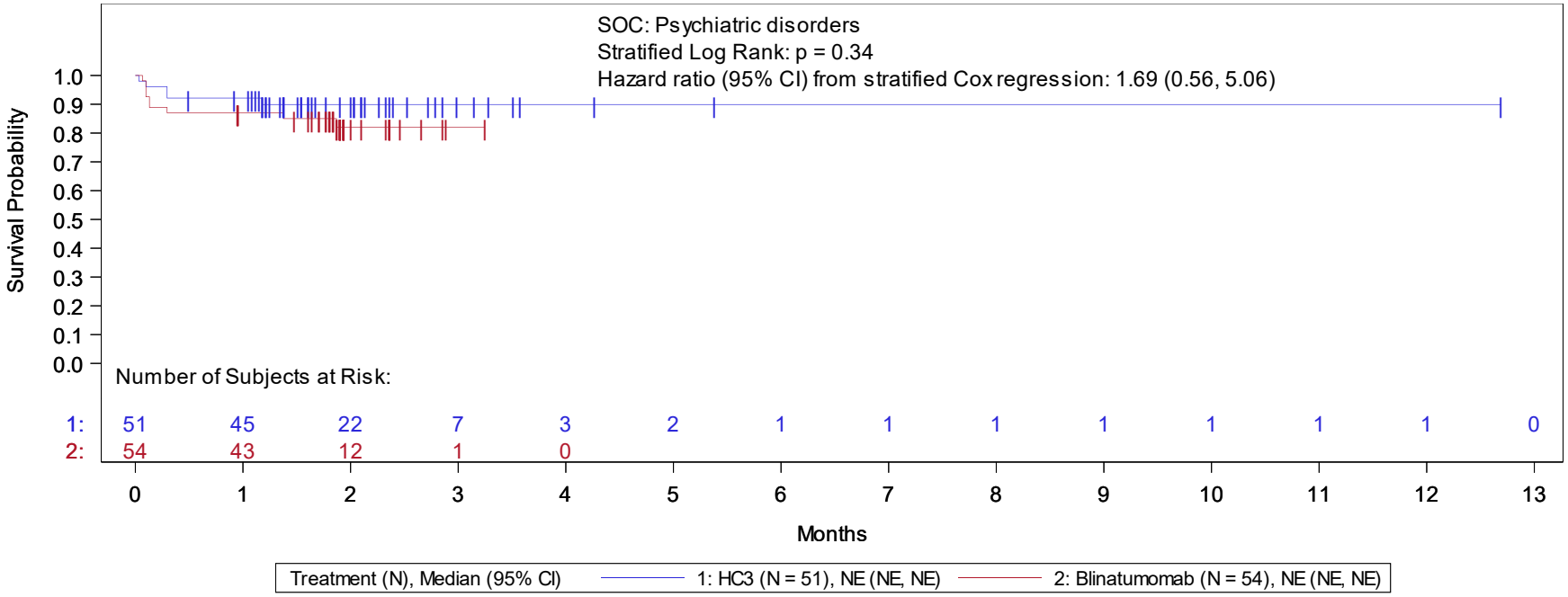

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

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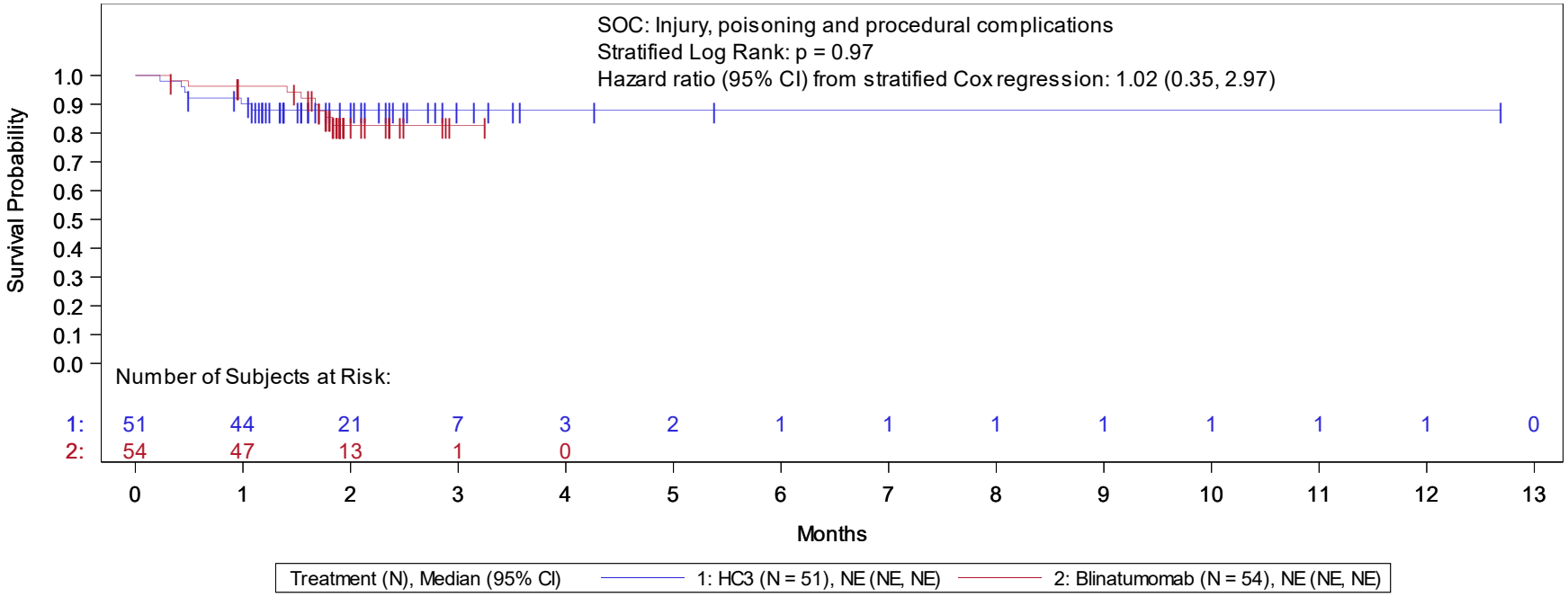

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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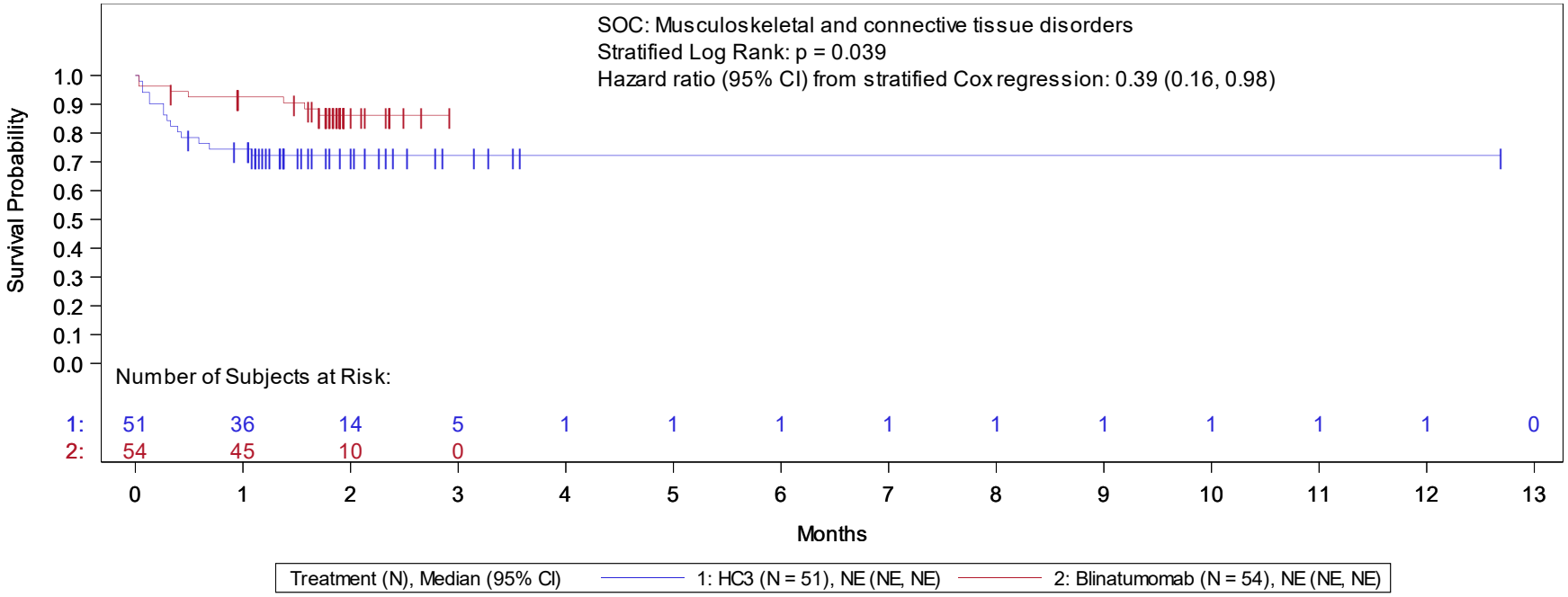

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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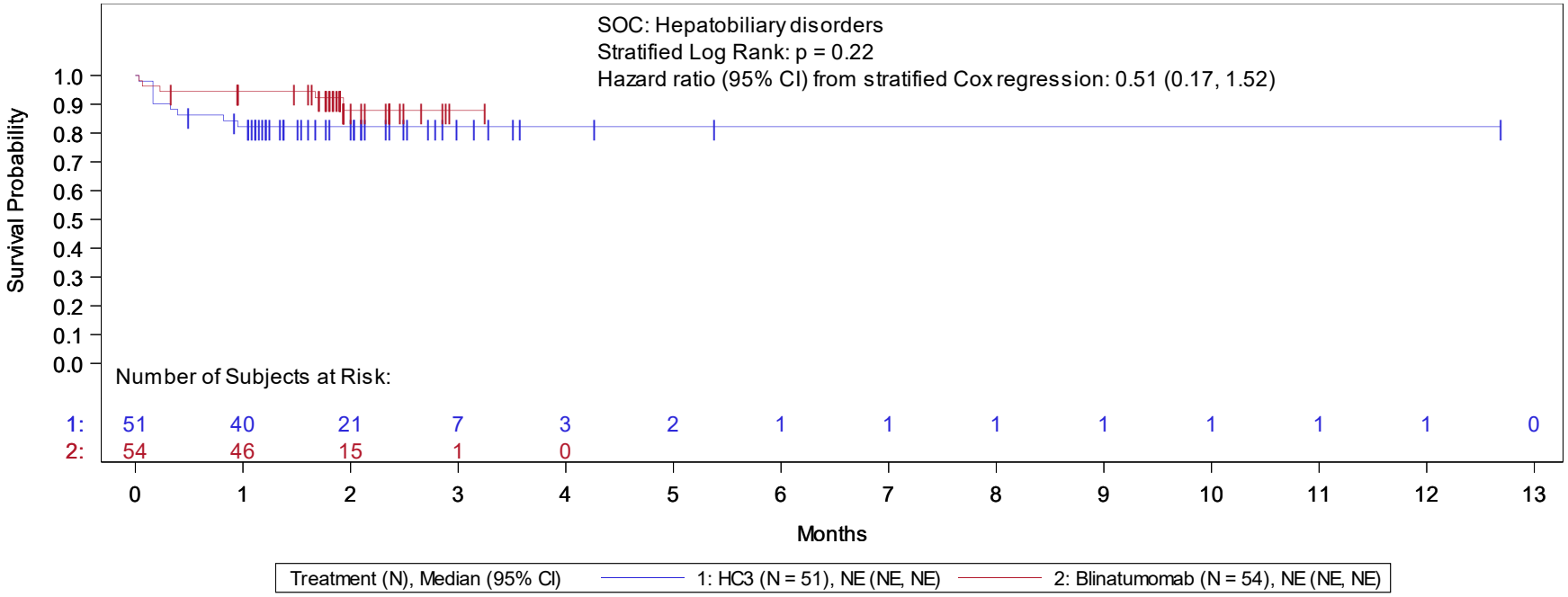

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

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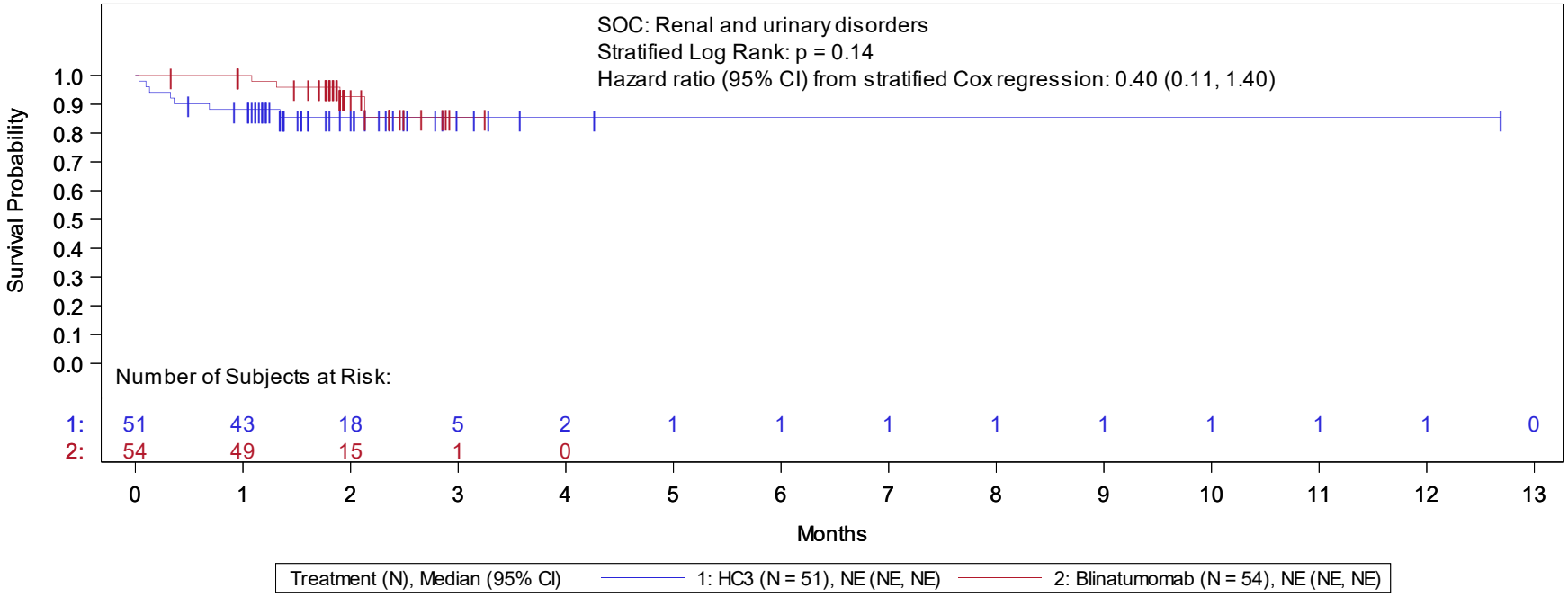

