	Screening (N=11)	End of Study (N=11)
Did you have to stay quiet when you had bleeds?		
Number Assessed	5	1
Never	2 (40.0)	1 (100.0)
Seldom	0	0
Sometimes	2 (40.0)	0
Often	1 (20.0)	0
Always	0	0
When you had bleeds, did you inform your parents immediately?		
Number Assessed	5	1
Never	1 (20.0)	0
Seldom	0	0
Sometimes	0	0
Often	1 (20.0)	0
Always	3 (60.0)	1 (100.0)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I injected myself.		
Number Assessed	8	7
Never	7 (87.5)	5 (71.4)
Seldom	0	0
Sometimes	1 (12.5)	1 (14.3)
Often	0	0
All the Time	0	1 (14.3)
In the past 4 weeks, my mother injected me.		
Number Assessed	8	7
Never	2 (25.0)	2 (28.6)
Seldom	0	0
Sometimes	1 (12.5)	2 (28.6)
Often	1 (12.5)	0
All the Time	4 (50.0)	3 (42.9)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, my father injected me.		
Number Assessed	8	7
Never	7 (87.5)	5 (71.4)
Seldom	0	1 (14.3)
Sometimes	0	0
Often	0	1 (14.3)
All the Time	1 (12.5)	0
In the past 4 weeks, a nurse injected me.		
Number Assessed	8	7
Never	2 (25.0)	1 (14.3)
Seldom	0	2 (28.6)
Sometimes	4 (50.0)	2 (28.6)
Often	0	0
All the Time	2 (25.0)	2 (28.6)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, a doctor injected me.		
Number Assessed	8	7
Never	7 (87.5)	3 (42.9)
Seldom	0	2 (28.6)
Sometimes	1 (12.5)	2 (28.6)
Often	0	0
All the Time	0	0
In the past 4 weeks, my swellings hurt.		
Number Assessed	8	7
Never	5 (62.5)	3 (42.9)
Seldom	0	2 (28.6)
Sometimes	1 (12.5)	2 (28.6)
Often	2 (25.0)	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, it was difficult for me to move my arms or legs.		
Number Assessed	8	7
Never	5 (62.5)	4 (57.1)
Seldom	0	2 (28.6)
Sometimes	2 (25.0)	1 (14.3)
Often	1 (12.5)	0
All the Time	0	0
In the past 4 weeks, I had difficulty walking as far as I wanted to.		
Number Assessed	8	7
Never	4 (50.0)	7 (100.0)
Seldom	1 (12.5)	0
Sometimes	3 (37.5)	0
Often	0	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was afraid of hurting myself.		
Number Assessed	8	7
Never	6 (75.0)	4 (57.1)
Seldom	1 (12.5)	2 (28.6)
Sometimes	1 (12.5)	1 (14.3)
Often	0	0
All the Time	0	0
In the past 4 weeks, I was in a bad mood because of my hemophilia.		
Number Assessed	8	7
Never	6 (75.0)	5 (71.4)
Seldom	0	1 (14.3)
Sometimes	0	1 (14.3)
Often	1 (12.5)	0
All the Time	1 (12.5)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 201[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was sad because of my hemophilia.		
Number Assessed	8	7
Never	3 (37.5)	4 (57.1)
Seldom	1 (12.5)	2 (28.6)
Sometimes	2 (25.0)	1 (14.3)
Often	1 (12.5)	0
All the Time	1 (12.5)	0
In the past 4 weeks, my hemophilia was a burden for me.		
Number Assessed	8	7
Never	6 (75.0)	3 (42.9)
Seldom	0	3 (42.9)
Sometimes	1 (12.5)	1 (14.3)
Often	0	0
All the Time	1 (12.5)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, my hemophilia made me angry.		
Number Assessed	8	7
Never	5 (62.5)	4 (57.1)
Seldom	0	3 (42.9)
Sometimes	1 (12.5)	0
Often	1 (12.5)	0
All the Time	1 (12.5)	0
In the past 4 weeks, I was worried because of my hemophilia.		
Number Assessed	8	7
Never	4 (50.0)	5 (71.4)
Seldom	1 (12.5)	2 (28.6)
Sometimes	1 (12.5)	0
Often	1 (12.5)	0
All the Time	1 (12.5)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_gol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt lonely because of my hemophilia.		
Number Assessed	8	7
Never	5 (62.5)	6 (85.7)
Seldom	1 (12.5)	1 (14.3)
Sometimes	1 (12.5)	0
Often	1 (12.5)	0
All the Time	0	0
In the past 4 weeks, I was afraid of bleeds.		
Number Assessed	8	6
Never	5 (62.5)	3 (50.0)
Seldom	2 (25.0)	1 (16.7)
Sometimes	0	2 (33.3)
Often	1 (12.5)	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I envied healthy boys my age.		
Number Assessed	8	7
Never	3 (37.5)	4 (57.1)
Seldom	0	2 (28.6)
Sometimes	3 (37.5)	1 (14.3)
Often	0	0
All the Time	2 (25.0)	0
In the past 4 weeks, I felt physically weaker than other boys.		
Number Assessed	8	7
Never	6 (75.0)	6 (85.7)
Seldom	1 (12.5)	0
Sometimes	1 (12.5)	1 (14.3)
Often	0	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt as well as other boys my age.		
Number Assessed	8	6
Never	0	0
Seldom	0	0
Sometimes	3 (37.5)	1 (16.7)
Often	1 (12.5)	1 (16.7)
All the Time	4 (50.0)	4 (66.7)
In the past 4 weeks, I felt contented about my body.		
Number Assessed	7	7
Never	0	0
Seldom	1 (14.3)	0
Sometimes	0	0
Often	1 (14.3)	1 (14.3)
All the Time	5 (71.4)	6 (85.7)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, hemophilia made my life more difficult.		
Number Assessed	8	7
Never	6 (75.0)	6 (85.7)
Seldom	1 (12.5)	0
Sometimes	0	1 (14.3)
Often	0	0
All the Time	1 (12.5)	0
In the past 4 weeks, I felt embarrassed about my hemophilia.		
Number Assessed	8	7
Never	6 (75.0)	7 (100.0)
Seldom	1 (12.5)	0
Sometimes	0	0
Often	0	0
All the Time	1 (12.5)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I had difficulty doing things with other kids my age.		
Number Assessed	8	7
Never	4 (50.0)	4 (57.1)
Seldom	2 (25.0)	0
Sometimes	2 (25.0)	3 (42.9)
Often	0	0
All the Time	0	0
In the past 4 weeks, I was unable to do as much with my friends because of my hemophilia.		