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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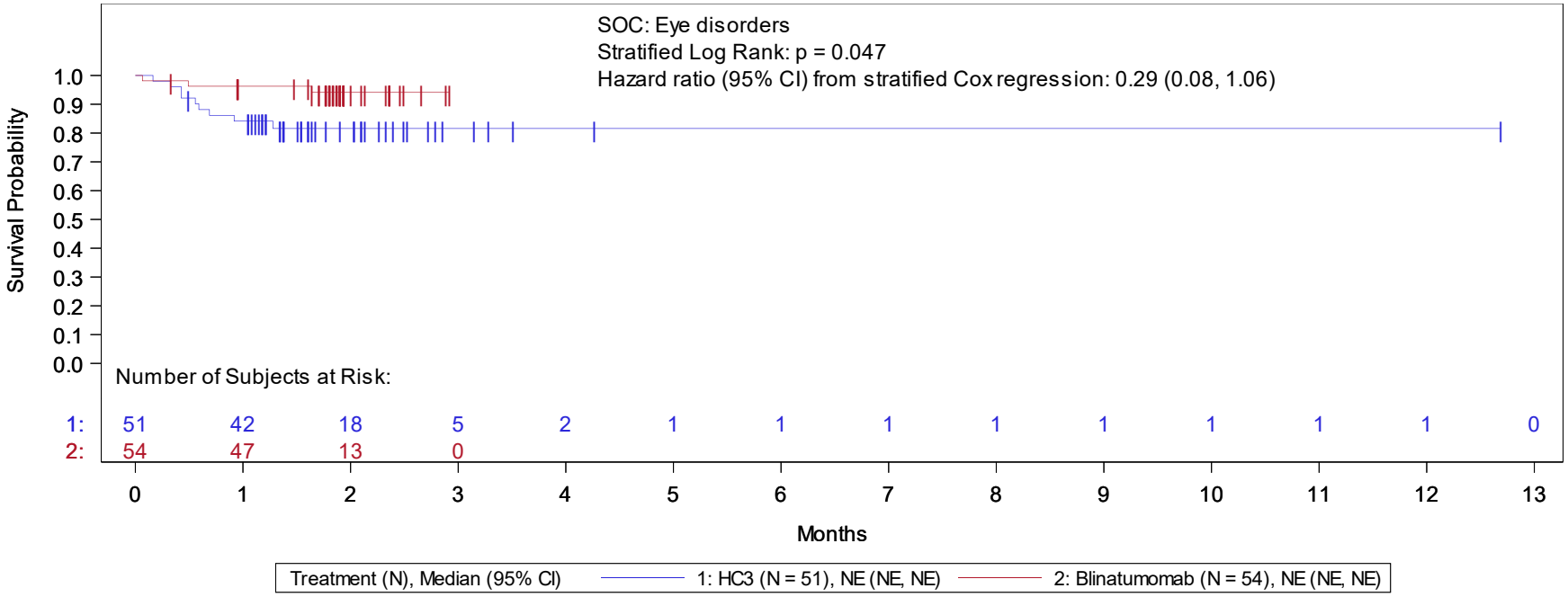

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. SOC = System organ class. PT = Preferred term. NE = Not estimable.

Data cut-off date: 17JUL2019

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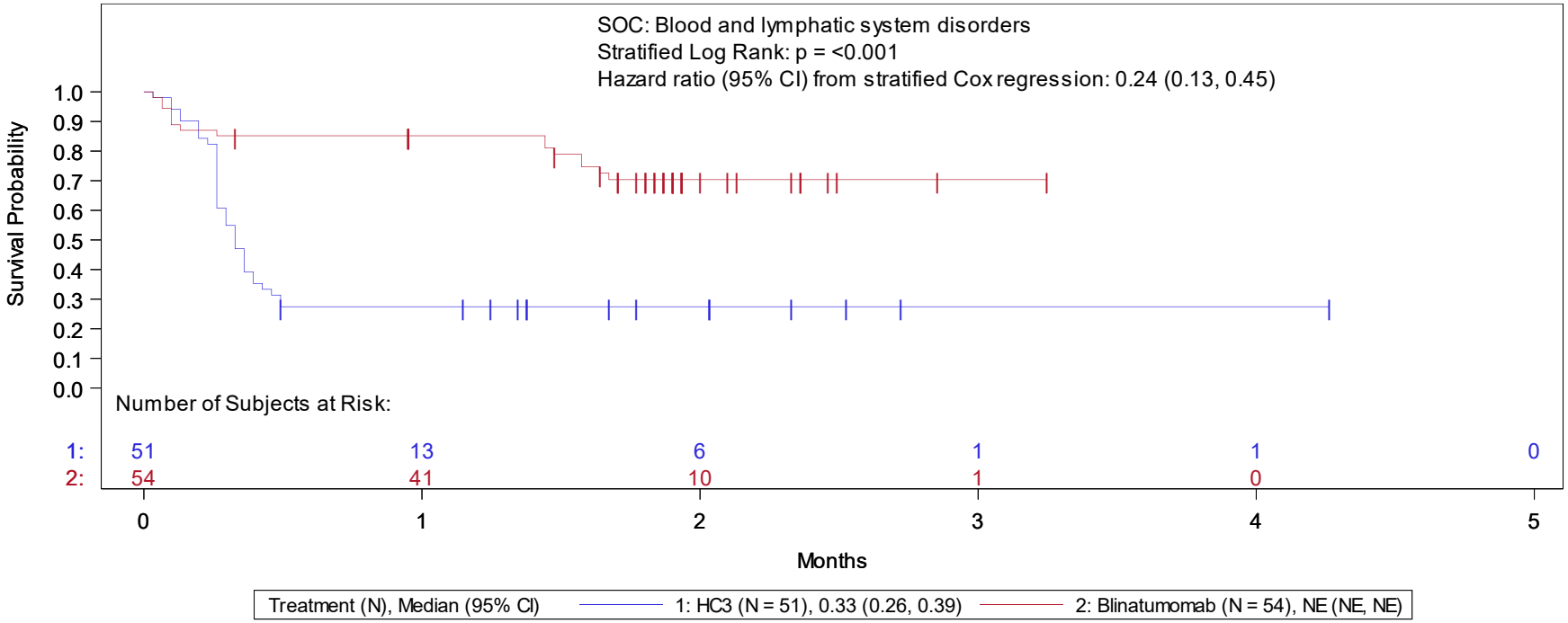
Figure 14-6.15.5. Kaplan-Meier Plot for Time to First Onset of Grade 3 and Above Treatment-Emergent Adverse Events (≥ 5% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)



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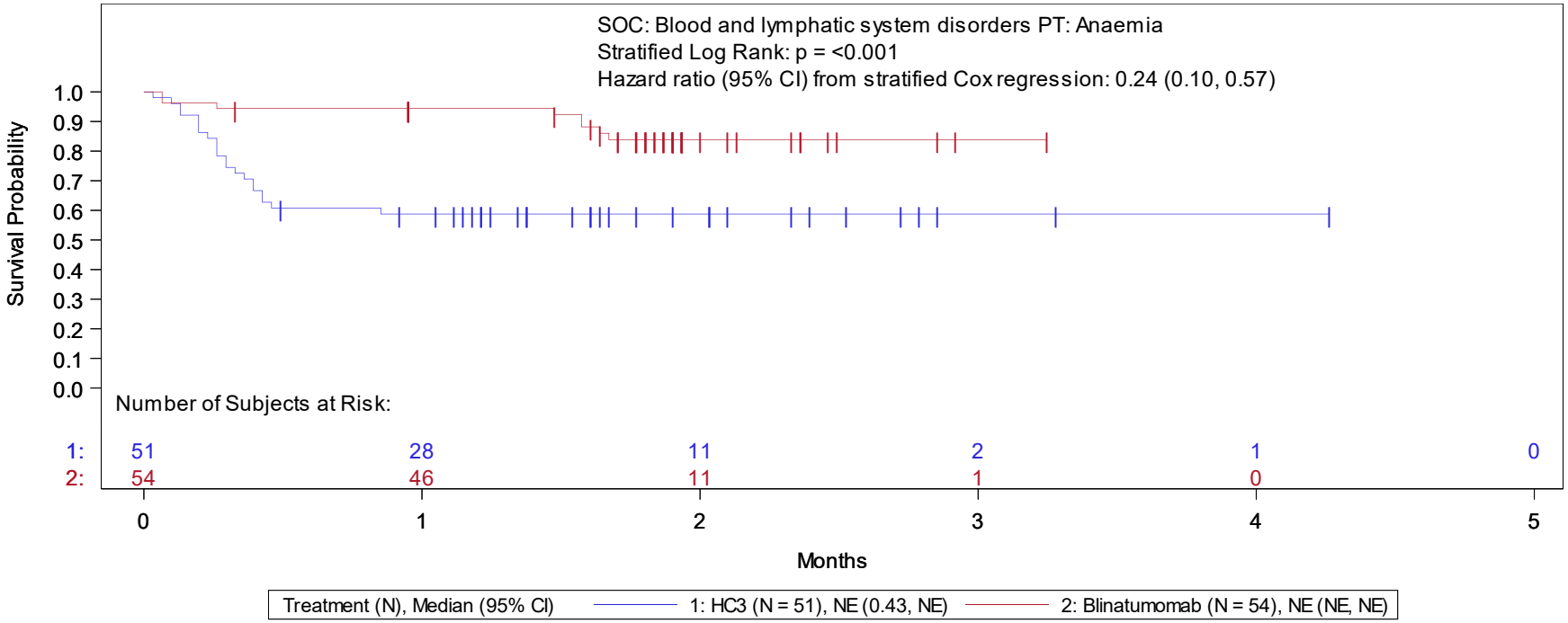

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
Data cut-off date: 17JUL2019

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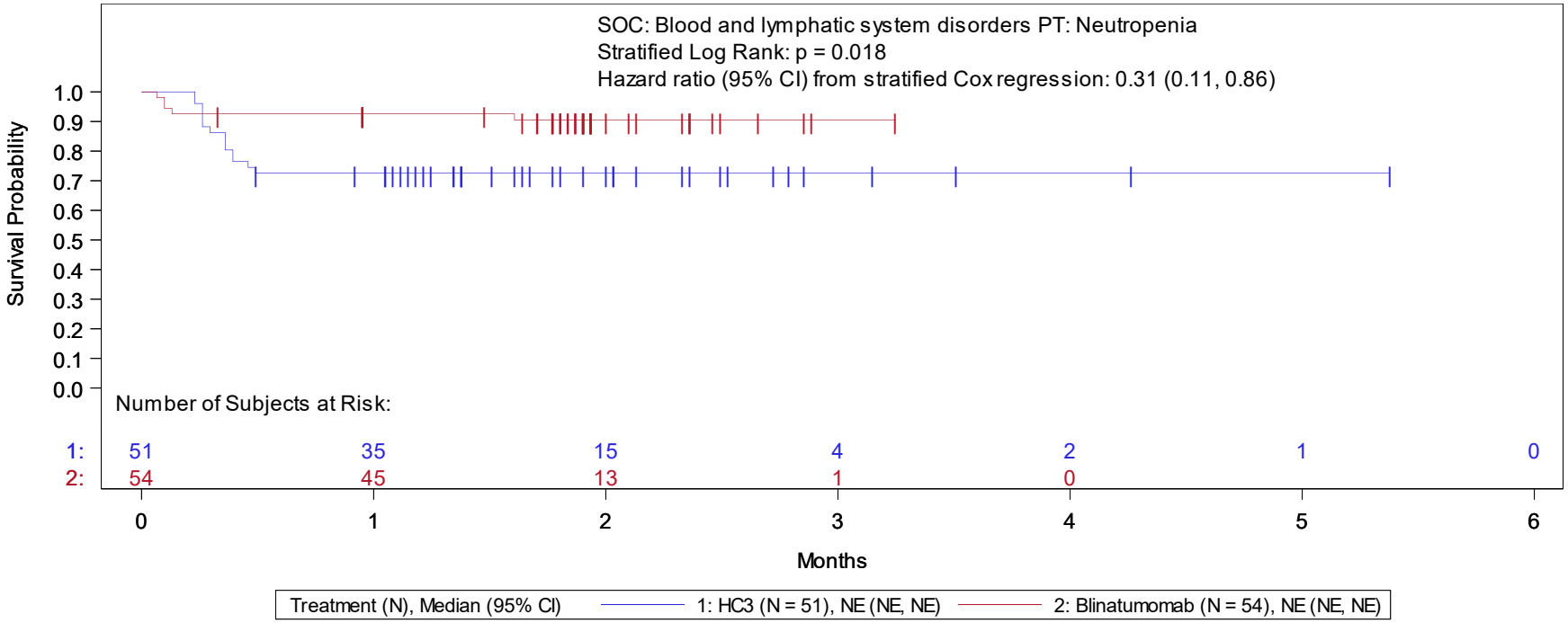

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
Data cut-off date: 17JUL2019