Number Assessed	8	7
Never	2 (25.0)	2 (28.6)
Seldom	1 (12.5)	1 (14.3)
Sometimes	4 (50.0)	4 (57.1)
Often	1 (12.5)	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt healthy in spite of my hemophilia.		
Number Assessed	8	7
Never	0	0
Seldom	1 (12.5)	0
Sometimes	2 (25.0)	0
Often	1 (12.5)	0
All the Time	4 (50.0)	7 (100.0)
In the past 4 weeks, my mother protected me too much.		
Number Assessed	8	7
Never	1 (12.5)	2 (28.6)
Seldom	0	2 (28.6)
Sometimes	1 (12.5)	0
Often	1 (12.5)	1 (14.3)
All the Time	5 (62.5)	2 (28.6)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 20[redacted]2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, my father protected me too much.		
Number Assessed	8	7
Never	1 (12.5)	2 (28.6)
Seldom	1 (12.5)	2 (28.6)
Sometimes	1 (12.5)	0
Often	1 (12.5)	1 (14.3)
All the Time	4 (50.0)	2 (28.6)
In the past 4 weeks, there were problems at home because of my hemophilia.		
Number Assessed	8	7
Never	6 (75.0)	6 (85.7)
Seldom	2 (25.0)	1 (14.3)
Sometimes	0	0
Often	0	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt I was causing my family trouble because of my hemophilia.		
Number Assessed	8	7
Never	6 (75.0)	7 (100.0)
Seldom	1 (12.5)	0
Sometimes	1 (12.5)	0
Often	0	0
All the Time	0	0
In the past 4 weeks, my parents limited their time at work or leisure because they had to look after me.		
Number Assessed	8	6
Never	4 (50.0)	4 (66.7)
Seldom	0	0
Sometimes	2 (25.0)	1 (16.7)
Often	1 (12.5)	1 (16.7)
All the Time	1 (12.5)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was able to talk to my friends about my hemophilia.		
Number Assessed	8	7
Never	3 (37.5)	2 (28.6)
Seldom	0	2 (28.6)
Sometimes	2 (25.0)	1 (14.3)
Often	1 (12.5)	1 (14.3)
All the Time	2 (25.0)	1 (14.3)
In the past 4 weeks, my best friend cared about how I was feeling.		
Number Assessed	8	7
Never	4 (50.0)	0
Seldom	0	0
Sometimes	0	2 (28.6)
Often	1 (12.5)	2 (28.6)
All the Time	3 (37.5)	3 (42.9)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, there was a best friend that I felt very close to.		
Number Assessed	8	7
Never	2 (25.0)	2 (28.6)
Seldom	0	1 (14.3)
Sometimes	0	0
Often	1 (12.5)	0
All the Time	5 (62.5)	4 (57.1)
In the past 4 weeks, my friends took care of me when I felt bad.		
Number Assessed	8	7
Never	2 (25.0)	1 (14.3)
Seldom	0	0
Sometimes	1 (12.5)	1 (14.3)
Often	3 (37.5)	3 (42.9)
All the Time	2 (25.0)	2 (28.6)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, others showed special consideration for me because of my hemophilia.		
Number Assessed	8	7
Never	2 (25.0)	1 (14.3)
Seldom	0	1 (14.3)
Sometimes	3 (37.5)	1 (14.3)
Often	1 (12.5)	2 (28.6)
All the Time	2 (25.0)	2 (28.6)
In the past 4 weeks, others showed understanding for my hemophilia.		
Number Assessed	7	7
Never	1 (14.3)	2 (28.6)
Seldom	0	0
Sometimes	2 (28.6)	0
Often	2 (28.6)	0
All the Time	2 (28.6)	5 (71.4)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was able to talk to others about problems in connection with my hemophilia.		
Number Assessed	8	7
Never	4 (50.0)	1 (14.3)
Seldom	0	0
Sometimes	1 (12.5)	4 (57.1)
Often	1 (12.5)	0
All the Time	2 (25.0)	2 (28.6)
In the past 4 weeks, others stood by me.		
Number Assessed	8	7
Never	1 (12.5)	1 (14.3)
Seldom	1 (12.5)	0
Sometimes	1 (12.5)	0
Often	4 (50.0)	2 (28.6)
All the Time	1 (12.5)	4 (57.1)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt different from others because of my hemophilia.		
Number Assessed	8	7
Never	4 (50.0)	6 (85.7)
Seldom	1 (12.5)	1 (14.3)
Sometimes	1 (12.5)	0
Often	2 (25.0)	0
All the Time	0	0
In the past 4 weeks, I was bothered by others knowing about my hemophilia.		
Number Assessed	8	7
Never	7 (87.5)	6 (85.7)
Seldom	0	0
Sometimes	0	1 (14.3)
Often	1 (12.5)	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, other kids teased me because of my hemophilia.		
Number Assessed	8	7
Never	6 (75.0)	6 (85.7)
Seldom	1 (12.5)	0
Sometimes	1 (12.5)	1 (14.3)
Often	0	0
All the Time	0	0
In the past 4 weeks, people behaved different towards me because of hemophilia.		
Number Assessed	8	7
Never	7 (87.5)	5 (71.4)
Seldom	0	2 (28.6)
Sometimes	1 (12.5)	0
Often	0	0
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt left out when others did things together.		
Number Assessed	8	7
Never	5 (62.5)	5 (71.4)
Seldom	0	1 (14.3)
Sometimes	3 (37.5)	1 (14.3)
Often	0	0
All the Time	0	0
In the past 4 weeks, because of hemophilia I had to refrain from sports that I like.		
Number Assessed	8	7
Never	2 (25.0)	4 (57.1)
Seldom	2 (25.0)	1 (14.3)
Sometimes	0	1 (14.3)
Often	3 (37.5)	0
All the Time	1 (12.5)	1 (14.3)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I had to do indoors activities more than other kids because of my hemophilia.		
Number Assessed	8	7
Never	6 (75.0)	6 (85.7)
Seldom	0	1 (14.3)
Sometimes	1 (12.5)	0
Often	0	0
All the Time	1 (12.5)	0
In the past 4 weeks, I had to refrain from sports like rollerblading or soccer.		
Number Assessed	8	7
Never	2 (25.0)	3 (42.9)
Seldom	2 (25.0)	1 (14.3)
Sometimes	1 (12.5)	1 (14.3)
Often	1 (12.5)	0
All the Time	2 (25.0)	2 (28.6)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.

[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.

Source: Listing 16.2.8.14

Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I did just as much sports as any other kids.		
Number Assessed	8	7
Never	2 (25.0)	2 (28.6)
Seldom	0	0
Sometimes	2 (25.0)	0
Often	0	2 (28.6)
All the Time	4 (50.0)	3 (42.9)
In the past 4 weeks, I participated in sports classes at school in spite of my hemophilia.		
Number Assessed	8	7
Never	2 (25.0)	1 (14.3)
Seldom	0	0
Sometimes	1 (12.5)	1 (14.3)
Often	0	0
All the Time	5 (62.5)	5 (71.4)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was able to participate at school in spite of my hemophilia.		
Number Assessed	8	7
Never	0	0
Seldom	0	0
Sometimes	1 (12.5)	0
Often	0	1 (14.3)
All the Time	7 (87.5)	6 (85.7)
In the past 4 weeks, I had to refrain from special school events because of my hemophilia.		
Number Assessed	8	7
Never	5 (62.5)	5 (71.4)
Seldom	0	1 (14.3)
Sometimes	2 (25.0)	0
Often	1 (12.5)	1 (14.3)
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I found it difficult to concentrate at school because I was in pain.		
Number Assessed	8	7
Never	3 (37.5)	4 (57.1)
Seldom	3 (37.5)	3 (42.9)
Sometimes	2 (25.0)	0
Often	0	0
All the Time	0	0
In the past 4 weeks, I tried to recognise early on when a bleed developed.		
Number Assessed	8	7
Never	3 (37.5)	2 (28.6)
Seldom	0	1 (14.3)
Sometimes	1 (12.5)	1 (14.3)
Often	4 (50.0)	0
All the Time	0	3 (42.9)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was careful with my body.		
Number Assessed	8	7
Never	0	0
Seldom	0	0
Sometimes	0	0
Often	3 (37.5)	3 (42.9)
All the Time	5 (62.5)	4 (57.1)
In the past 4 weeks, I was able to tell whether or not I was bleeding.		
Number Assessed	8	7
Never	1 (12.5)	1 (14.3)
Seldom	1 (12.5)	0
Sometimes	3 (37.5)	0
Often	2 (25.0)	1 (14.3)
All the Time	1 (12.5)	5 (71.4)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was in control of my complaints due to hemophilia.		
Number Assessed	8	7
Never	3 (37.5)	0
Seldom	0	0
Sometimes	0	0
Often	2 (25.0)	2 (28.6)
All the Time	3 (37.5)	5 (71.4)
In the past 4 weeks, I felt well informed about hemophilia.		
Number Assessed	8	7
Never	0	0
Seldom	0	0
Sometimes	0	1 (14.3)
Often	2 (25.0)	1 (14.3)
All the Time	6 (75.0)	5 (71.4)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, hemophilia was a normal part of my life.		
Number Assessed	8	7
Never	1 (12.5)	2 (28.6)
Seldom	0	0
Sometimes	1 (12.5)	2 (28.6)
Often	1 (12.5)	0
All the Time	5 (62.5)	3 (42.9)
In the past 4 weeks, I accepted having hemophilia.		
Number Assessed	8	7
Never	1 (12.5)	0
Seldom	0	0
Sometimes	1 (12.5)	0
Often	1 (12.5)	0
All the Time	5 (62.5)	7 (100.0)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I was satisfied with the hemophilia centre.		
Number Assessed	8	7
Never	0	0
Seldom	0	0
Sometimes	0	0
Often	0	0
All the Time	8 (100.0)	7 (100.0)
In the past 4 weeks, the treatment I got was okay.		
Number Assessed	8	7
Never	0	0
Seldom	0	0
Sometimes	1 (12.5)	0
Often	0	0
All the Time	7 (87.5)	7 (100.0)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I trusted my doctors and nurses.		
Number Assessed	8	7
Never	0	0
Seldom	0	0
Sometimes	0	0
Often	0	0
All the Time	8 (100.0)	7 (100.0)
In the past 4 weeks, I disliked visiting the hemophilia centre.		
Number Assessed	8	7
Never	6 (75.0)	3 (42.9)
Seldom	2 (25.0)	1 (14.3)
Sometimes	0	2 (28.6)
Often	0	1 (14.3)
All the Time	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, the injections annoyed me.		
Number Assessed	8	7
Never	6 (75.0)	5 (71.4)
Seldom	0	1 (14.3)
Sometimes	1 (12.5)	0
Often	0	1 (14.3)
All the Time	1 (12.5)	0
In the past 4 weeks, I was annoyed about the amount of time spent having injections.		
Number Assessed	8	7
Never	6 (75.0)	5 (71.4)
Seldom	1 (12.5)	0
Sometimes	1 (12.5)	0
Often	0	0
All the Time	0	2 (28.6)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=11)	End of Study (N=11)
In the past 4 weeks, I felt interrupted in my activities by injections.		
Number Assessed	8	7
Never	5 (62.5)	6 (85.7)
Seldom	0	0
Sometimes	2 (25.0)	1 (14.3)
Often	1 (12.5)	0
All the Time	0	0
In general, would you say your health is?		
Number Assessed	8	7
Excellent	2 (25.0)	4 (57.1)
Very Good	4 (50.0)	3 (42.9)
Good	2 (25.0)	0
Fair	0	0
Poor	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.14
Chiltern • [redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

Source: Study 3002 CSR Table 14.3.5.2.

Table A.4-3 Study 3002: QOL Questionnaire for Children and Teenager (Ages 4-7) (Safety Population)