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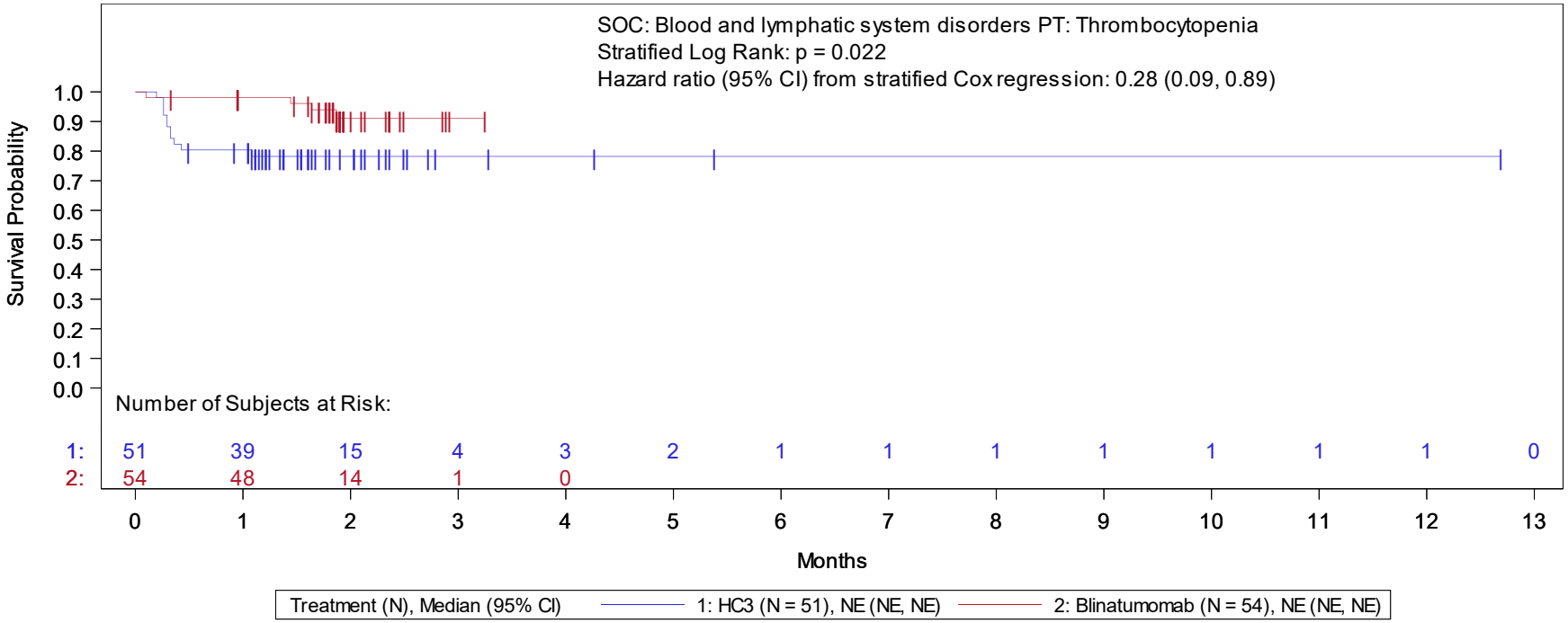

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
Data cut-off date: 17JUL2019

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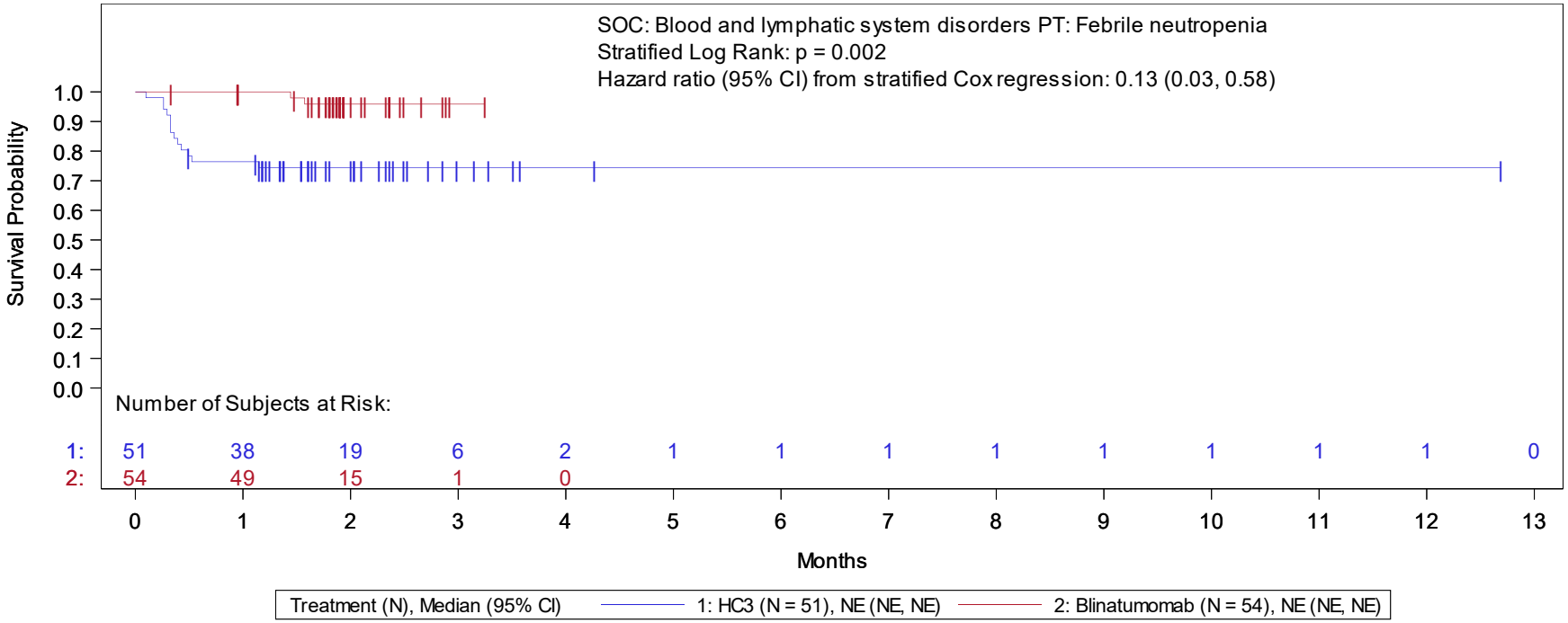

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
Data cut-off date: 17JUL2019

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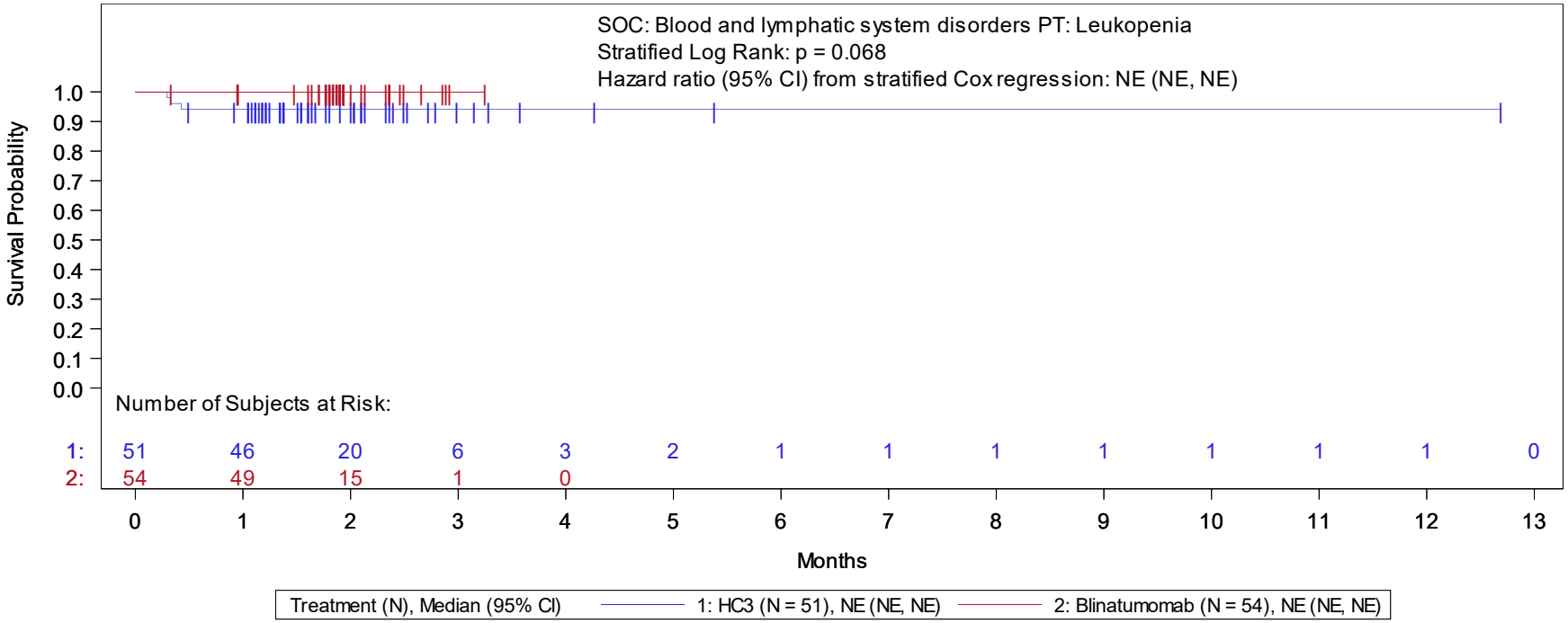

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Data cut-off date: 17JUL2019

Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-grade3-ge5-soc-pref-saf.sas
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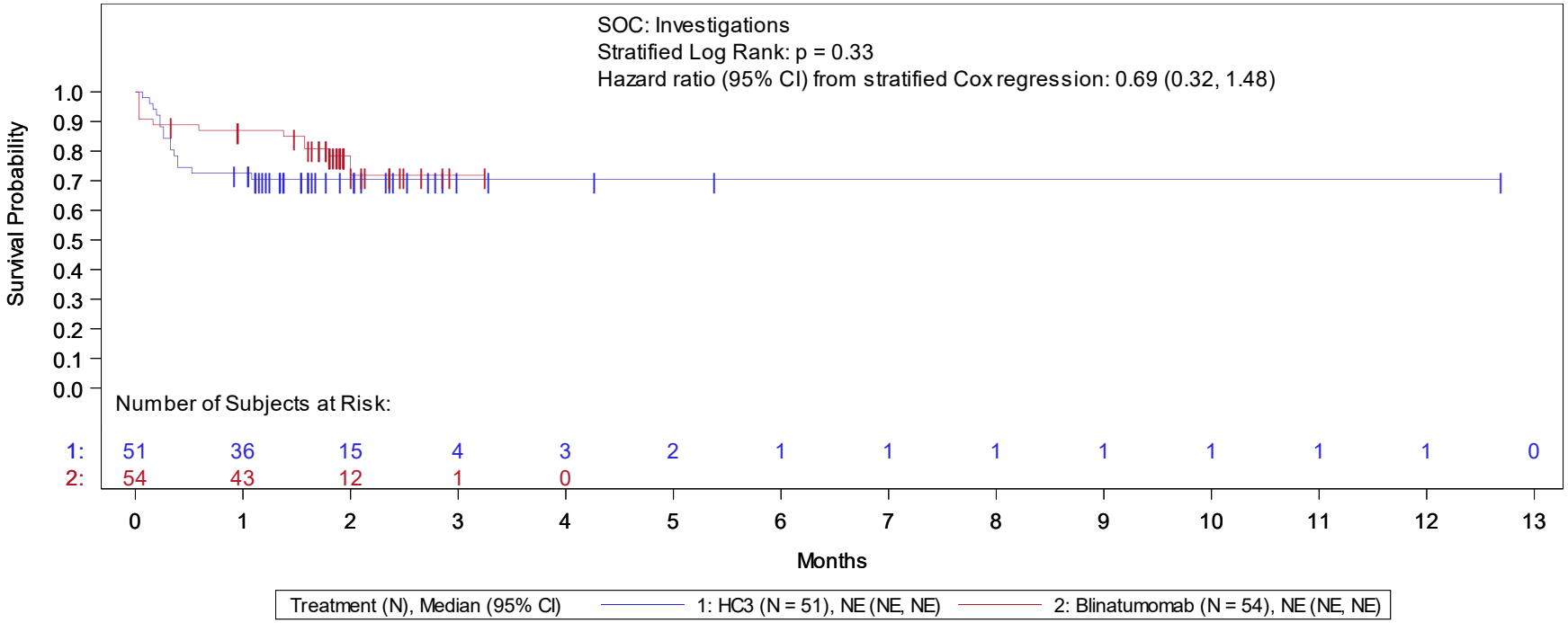

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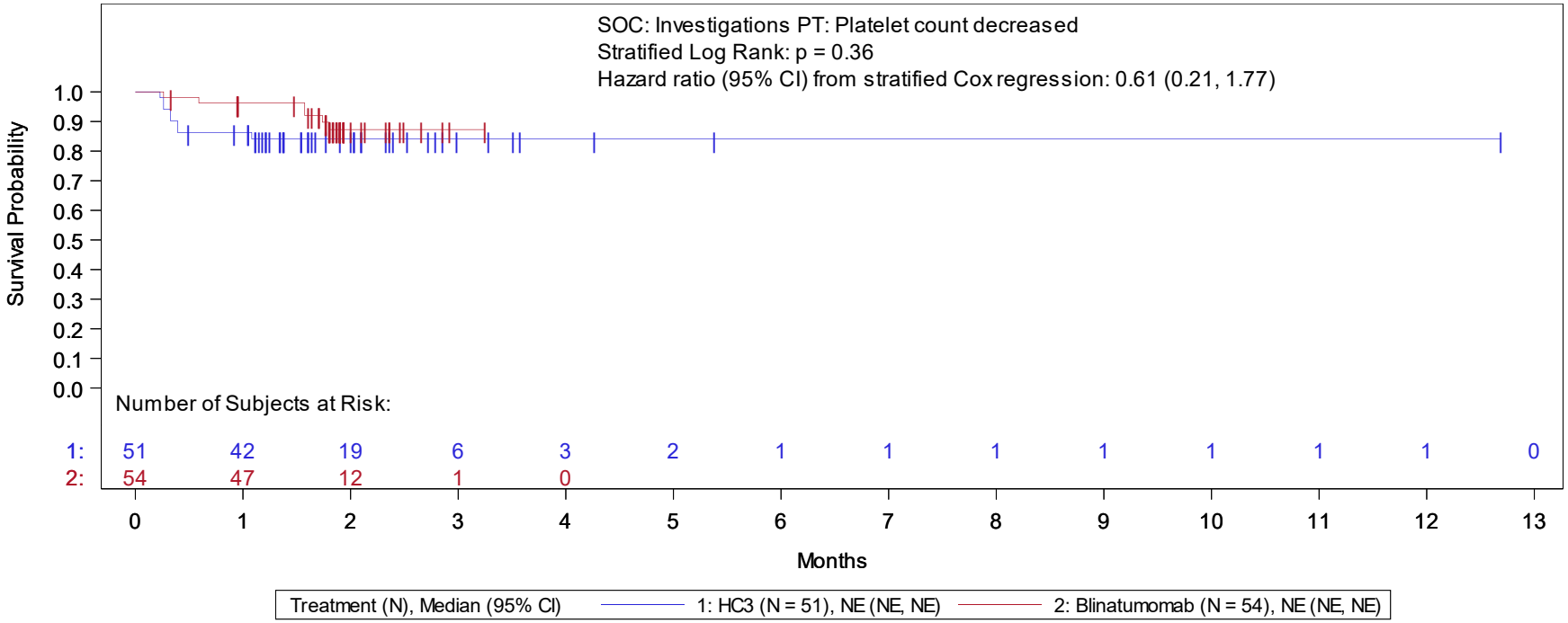