	Screening (N=10)	End of Study (N=10)
Transformed Scale Score [1]		
n	12	11
Mean (SD)	20.90 (9.465)	21.58 (11.510)
Median	20.54	20.37
Q1, Q3	14.55, 24.60	11.11, 27.78
Min, Max	7.7, 45.3	5.6, 44.4
Transformed Scale Score [1] Change from Baseline		
n	--	10
Mean (SD)		3.03 (15.269)
Median		4.72
Q1, Q3		-9.26, 11.06
Min, Max		-23.1, 25.0
How frequent were your bleeds in the last 4 weeks?		
Number Assessed	12	11
No Bleeds	10 (83.3)	8 (72.7)
1	1 (8.3)	1 (9.1)
2	0	2 (18.2)
More Than 2	1 (8.3)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
How much were you troubled by bleeds during the last 4 weeks?		
Number Assessed	5	3
Not At All	3 (60.0)	0
Somewhat	2 (40.0)	3 (100.0)
Very Much	0	0
How severe were your bleeds during the last 4 weeks?		
Number Assessed	2	3
Slight	0	1 (33.3)
Moderate	1 (50.0)	2 (66.7)
Very Severe	1 (50.0)	0
Did you feel a strange sensation in your joints before you had a bleed?		
Number Assessed	3	3
Never	1 (33.3)	2 (66.7)
Sometimes	2 (66.7)	0
Always	0	1 (33.3)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
Did you have to stay quiet when you had bleeds?		
Number Assessed	3	3
Never	2 (66.7)	1 (33.3)
Sometimes	1 (33.3)	2 (66.7)
Always	0	0
When you had bleeds, did you inform your parents immediately?		
Number Assessed	3	3
Never	0	0
Sometimes	2 (66.7)	2 (66.7)
Always	1 (33.3)	1 (33.3)
In the past 4 weeks, I injected myself.		
Number Assessed	12	11
Never	12 (100.0)	11 (100.0)
Sometimes	0	0
Very Often	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, my mother injected me.		
Number Assessed	11	11
Never	3 (27.3)	4 (36.4)
Sometimes	2 (18.2)	1 (9.1)
Very Often	6 (54.5)	6 (54.5)
In the past 4 weeks, my father injected me.		
Number Assessed	12	11
Never	7 (58.3)	8 (72.7)
Sometimes	3 (25.0)	1 (9.1)
Very Often	2 (16.7)	2 (18.2)
In the past 4 weeks, a nurse injected me.		
Number Assessed	11	11
Never	6 (54.5)	4 (36.4)
Sometimes	4 (36.4)	5 (45.5)
Very Often	1 (9.1)	2 (18.2)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, a doctor injected me.		
Number Assessed	11	11
Never	9 (81.8)	8 (72.7)
Sometimes	2 (18.2)	2 (18.2)
Very Often	0	1 (9.1)
In the past 4 weeks, my swellings hurt.		
Number Assessed	12	11
Never	6 (50.0)	9 (81.8)
Sometimes	5 (41.7)	2 (18.2)
Very Often	1 (8.3)	0
In the past 4 weeks, it was difficult for me to move my arms or legs.		
Number Assessed	12	11
Never	7 (58.3)	9 (81.8)
Sometimes	4 (33.3)	2 (18.2)
Very Often	1 (8.3)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, I was afraid of hurting myself.		
Number Assessed	12	11
Never	8 (66.7)	10 (90.9)
Sometimes	3 (25.0)	1 (9.1)
Very Often	1 (8.3)	0
In the past 4 weeks, I was in a bad mood because of my hemophilia.		
Number Assessed	12	11
Never	8 (66.7)	6 (54.5)
Sometimes	3 (25.0)	4 (36.4)
Very Often	1 (8.3)	1 (9.1)
In the past 4 weeks, I was sad because of my hemophilia.		
Number Assessed	12	11
Never	10 (83.3)	8 (72.7)
Sometimes	2 (16.7)	3 (27.3)
Very Often	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]20[redacted]2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, my hemophilia made me angry.		
Number Assessed	12	11
Never	10 (83.3)	7 (63.6)
Sometimes	1 (8.3)	2 (18.2)
Very Often	1 (8.3)	2 (18.2)
In the past 4 weeks, I was afraid of bleeds.		
Number Assessed	12	11
Never	9 (75.0)	9 (81.8)
Sometimes	3 (25.0)	2 (18.2)
Very Often	0	0
In the past 4 weeks, I envied healthy boys my age.		
Number Assessed	12	11
Never	9 (75.0)	9 (81.8)
Sometimes	2 (16.7)	1 (9.1)
Very Often	1 (8.3)	1 (9.1)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, I felt embarrassed about my hemophilia.		
Number Assessed	12	11
Never	11 (91.7)	10 (90.9)
Sometimes	1 (8.3)	1 (9.1)
Very Often	0	0
In the past 4 weeks, my mother protected me too much.		
Number Assessed	11	11
Never	6 (54.5)	5 (45.5)
Sometimes	2 (18.2)	4 (36.4)
Very Often	3 (27.3)	2 (18.2)
In the past 4 weeks, my father protected me too much.		
Number Assessed	11	11
Never	6 (54.5)	6 (54.5)
Sometimes	4 (36.4)	3 (27.3)
Very Often	1 (9.1)	2 (18.2)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted] 20[redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, my parents told me off when I hurt myself.		
Number Assessed	12	11
Never	11 (91.7)	9 (81.8)
Sometimes	1 (8.3)	1 (9.1)
Very Often	0	1 (9.1)
In the past 4 weeks, my parents forbade me to do certain things because of my hemophilia.		
Number Assessed	12	11
Never	5 (41.7)	7 (63.6)
Sometimes	6 (50.0)	4 (36.4)
Very Often	1 (8.3)	0
In the past 4 weeks, I was unable to do as much with my friends because of my hemophilia.		
Number Assessed	12	11
Never	9 (75.0)	9 (81.8)
Sometimes	3 (25.0)	2 (18.2)
Very Often	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, I felt different from others because of my hemophilia.		
Number Assessed	12	11
Never	8 (66.7)	8 (72.7)
Sometimes	3 (25.0)	3 (27.3)
Very Often	1 (8.3)	0
In the past 4 weeks, I felt left out when others did things together.		
Number Assessed	12	11
Never	10 (83.3)	8 (72.7)
Sometimes	2 (16.7)	3 (27.3)
Very Often	0	0
In the past 4 weeks, I did just as much sports as any other kids.		
Number Assessed	9	11
Never	0	0
Sometimes	2 (22.2)	5 (45.5)
Very Often	7 (77.8)	6 (54.5)

Notes: Proportions are based on the number of subjects with a response by visit and parameter.

[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.

Source: Listing 16.2.8.13

Chiltern • [redacted] 2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, I was able to take part in games at nursery school/kindergarten in spite of my hemophilia.		
Number Assessed	11	11
Never	0	2 (18.2)
Sometimes	2 (18.2)	1 (9.1)
Very Often	9 (81.8)	8 (72.7)
In the past 4 weeks, because of hemophilia I had to refrain from playing games that I enjoy.		
Number Assessed	11	11
Never	8 (72.7)	9 (81.8)
Sometimes	3 (27.3)	2 (18.2)
Very Often	0	0
In the past 4 weeks, I disliked visiting the hemophilia centre.		
Number Assessed	11	11
Never	9 (81.8)	8 (72.7)
Sometimes	1 (9.1)	3 (27.3)
Very Often	1 (9.1)	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

	Screening (N=10)	End of Study (N=10)
In the past 4 weeks, the injections annoyed me.		
Number Assessed	11	11
Never	6 (54.5)	4 (36.4)
Sometimes	4 (36.4)	5 (45.5)
Very Often	1 (9.1)	2 (18.2)
In general, would you say your health is?		
Number Assessed	11	11
Excellent	5 (45.5)	3 (27.3)
Good	6 (54.5)	8 (72.7)
Poor	0	0

Notes: Proportions are based on the number of subjects with a response by visit and parameter.
[1] Transformed Scale Score (TSS) = 100 x(sum of the n item scores - n)/(maximal possible raw score - minimal possible raw score of the n items) = 100 x(sum of the n item scores - n)/(n x R - n), where R=3 for age group 4-7 years old and R=5 for age group 8-12 years old.
Source: Listing 16.2.8.13
Chiltern • [redacted]20[redacted]:2:39 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_qol.sas • BSutton

Source: Study 3002 CSR Table 14.3.5.1.