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Program: /userdata/stat/amg103/onc/20120215/analysis/german_hta_pac/figures/f-km-ae-ont-grade3-ge5-soc-pref-saf.sas
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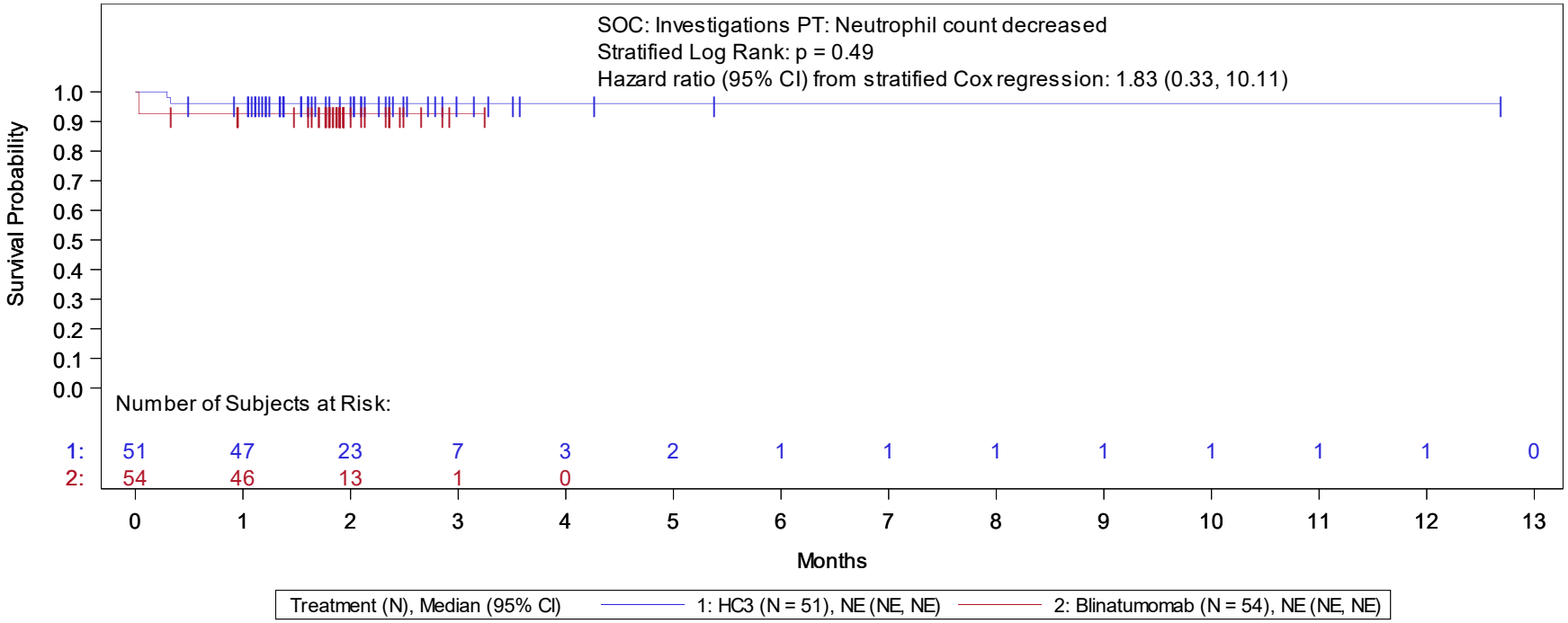

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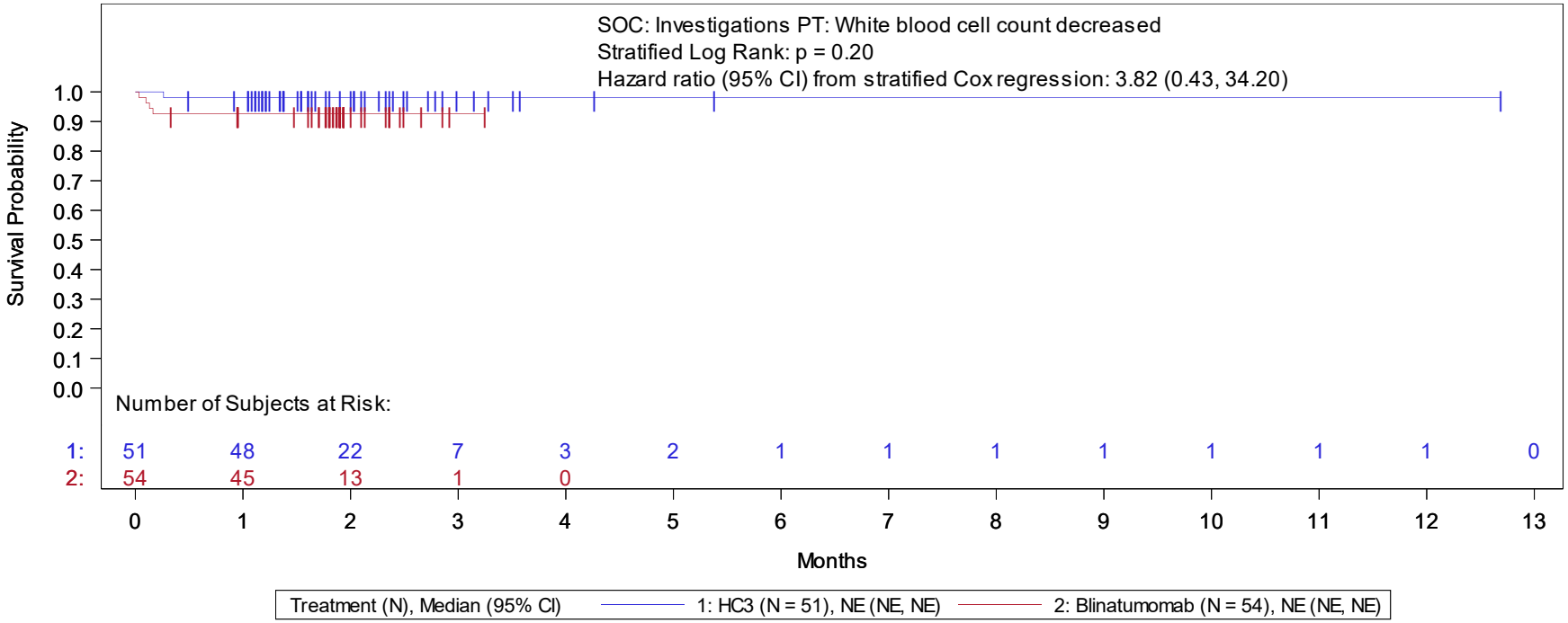

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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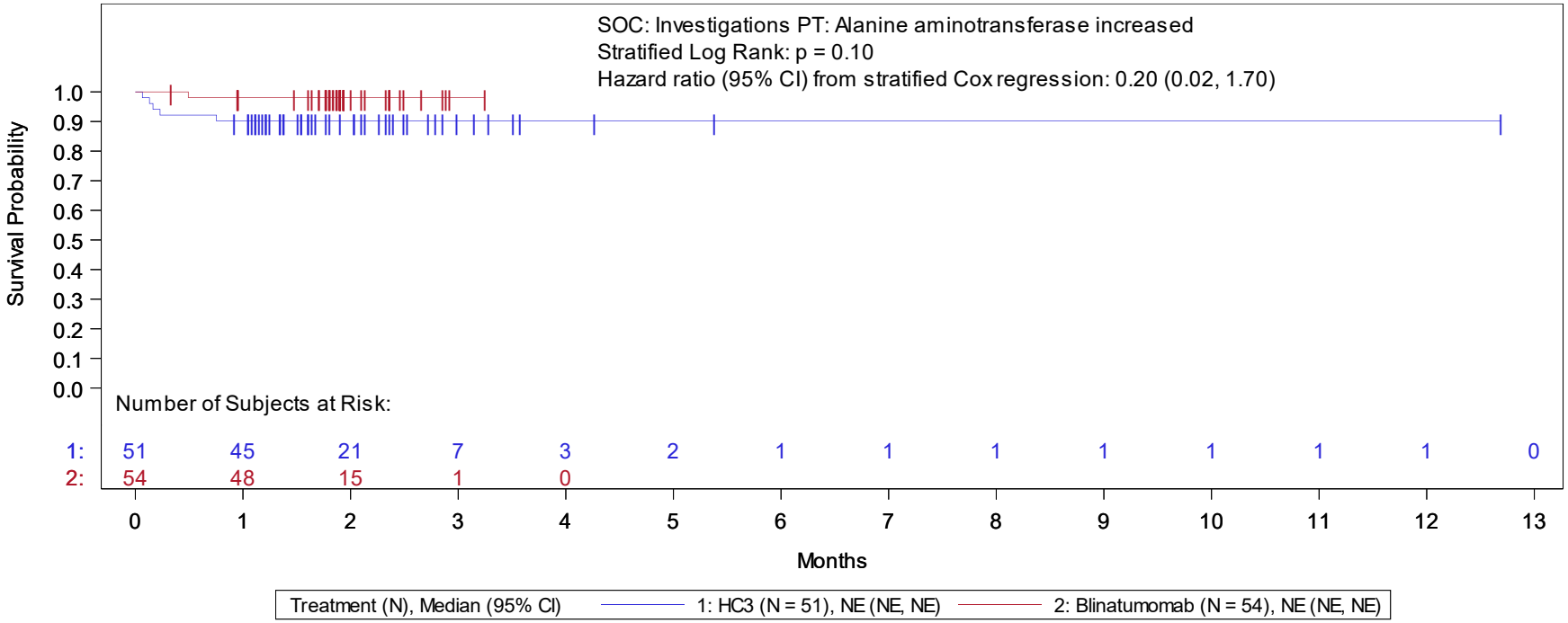

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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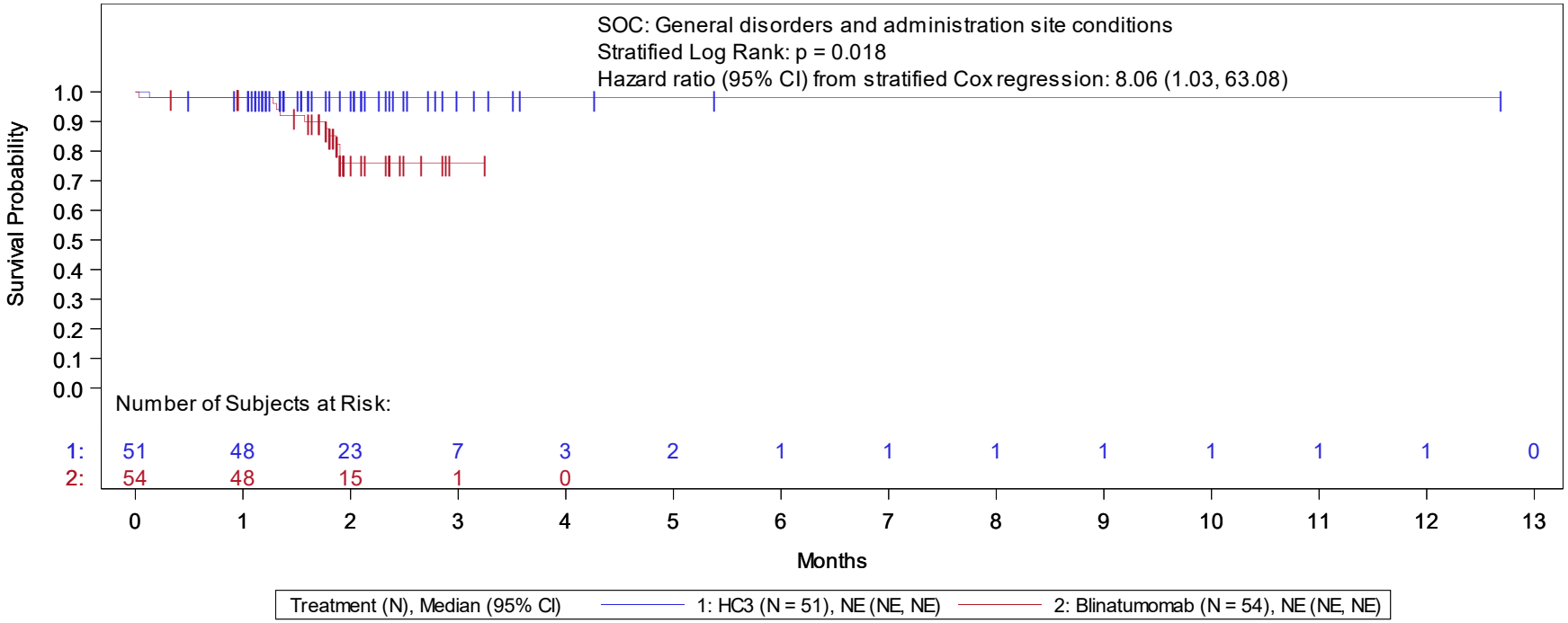

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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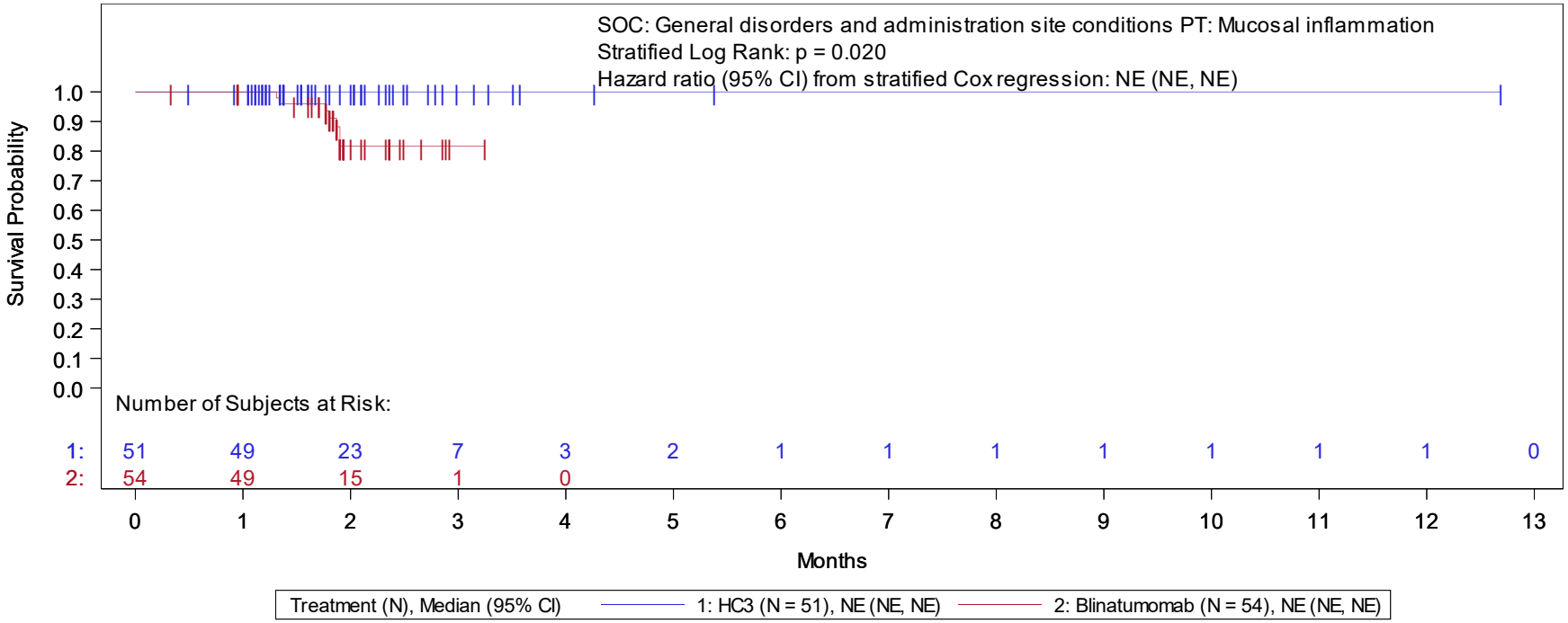