Table A.4-4 Study 3002: Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Relationship (Safety Population)

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
Any Treatment-Emergent AEs	26 (96.3)	152
Related	0	0
Not Related	26 (96.3)	152
Missing	0	0
INFECTIONS AND INFESTATIONS	18 (66.7)	42
Related	0	0
Not Related	18 (66.7)	42
Missing	0	0
NASOPHARYNGITIS	4 (14.8)	6
Related	0	0
Not Related	4 (14.8)	6
Missing	0	0
BRONCHITIS	3 (11.1)	4
Related	0	0
Not Related	3 (11.1)	4
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 20[redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
EAR INFECTION	3 (11.1)	4
Related	0	0
Not Related	3 (11.1)	4
Missing	0	0
GASTROENTERITIS	3 (11.1)	3
Related	0	0
Not Related	3 (11.1)	3
Missing	0	0
PHARYNGITIS	2 (7.4)	3
Related	0	0
Not Related	2 (7.4)	3
Missing	0	0
VIRAL INFECTION	2 (7.4)	3
Related	0	0
Not Related	2 (7.4)	3
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
MOLLUSCUM CONTAGIOSUM	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
UPPER RESPIRATORY TRACT INFECTION	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
INFLUENZA	1 (3.7)	2
Related	0	0
Not Related	1 (3.7)	2
Missing	0	0
PHARYNGITIS STREPTOCOCCAL	1 (3.7)	2
Related	0	0
Not Related	1 (3.7)	2
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
GASTROENTERITIS SALMONELLA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
GASTROENTERITIS VIRAL	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
IMPETIGO	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
MENINGOCOCCAL INFECTION	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
OTITIS MEDIA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
POST PROCEDURAL INFECTION	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
RESPIRATORY TRACT INFECTION	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
RESPIRATORY TRACT INFECTION VIRAL	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
TONSILLITIS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
TOOTH ABSCESS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (37.0)	35
Related	0	0
Not Related	10 (37.0)	35
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
CONTUSION	5 (18.5)	9
Related	0	0
Not Related	5 (18.5)	9
Missing	0	0
HEAD INJURY	3 (11.1)	3
Related	0	0
Not Related	3 (11.1)	3
Missing	0	0
INJURY	2 (7.4)	4
Related	0	0
Not Related	2 (7.4)	4
Missing	0	0
FALL	1 (3.7)	5
Related	0	0
Not Related	1 (3.7)	5
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
FACE INJURY	1 (3.7)	3
Related	0	0
Not Related	1 (3.7)	3
Missing	0	0
LIP INJURY	1 (3.7)	2
Related	0	0
Not Related	1 (3.7)	2
Missing	0	0
ARTHROPOD STING	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
FOREARM FRACTURE	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

□

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
GINGIVAL INJURY	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
LACERATION	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
LIGAMENT SPRAIN	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
LIMB INJURY	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
PROCEDURAL PAIN	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
THERMAL BURN	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
TONGUE INJURY	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
GASTROINTESTINAL DISORDERS	10 (37.0)	15
Related	0	0
Not Related	10 (37.0)	15
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
DENTAL DISCOMFORT	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
DIARRHOEA	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
TOOTHACHE	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
VOMITING	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 20[redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
DENTAL CARIES	1 (3.7)	3
Related	0	0
Not Related	1 (3.7)	3
Missing	0	0
ABDOMINAL PAIN	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
ABDOMINAL PAIN UPPER	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
CONSTIPATION	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 20[redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
NAUSEA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	9 (33.3)	15
Related	0	0
Not Related	9 (33.3)	15
Missing	0	0
PYREXIA	9 (33.3)	14
Related	0	0
Not Related	9 (33.3)	14
Missing	0	0
INJECTION SITE ERYTHEMA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (29.6)	10
Related	0	0
Not Related	8 (29.6)	10
Missing	0	0
ARTHRALGIA	4 (14.8)	5
Related	0	0
Not Related	4 (14.8)	5
Missing	0	0
PAIN IN EXTREMITY	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
BACK PAIN	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 20[redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
GROIN PAIN	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
TENDONITIS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (25.9)	10
Related	0	0
Not Related	7 (25.9)	10
Missing	0	0
COUGH	4 (14.8)	4
Related	0	0
Not Related	4 (14.8)	4
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
OROPHARYNGEAL PAIN	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
EPISTAXIS	1 (3.7)	4
Related	0	0
Not Related	1 (3.7)	4
Missing	0	0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (14.8)	4
Related	0	0
Not Related	4 (14.8)	4
Missing	0	0
ANAEMIA	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
EOSINOPHILIA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
IRON DEFICIENCY ANAEMIA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (11.1)	7
Related	0	0
Not Related	3 (11.1)	7
Missing	0	0
RASH	1 (3.7)	2
Related	0	0
Not Related	1 (3.7)	2
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
ECCHYMOSIS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
ECZEMA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
ERYTHEMA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
SWELLING FACE	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
URTICARIA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
NERVOUS SYSTEM DISORDERS	3 (11.1)	5
Related	0	0
Not Related	3 (11.1)	5
Missing	0	0
HEADACHE	2 (7.4)	4
Related	0	0
Not Related	2 (7.4)	4
Missing	0	0
POST-TRAUMATIC HEADACHE	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
EYE DISORDERS	2 (7.4)	2
Related	0	0
Not Related	2 (7.4)	2
Missing	0	0
CONJUNCTIVITIS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
CONJUNCTIVITIS ALLERGIC	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
EAR AND LABYRINTH DISORDERS	1 (3.7)	2
Related	0	0
Not Related	1 (3.7)	2
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
EAR PAIN	1 (3.7)	2
Related	0	0
Not Related	1 (3.7)	2
Missing	0	0
IMMUNE SYSTEM DISORDERS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
SEASONAL ALLERGY	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
INVESTIGATIONS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1

Source: Listing 16.2.7.1

Chiltern • [redacted] 20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
SERUM FERRITIN DECREASED	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
METABOLISM AND NUTRITION DISORDERS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
VITAMIN D DEFICIENCY	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted] 2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

System Organ Class Preferred Term Relationship	Total (N=27) n (%)	E
SKIN PAPILLOMA	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
PSYCHIATRIC DISORDERS	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0
ATTENTION DEFICIT/HYPERACTIVITY DISORDER	1 (3.7)	1
Related	0	0
Not Related	1 (3.7)	1
Missing	0	0

Notes: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of specified events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using MedDRA version 14.1
Source: Listing 16.2.7.1
Chiltern • [redacted]20[redacted]:2:36 PM • K:\CSL_Behring\33177\21_Stat\Programs\Tables\t_aerel.sas • BPierce

Source: Study 3002 CSR Table 14.3.1.4.1.