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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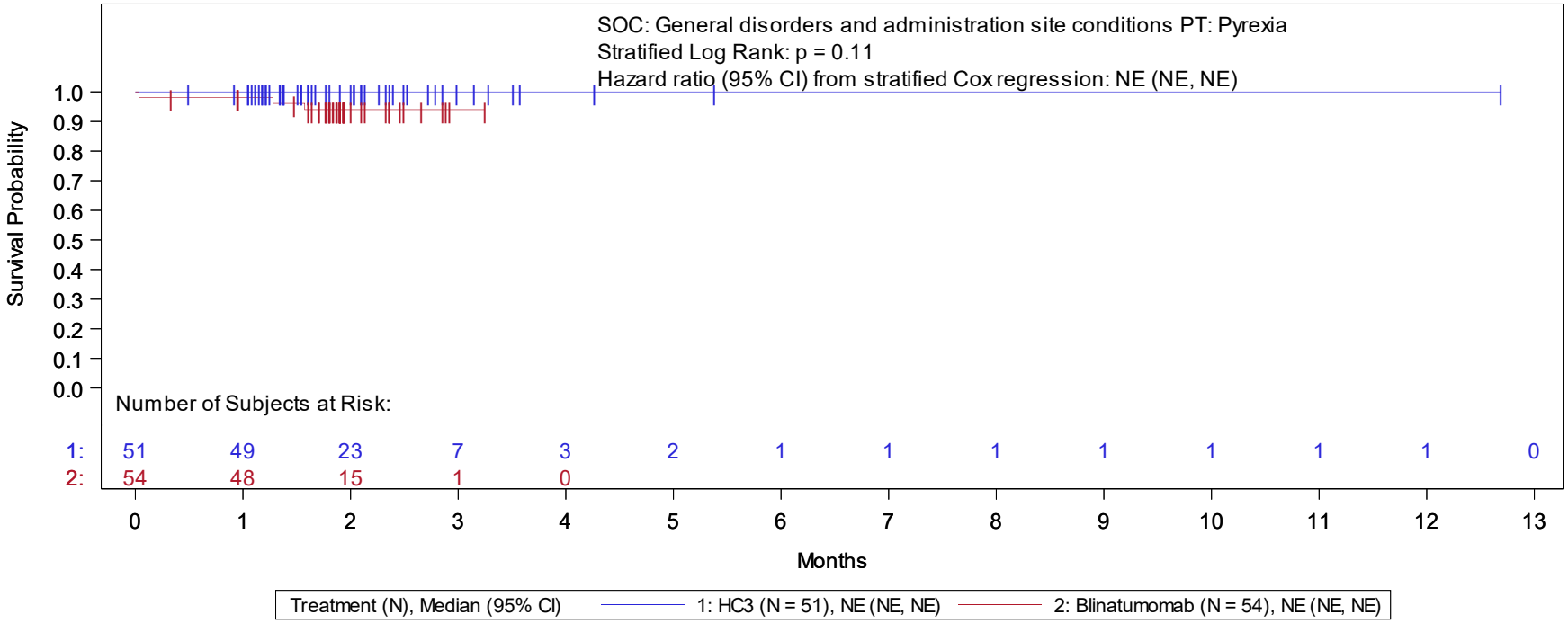

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
Data cut-off date: 17JUL2019

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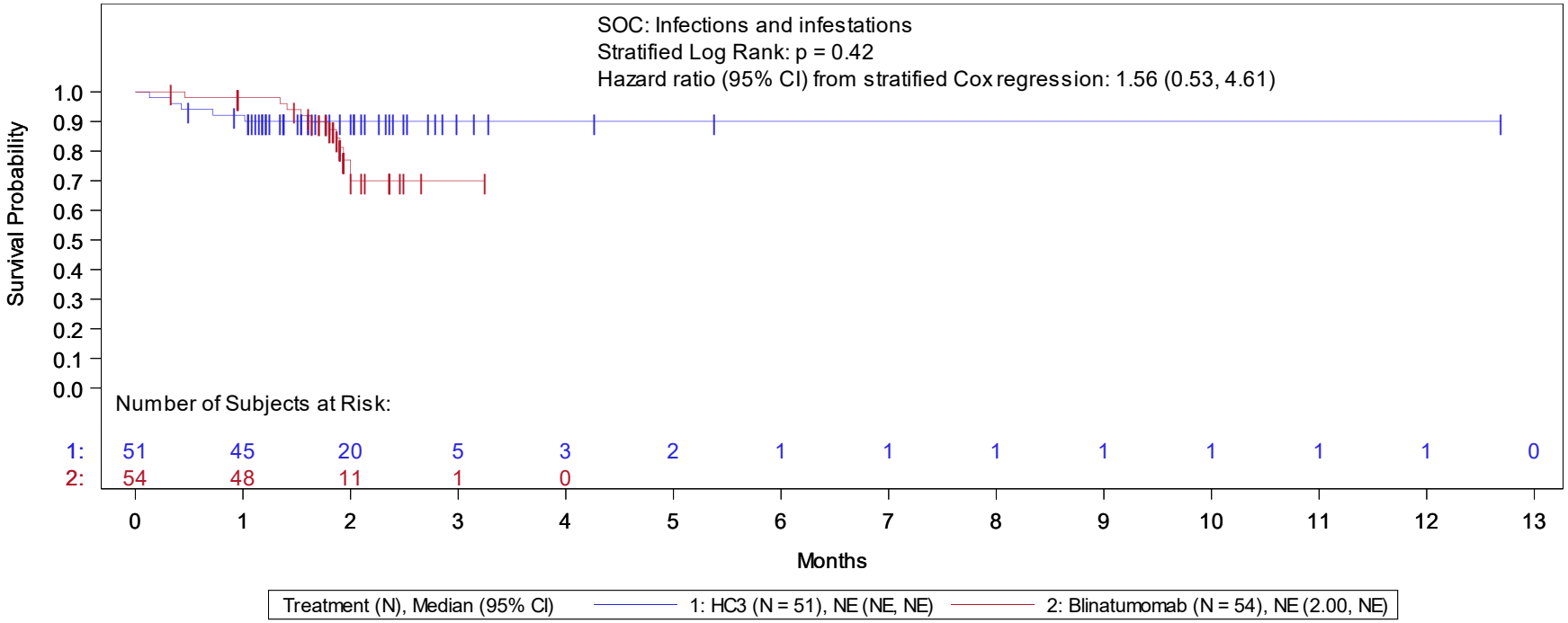

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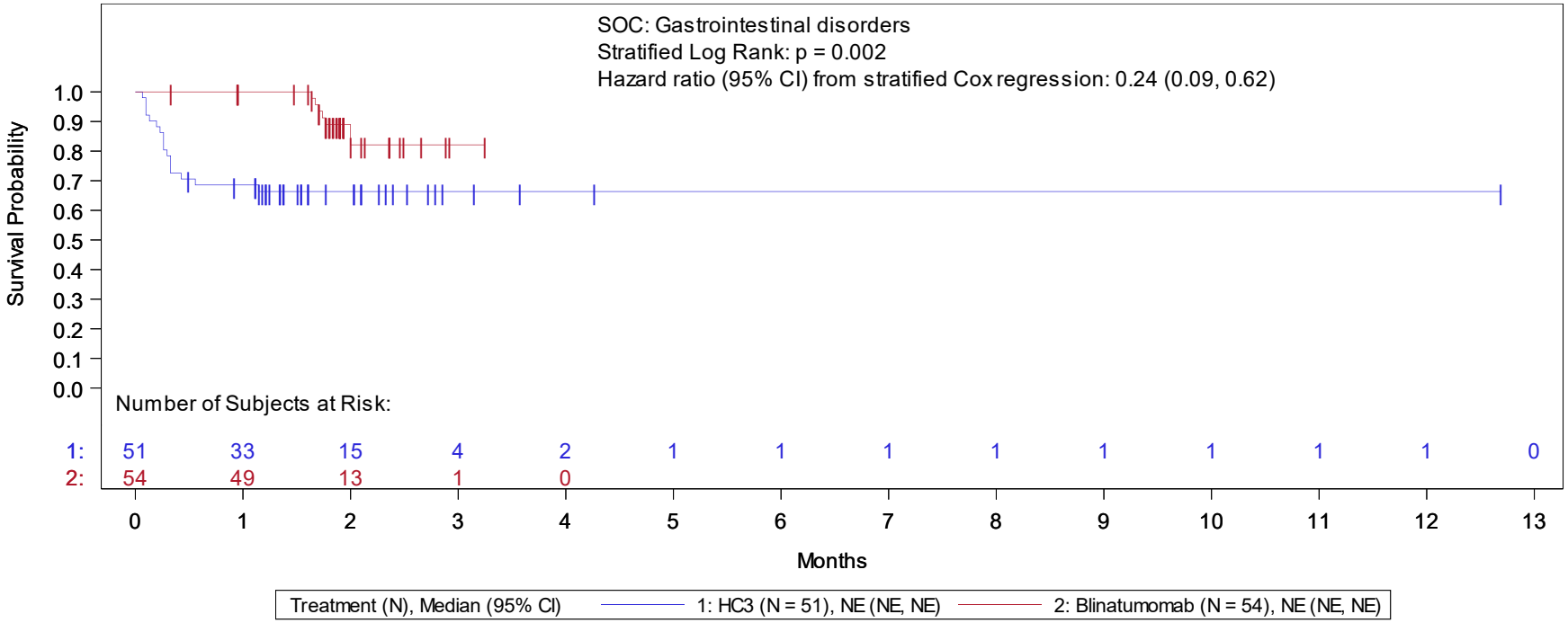

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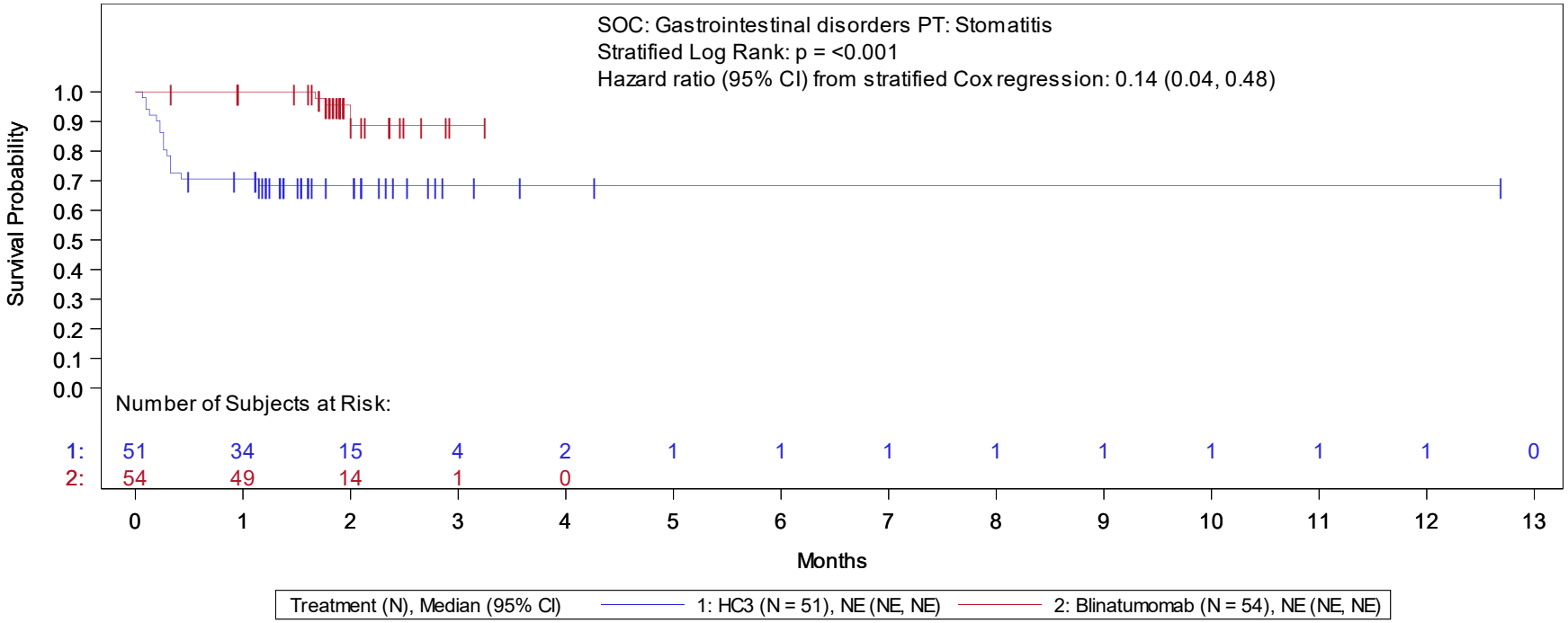

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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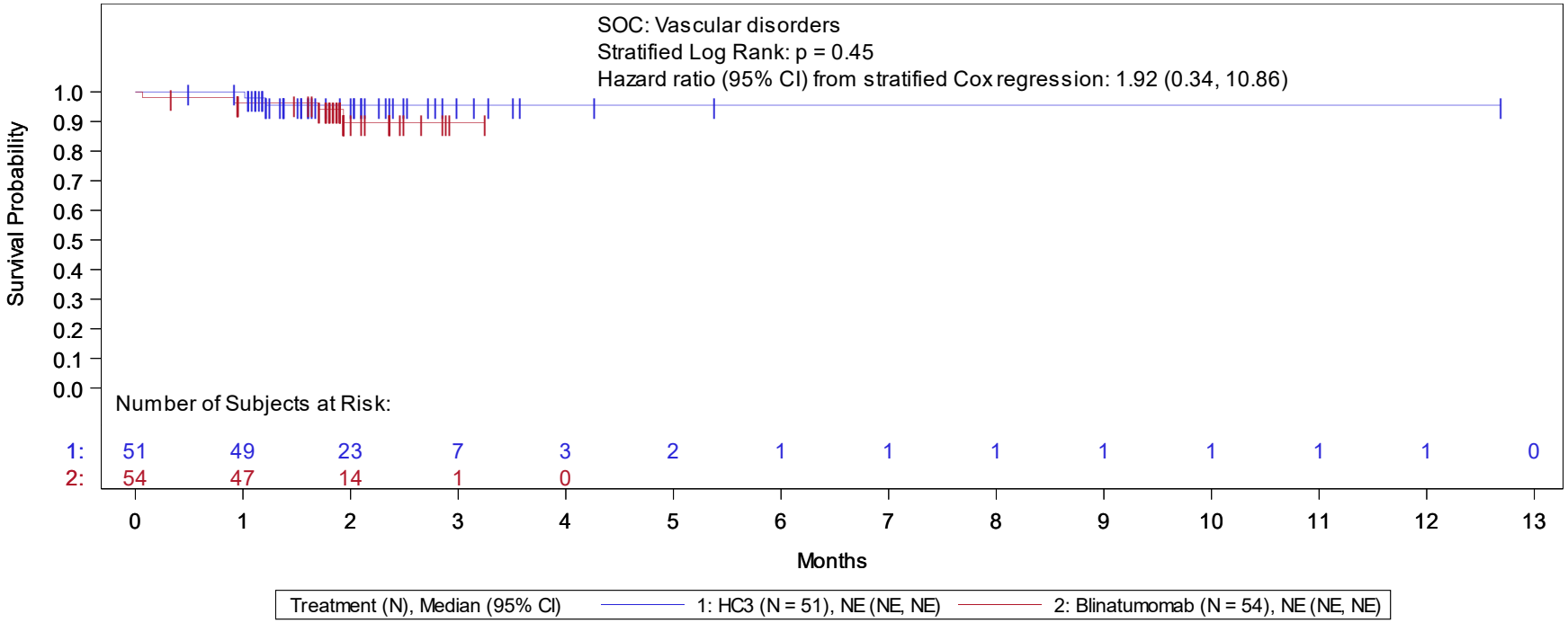

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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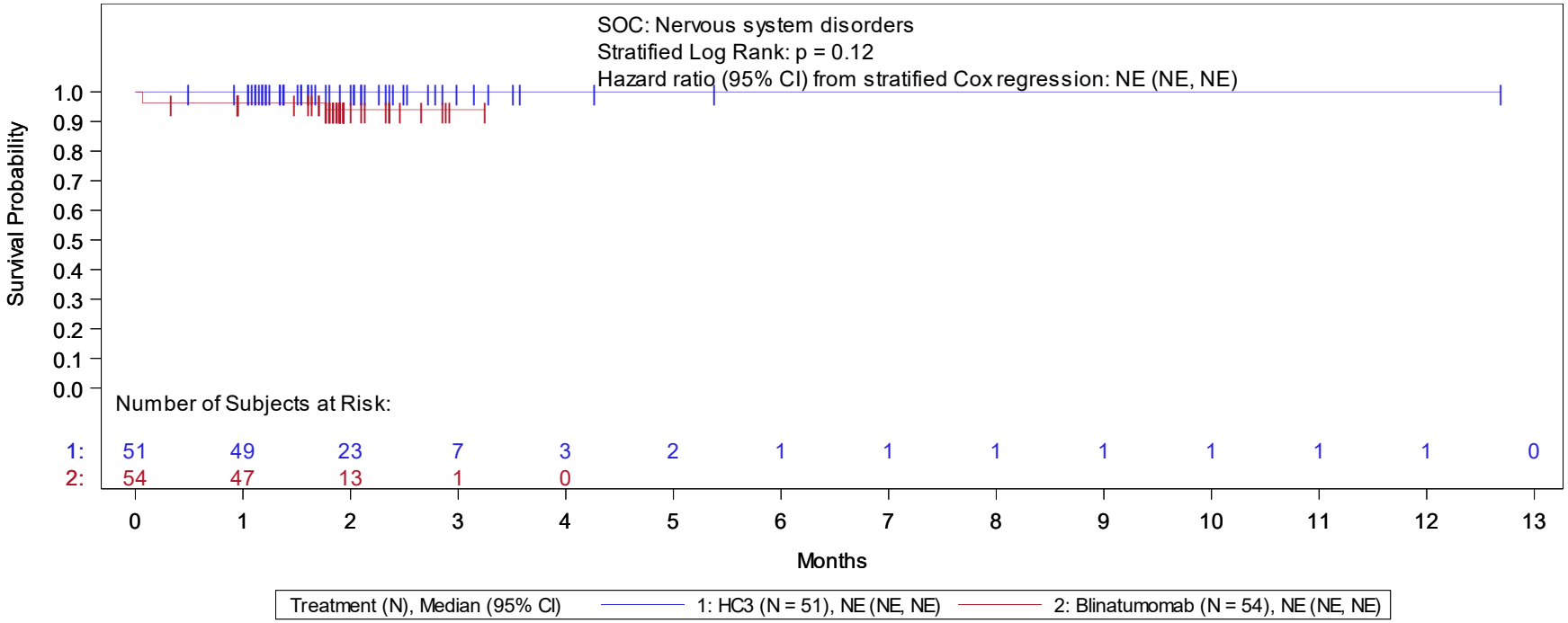

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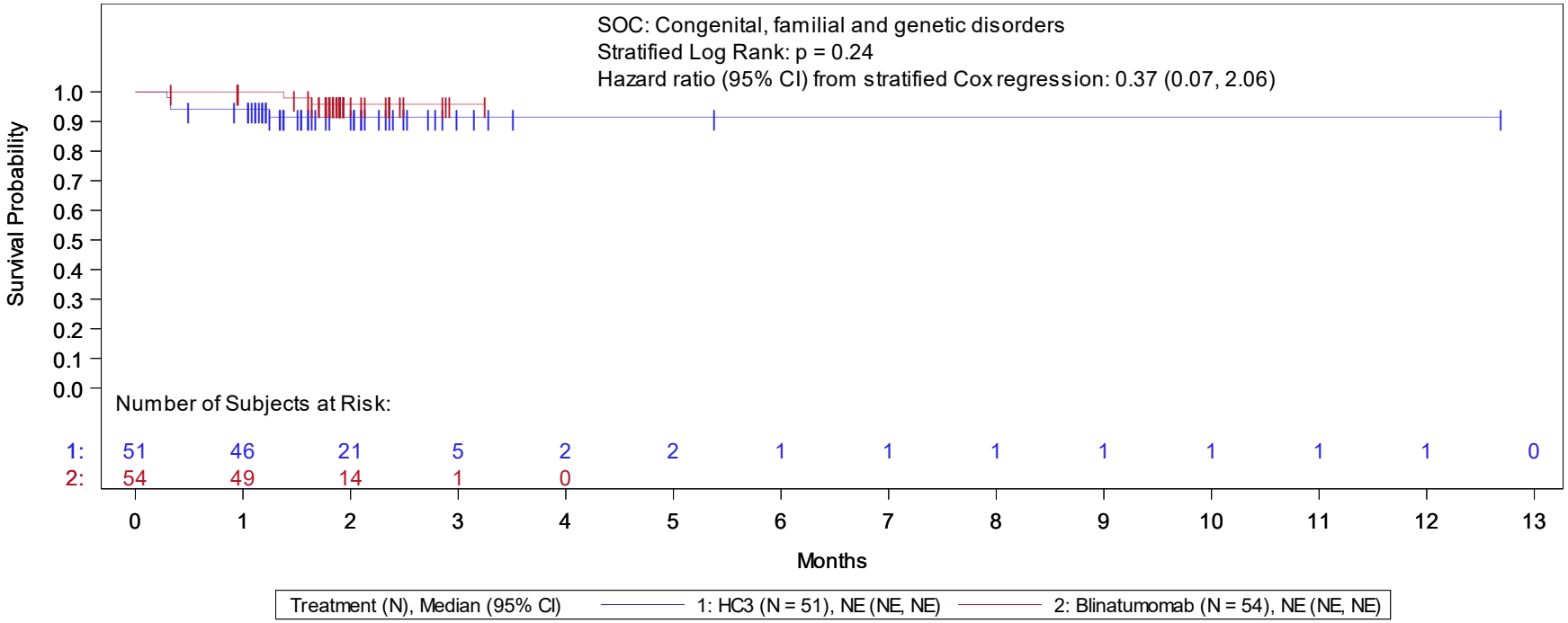

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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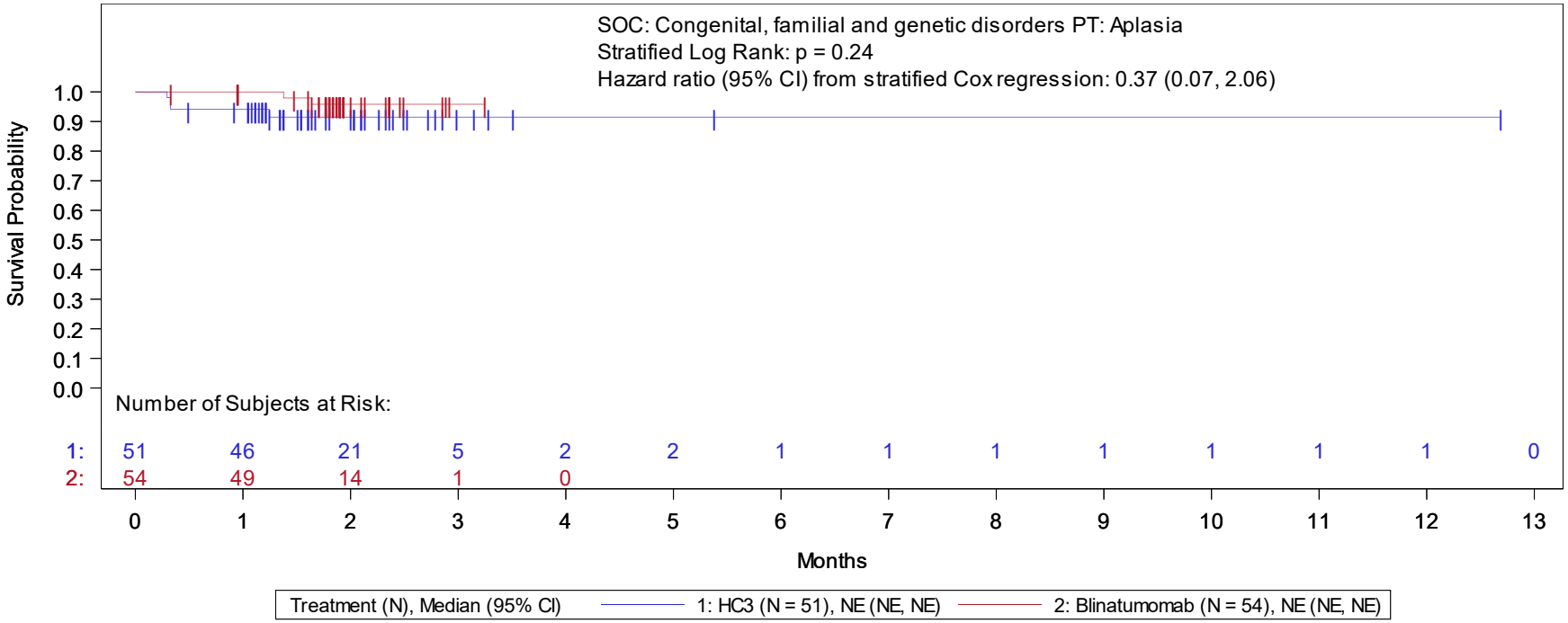

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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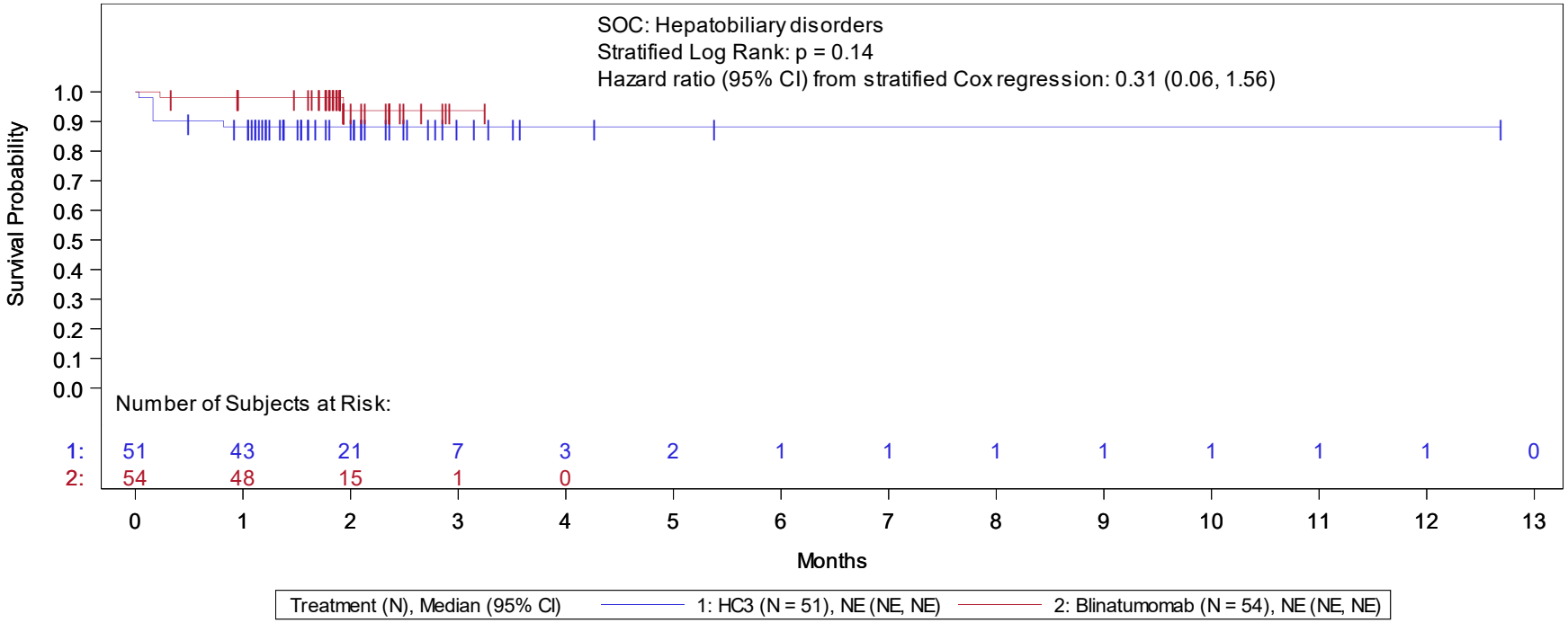