A.5 Study 3003

Table A.5-1 Study 3003: Summary of Investigator's (Surgeon's) Clinical Assessment of Hemostatic Efficacy for Surgical Prophylaxis (Surgical Population)

Assessment	Total (N=7)
Number of Surgeries	7
Assessment of Hemostasis Efficacy at Surgery 0 Hours	
Excellent	4
Good	1
Moderate	0
Poor/No Response	0
Assessment of Hemostasis Efficacy at Surgery 24 Hours	
Excellent	2
Good	0
Moderate	0
Poor/No Response	0
Assessment of Hemostasis Efficacy at Surgery 48 Hours	
Excellent	2
Good	0
Moderate	0
Poor/No Response	0

Source: Listing 16.2.6.4
Chiltern • [redacted]20[redacted]:4:40 PM • K:\CSL_Behring\32670\21_Stat\Programs\Tables\t_hemos_surg.sas • ZScott

Page 1 of 2

Assessment	Total (N=7)
Assessment of Hemostasis Efficacy at Surgery 72 Hours	
Excellent	2
Good	0
Moderate	0
Poor/No Response	0
Assessment of Hemostasis Efficacy at Discharge	
Excellent	4
Good	0
Moderate	0
Poor/No Response	0
Assessment of Hemostasis Efficacy Overall	
Excellent	2
Good	0
Moderate	0
Poor/No Response	0

Source: Listing 16.2.6.4
Chiltern • [redacted]20[redacted] 4:40 PM • K:\CSL_Behring\32670\21_Stat\Programs\Tables\t_hemos_surg.sas • ZScott

Page 2 of 2

Source: Study 3003 aCSR Table 14.4.3.

Table A.5-2 Study 3003: FIX Activity Concentrations from Central Laboratory (All Subjects)

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
0360014-2020	Day 1	[redacted]:09:00					27.0		
0360015-2021	Day 1	[redacted]:16:20					14.0		
0400001-0020	Day 1	[redacted]:12:30					11.9		
	Month 6	[redacted]:10:18					17.8		
	RFIXPK	#6M+0D :10:18		-0.017			18.0	0.0	
	RFIXPK	#6M+0D :10:48	0.5	0.483	-0.017		137.9	119.9	
	RFIXPK	#6M+2D :10:20	72.0	48.017	-23.983		86.8	68.8	
	RFIXPK	#6M+7D :10:00	168.0	167.683	-0.317		40.1	22.1	
	RFIXPK	#6M+14 :10:00	336.0	335.683	-0.317		19.1	1.1	
	RFIXPK	#6M+21 :10:20	504.0	504.017	0.017		10.3	-7.7	
0400002-2004	Day 1	[redacted]:09:34					13.2		
0400002-2007	Day 1	[redacted]:10:20					10.3		
1240021-2018	Day 1	[redacted]:08:10					56.5		
2030006-2022	Day 1	[redacted]:10:07					5.0		

Chiltern • [redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
2030007-2011	Day 1	[redacted]20[redacted]:11:24					11.4		
2030008-2001	Day 1	[redacted]20[redacted]:10:40					18.0		
	Month 6	[redacted]20[redacted]:09:50					13.0		
2500001-0055	Day 1	[redacted]20[redacted]:11:45					7.2		
2500015-0042	Day 1	[redacted]20[redacted]:13:46					34.4		
2500017-0053	Day 1	[redacted]20[redacted]:10:48					20.2		
2500017-2016	Day 1	[redacted]20[redacted]:11:18					13.6		
2500017-2025	Day 1	[redacted]20[redacted]:11:33					16.6		
2500026-2005	Day 1	[redacted]20[redacted]:15:20					7.5		
2500026-2006	Day 1	[redacted]20[redacted]:12:00					10.8		
2500026-2008	Day 1	[redacted]20[redacted]:11:45					8.4		

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
2500029-2012	Day 1	[redacted]:11:28					11.5		
2760001-0017	Day 1	[redacted]:15:45					39.8		
2760034-0015	Day 1	[redacted]:10:30					19.5		
2760065-0018	Day 1	[redacted]:12:15					17.1		
2760066-0002	Day 1	[redacted]:17:44					31.9		
2760066-0004	Day 1	[redacted]:11:37					19.4		
2760078-2009	Day 1	[redacted]:15:20					14.6		
2760078-2019	Day 1	[redacted]:08:29					16.0		
2760079-2024	Day 1	[redacted]:10:30					11.9		
3760001-0026	Day 1	[redacted]:11:25					36.5		
	Month 6	[redacted]:10:41					24.9		

Chiltern • [redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
3760001-0027	Day 1	[redacted]20[redacted]:12:10					80.3		
	Month 6	[redacted]20[redacted]:09:48					32.7		
3760001-0028	Day 1	[redacted]20[redacted]:12:20					53.1		
	Month 6	[redacted]20[redacted]:11:00					21.9		
3760001-0029	Day 1	[redacted]20[redacted]:12:15					23.1		
	Month 6	[redacted]20[redacted]:12:34					22.0		
3760001-0031	Day 1	[redacted]20[redacted]:08:25					9.0		
	Month 6	[redacted]20[redacted]:11:40					14.1		
	RFIXPK	#6M+72D :11:11		-0.033			10.3	0.0	
	RFIXPK	#6M+72D :11:51	0.5	0.633	0.133		102.4	92.1	
	RFIXPK	#6M+75D :09:23	72.0	70.167	-1.833		59.8	49.5	
	RFIXPK	#6M+79D :09:06	168.0	165.883	-2.117		34.8	24.5	
	RFIXPK	#6M+66D :08:55	336.0	333.700	-2.300		15.2	4.9	
	Unscheduled 110.06	#6M+71D :08:55					10.5		
3760001-0032	Day 1	[redacted]20[redacted]:09:05					29.3		
	Month 6	[redacted]20[redacted]:08:55					16.9		

Notes: BLQ = Below Limit of Quantification.

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
3760001-0034	Day 1	[redacted]20[redacted]:10:05					5.0		
	Month 6	[redacted]20[redacted]:12:00					6.3		
3760001-0035	Day 1	[redacted]20[redacted]:11:20					24.2		
	Month 6	[redacted]20[redacted]:11:02					25.8		
3760001-0036	Day 1	[redacted]20[redacted]:10:25					29.3		
	Surgery PK	#-4D 10:45		-164.517		75 IU/kg	50.6	27.5	
	Surgery PK	# 3D 07:12		-0.067		75 IU/kg	23.1	0.0	
	Surgery PK	#3D 07:40	0.5	0.400	-0.100	75 IU/kg	87.6	64.5	
	Surgery PK	#6D 09:35	72.0	74.317	2.317	75 IU/kg	42.7	19.6	
	Surgery PK	#6D 12:25		77.150		75 IU/kg	79.6	56.5	
	Unscheduled 509.03	#10D 09:50					44.2		
	Surgery PK	#37D 12:02		820.767		75 IU/kg	57.7	34.6	
	Month 6	#93D 12:10					27.5		
3760001-0037	Day 1	[redacted]20[redacted]:12:35					50.2		
	Month 6	[redacted]20[redacted]:12:39					12.9		

Notes: BLQ = Below Limit of Quantification.

#新薬情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
3760001-0039	Day 1	[redacted]20[redacted]:12:50					36.6		
	Month 6	[redacted]20[redacted]:12:30					8.5		
	RFIXPK	#6M+47D :09:48		0.000			10.9	0.0	
	RFIXPK	#6M+47D :10:31	0.5	0.717	0.217		102.2	91.3	
	RFIXPK	#6M+50D :11:14	72.0	73.433	1.433		51.7	40.8	
	RFIXPK	#6M+54D :11:52	168.0	170.067	2.067		33.1	22.2	
	RFIXPK	#6M+61D :11:52	336.0	338.067	2.067		16.2	5.3	
	RFIXPK	#6M+68D :11:16	504.0	505.467	1.467		5.1	-5.8	
3760001-2026	Day 1	[redacted]20[redacted]:13:43					32.3		
3760001-2027	Day 1	[redacted]20[redacted]:14:02					17.3		
3760001-2028	Day 1	[redacted]20[redacted]:14:30					10.3		
3800015-0056	Day 1	[redacted]20[redacted]:09:28					10.5		
	Month 6	[redacted]20[redacted]:09:12					11.3		
3800023-0009	Day 1	[redacted]20[redacted]:10:35					10.9		
	Month 6	[redacted]20[redacted]:10:35					16.0		

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
3800023-0010	Day 1	[redacted]09:05					20.7		
	Month 6	[redacted]15:05					16.4		
3800023-0051	Day 1	[redacted]10:50					12.2		
	Month 6	[redacted]11:05					49.7		
3800023-0057	Day 1	[redacted]11:10					10.4		
	Month 6	[redacted]11:10					13.4		
3800023-2010	Day 1	[redacted]10:50					13.5		
	Month 6	[redacted]09:45					20.4		
3800023-2030	Day 1	[redacted]11:30					8.5		
3800025-0025	Day 1	[redacted]12:00					51.7		
	Month 6	[redacted]08:13					11.9		
3920026-0030	Day 1	[redacted]15:20					21.4		
	Month 6	[redacted]14:15					14.7		

Notes: BLQ = Below Limit of Quantification.

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
3920027-0003	Day 1	[redacted]20[redacted]:10:55					14.5		
	Month 6	[redacted]20[redacted]:11:00					10.8		
	RFIXPK	#6M+0D :11:00		-0.017			10.8	0.0	
	RFIXPK	#6M+0D :11:32	0.5	0.517	0.017		102.9	92.1	
	RFIXPK	#6M+3D :09:15	72.0	70.233	-1.767		58.1	47.3	
	RFIXPK	#6M+6D :09:24	168.0	166.383	-1.617		33.8	23.0	
	RFIXPK	#6M+13D :09:32	336.0	334.517	-1.483		14.3	3.5	
	RFIXPK	#6M+21D :10:18	504.0	527.283	23.283		5.2	-5.6	
3920028-0038	Day 1	[redacted]20[redacted]:13:30					12.3		
	Month 6	[redacted]20[redacted]:11:33					12.5		
3920029-0023	Day 1	[redacted]20[redacted]:13:20					24.3		
	Month 6	[redacted]20[redacted]:12:03					12.7		
3920030-0001	Day 1	[redacted]20[redacted]:15:28					3.1		
	Month 6	[redacted]20[redacted]:11:58					5.9		
	Surgery PK	#6M+0D :11:58		-0.433		75 IU/kg	5.9	0.0	
	Surgery PK	#6M+0D :12:55	0.5	0.517	0.01775	IU/kg	58.1	52.2	
	Surgery PK	#6M+1D :08:10		19.767		75 IU/kg	41.6	35.7	

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 1									
3920031-0040	Day 1	[redacted]:10:15					35.3		
	Month 6	[redacted]:09:15					27.4		
7240007-0006	Day 1	[redacted]:09:30					4.6		
	Month 6	[redacted]:10:00					7.6		
7240007-2017	Day 1	[redacted]:12:00					16.0		
	Month 6	[redacted]:11:00					11.0		
7240009-0005	Day 1	[redacted]:12:20					20.7		
	Month 6	[redacted]:12:19					11.3		
7240009-0043	Day 1	[redacted]:13:22					4.0		
	Month 6	[redacted]:14:47					13.1		
8400160-0021	Day 1	[redacted]:11:52					52.4		
	Month 6	[redacted]:15:07					31.6		

Chiltern • [redacted]:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 2									
1000008-0007	Day 1	[redacted]20[redacted]:09:45					31.4		
	Month 6	[redacted]20[redacted]:09:45					14.1		
1000008-0008	Day 1	[redacted]20[redacted]:09:30					21.7		
	Month 6	[redacted]20[redacted]:10:10					10.4		
1000008-0012	Day 1	[redacted]20[redacted]:09:00					15.2		
	Month 6	[redacted]20[redacted]:09:15					10.5		
1000008-0013	Day 1	[redacted]20[redacted]:10:00					16.3		
	Month 6	[redacted]20[redacted]:10:40					14.7		
2500001-0019	Day 1	[redacted]20[redacted]:16:32					43.4		
2500002-0063	Day 1	[redacted]20[redacted]:10:10					40.4		
	Unscheduled 50.03	#131D:09:35					23.6		
	Month 6	[redacted]20[redacted]:09:35					11.8		
2500002-0066	Day 1	[redacted]20[redacted]:10:36					32.2		
	Unscheduled 50.02	#90D 10:40					42.7		
	Month 6	[redacted]20[redacted]:11:10					46.7		