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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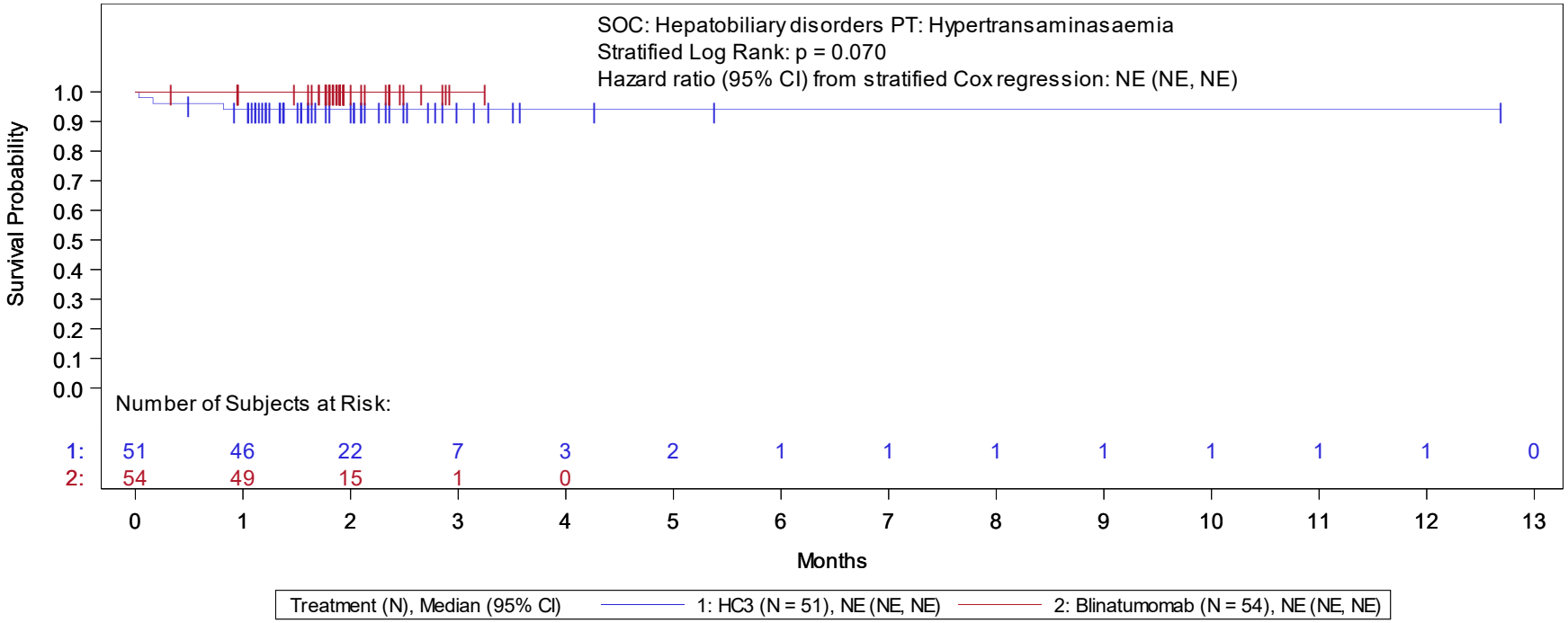

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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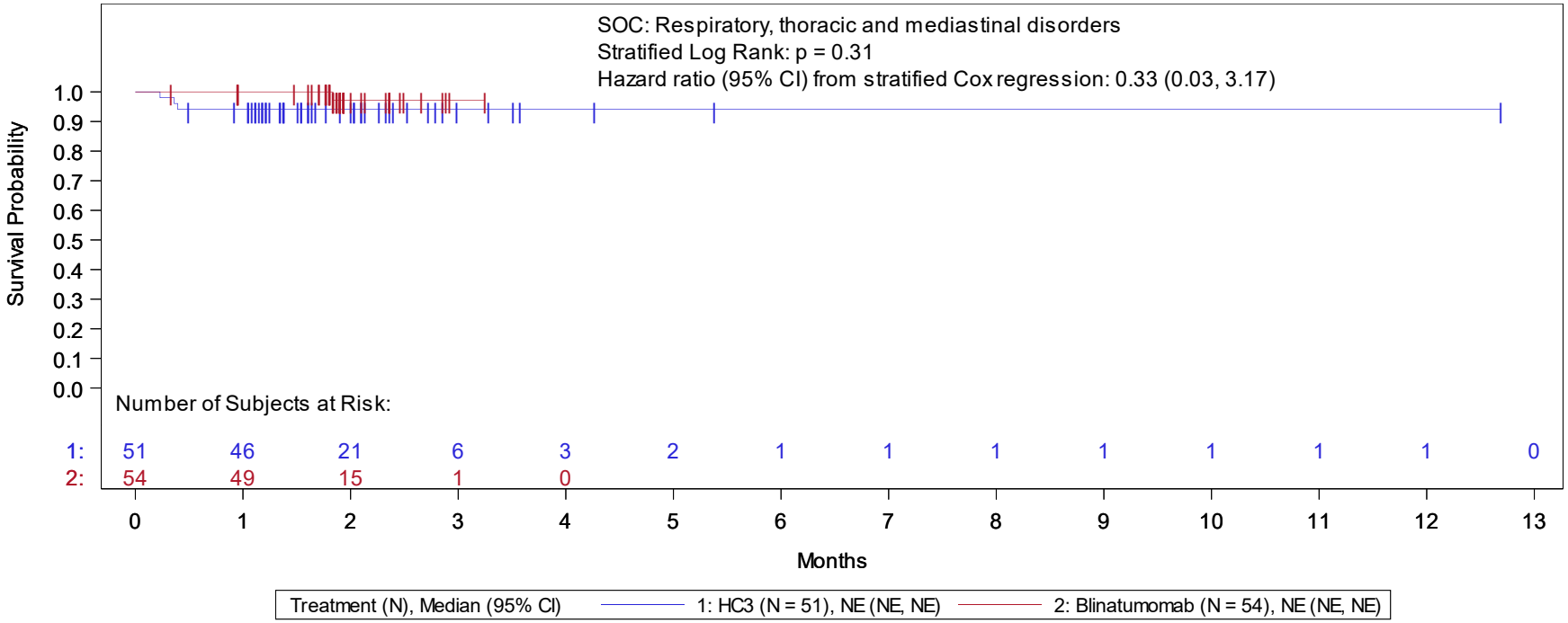

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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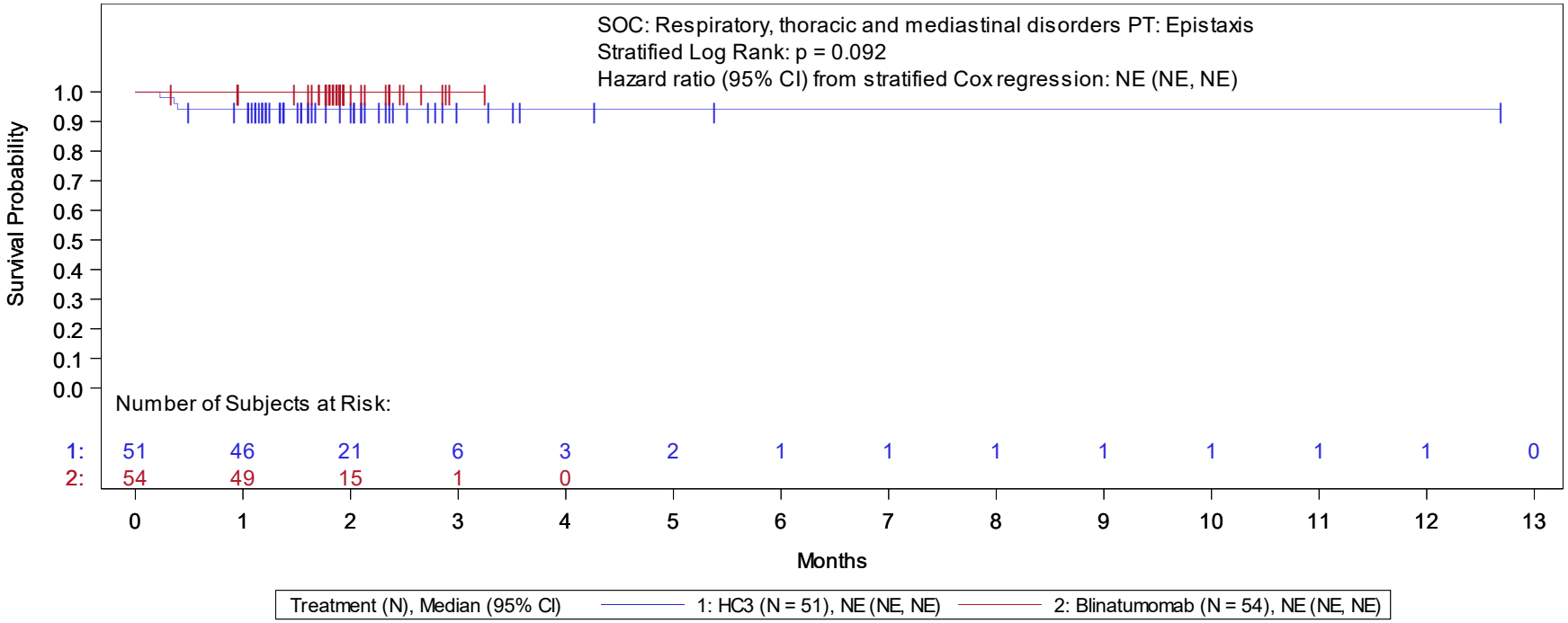

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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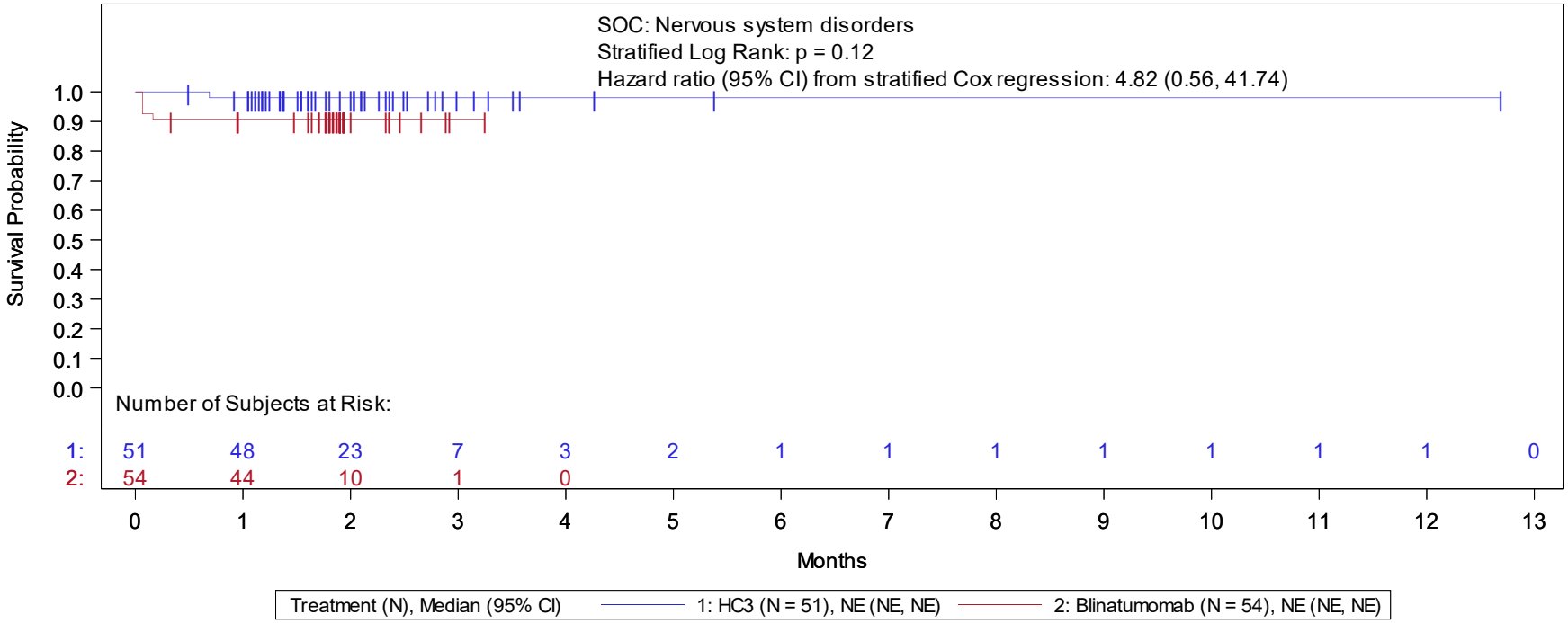
Figure 14-6.15.6. Kaplan-Meier Plot for Time to First Onset of Serious Treatment-Emergent Adverse Events (≥ 5% in one arm) by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)



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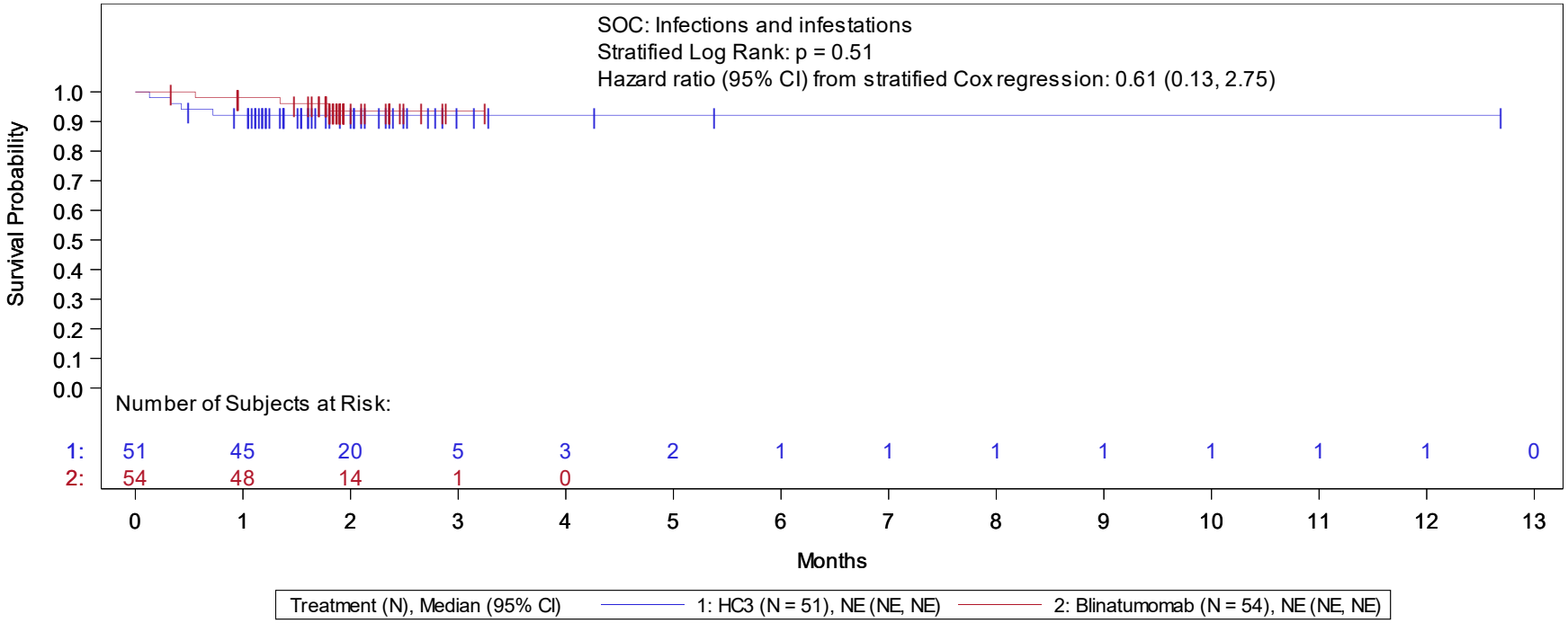

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
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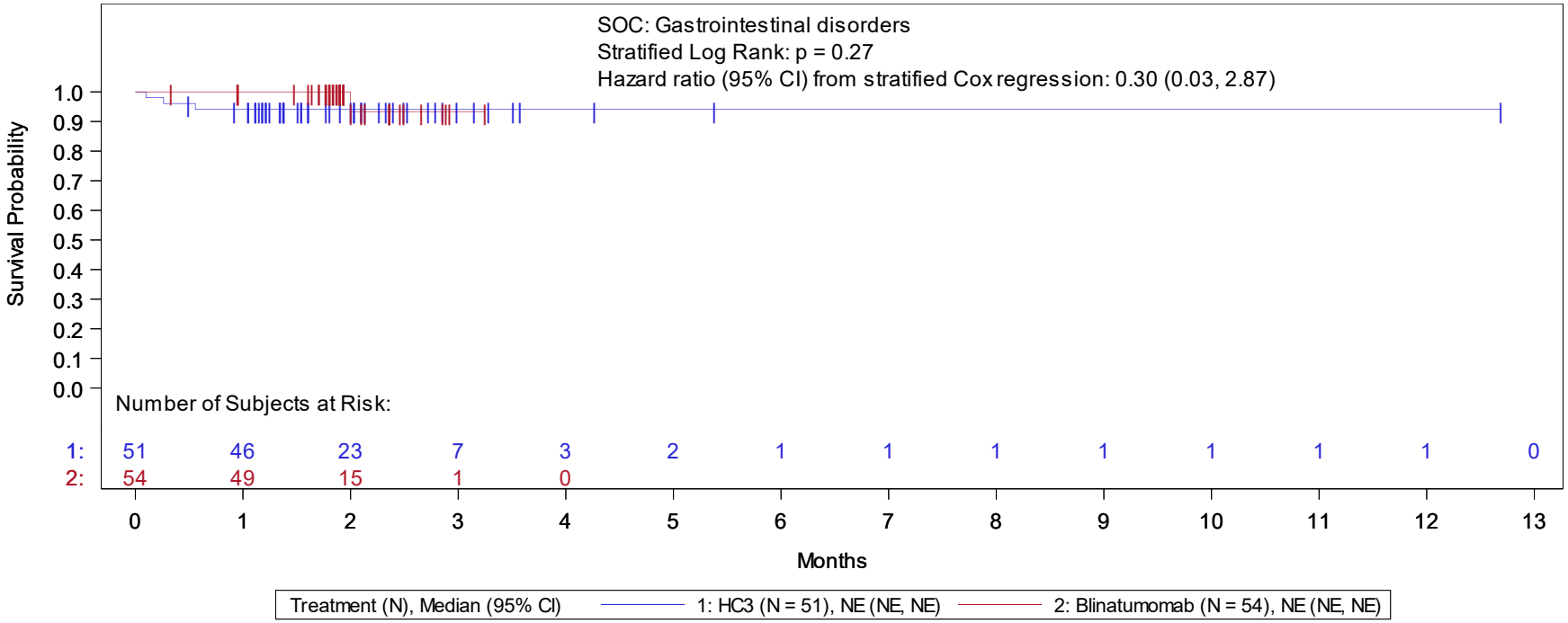

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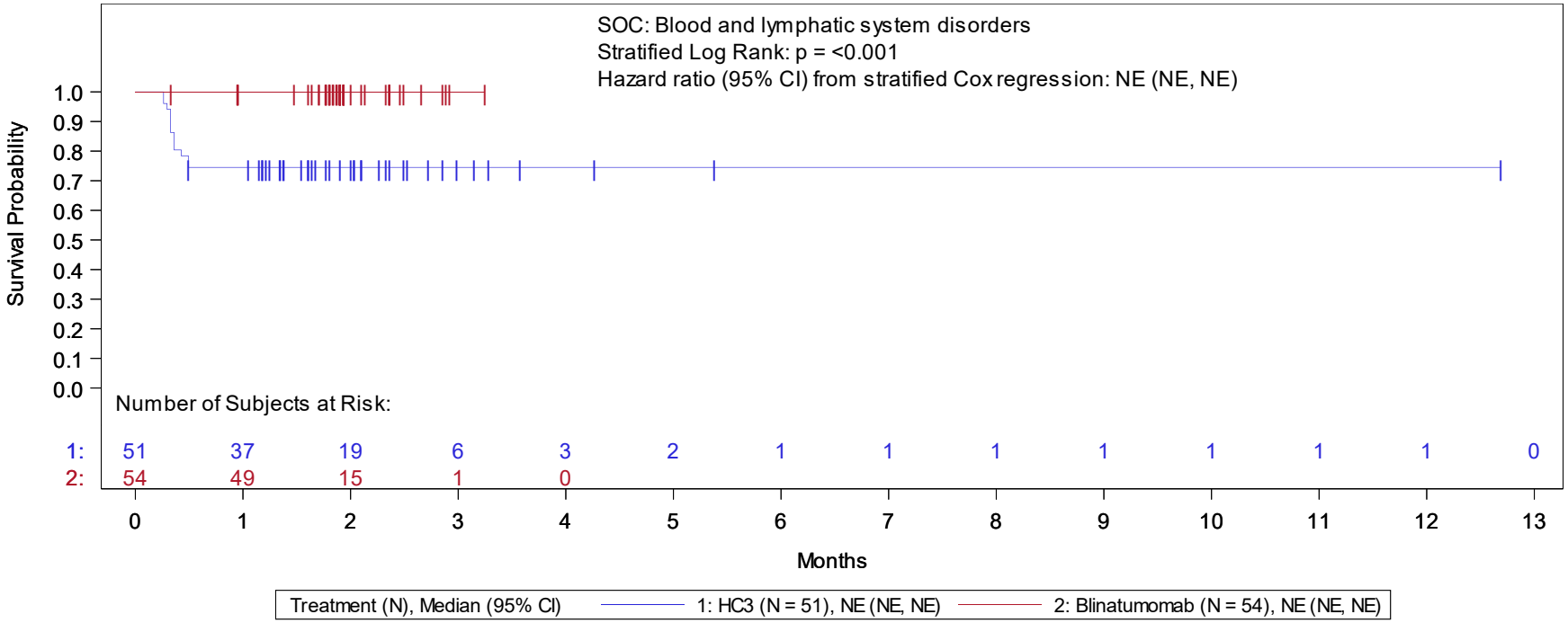

N = Number of subjects in the analysis set. n = Number of subjects with observed data. KM = Kaplan-Meier. CI = Confidence Interval. NE = Not estimable.
Data cut-off date: 17JUL2019

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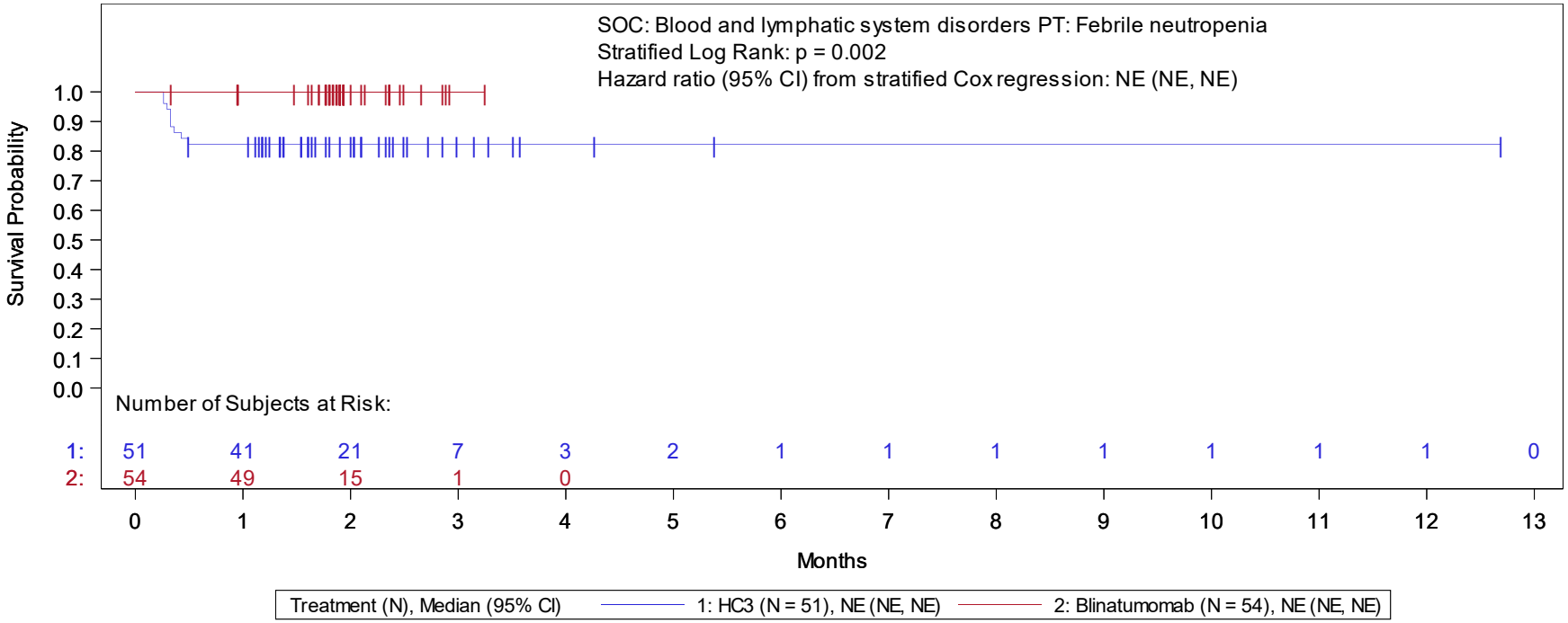

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Data cut-off date: 17JUL2019

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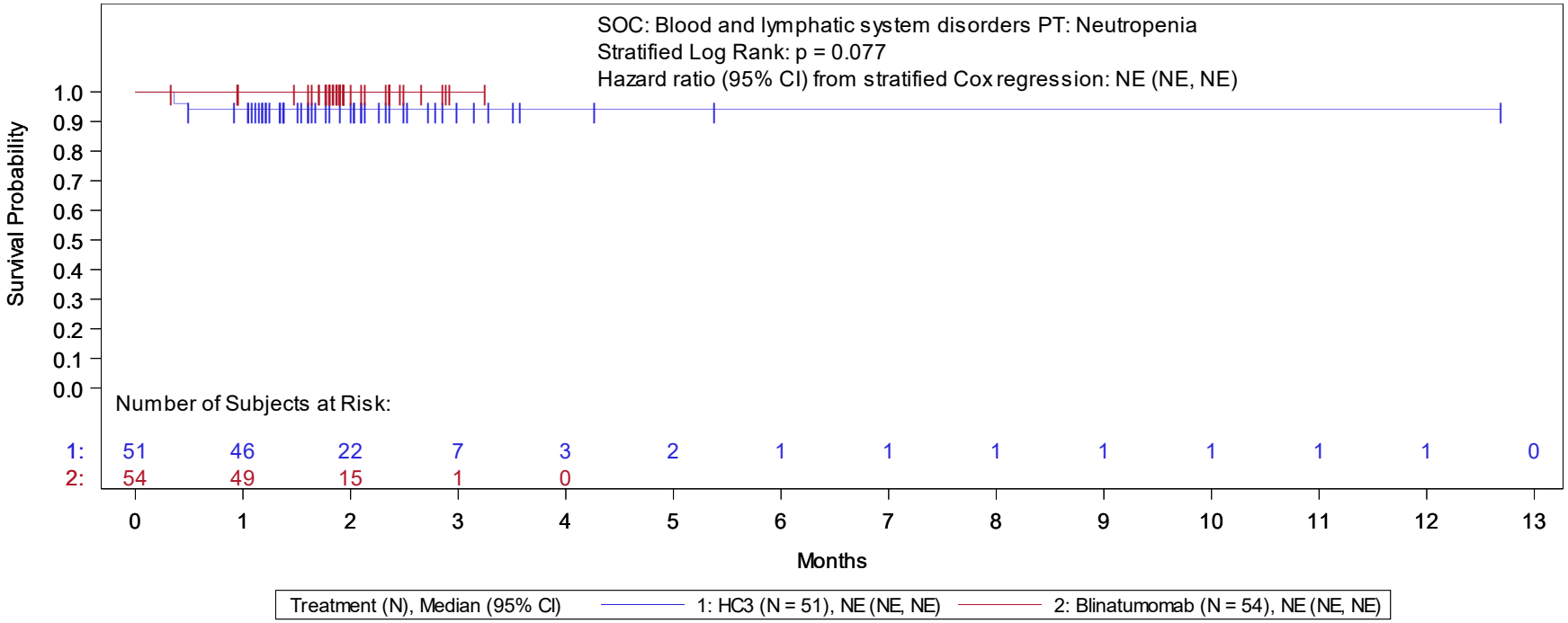

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