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 2									
2500002-0068	Day 1	[redacted]20[redacted]:11:43					29.4		
	Month 6	20[redacted]:11:40					87.1		
2500002-0069	Day 1	[redacted]20[redacted]:12:35					37.2		
	Month 6	20[redacted]:11:15					77.7		
3800015-0033	Day 1	[redacted]20[redacted]:11:55					21.7		
	Month 6	20[redacted]:12:09					13.7		
3920025-0047	Day 1	[redacted]20[redacted]:13:00					51.0		
	Unscheduled 20.02	#42D 14:06					9.0		
	Unscheduled 50.02	#54D 12:37					6.2		
	Month 6	[redacted]20[redacted]:13:08					19.3		
3920030-0050	Day 1	[redacted]20[redacted]:09:11					14.6		
	Month 6	20[redacted]:10:34					10.6		

Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 2									
3920030-0058	Day 1	[redacted]20[redacted]:14:35					21.2		
	Month 6	[redacted]20[redacted]:14:59					12.0		
	RFIXPK	#6M+0D :14:59		-0.017			12.0	0.0	
	RFIXPK	#6M+0D :15:54	0.5	0.900	0.400		105.5	93.5	
	RFIXPK	#6M+4D :15:04	72.0	96.067	24.067		47.9	35.9	
	RFIXPK	#6M+6D :15:51	168.0	144.850	-23.150		33.3	21.3	
	RFIXPK #6M+14D	:14:13	336.0	335.217	-0.783		14.2	2.2	
	RFIXPK	:15:08	504.0	504.133	0.133		4.9	-7.1	
		#6M21D							
7240007-0061	Day 1	[redacted]20[redacted]:10:00					22.7		
7240008-0011	Day 1	[redacted]20[redacted]:11:50					19.0		
	Month 6	[redacted]20[redacted]:10:20					11.2		
8400191-0045	Day 1	[redacted]20[redacted]:09:25					77.2		
	RFIXPK	#126D :11:47		-0.550		50 IU/kg	30.9	0.0	
	RFIXPK	#126D :12:59	0.5	0.650	0.150	50 IU/kg	66.3	35.4	
	Surgery PK	#140D :09:59	0.5				50.8		
	Month 6	[redacted]20[redacted]:11:56					17.0		

Chiltern • [redacted]20[redacted]4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 3									
3800023-2054	Screening	[redacted]20[redacted]:10:15					4.6		
	RFIXPK	#13D :10:00		-0.017			3.6		
	RFIXPK	#13D :10:37	0.5	0.600	0.100		120.2		
	RFIXPK	#16D :09:30	72.0	71.483	-0.517		52.9		
	RFIXPK	#20D :09:25	168.0	167.400	-0.600		26.5		
	Surgery PK	#51D :08:25		-0.033		75 IU/kg	23.1	0.0	
	Surgery PK	#51D :09:00	0.5	0.550	0.050	75 IU/kg	121.7	98.6	
	Surgery PK	#51D :14:15		5.800		75 IU/kg	107.9	84.8	
	Surgery PK	#51D :16:15		7.800		75 IU/kg	105.2	82.1	
	Surgery PK	#52D :07:35		23.133		75 IU/kg	80.8	57.7	
	Surgery PK	#52D :10:15	24.0	25.800	1.800	75 IU/kg	84.0	60.9	
	Surgery PK	#52D :10:50		26.383		75 IU/kg	124.9	101.8	
	Surgery PK	#53D :12:00	48.0	51.550	3.550	75 IU/kg	102.6	79.5	
	Surgery PK	#53D :12:35		52.133		75 IU/kg	139.2	116.1	
	Surgery PK	#54D :14:00	72.0	77.550	5.550	75 IU/kg	99.5	76.4	
	Surgery PK	#79D :10:50		674.383		75 IU/kg	28.9	5.8	

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 3									
4580001-2051	Screening	[redacted]20[redacted]:13:30					1.0		
	RFIXPK	#28D :15:06		-0.067			2.7	0.0	
	RFIXPK	#28D :15:45	0.5	0.583	0.083		117.0	114.3	
	RFIXPK	#31D :10:40	72.0	67.500	-4.500		50.0	47.3	
	RFIXPK	#35D :12:00	168.0	164.833	-3.167		27.8	25.1	
	RFIXPK	#43D :11:20	336.0	356.167	20.167		7.4	4.7	
	RFIXPK	#48D :11:45	504.0	476.583	-27.417		4.1	1.4	
	Surgery PK	#49D :10:30	0.5	0.500	0.000		100.7		
	Surgery PK	#49D :14:25		4.417			83.3		
	Surgery PK	#51D :10:10	48.0	48.167	0.167		51.1		
	Surgery PK	#51D :10:45		48.750			91.4		
	Surgery PK	#83D :11:50		817.833			36.7		

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

#新薬承認情報提供時に置き換え

Site - Subject ID	Study Part	Sample Date:Time	Scheduled Time (hr)	Actual Time (hr)	Deviation (hr)	Dose IU/kg	FIX Concentration Uncorrected (%)	FIX Concentration Corrected (%)	Sample Quality
Treatment Arm 3									
6080001-2053	RFIXPK	[redacted]:11:35	0.5	-823991.250	-823991.750		108.8	108.8	
	Screening	#-28D :08:38					BLQ		
	RFIXPK	#0D :10:35		-0.250			BLQ	0.0	
	RFIXPK	#3D :11:10	72.0	72.333	0.333		47.7	47.7	
	Surgery PK	#4D :06:55	0.5	0.667	0.167	75 IU/kg	97.5		
	Surgery PK	#6D :08:00	48.0	49.750	1.750	75 IU/kg	50.6		
	Surgery PK	#7D :08:00	72.0	73.750	1.750	75 IU/kg	60.3		
	Surgery PK	#8D :08:15		98.000		75 IU/kg	50.8		
	Surgery PK	#10D :07:15		145.000		75 IU/kg	51.1		
	Surgery PK	#14D :08:00		241.750		75 IU/kg	54.6		
	Surgery PK	#16D :07:30		289.250		75 IU/kg	68.3		
	Surgery PK	#24D :07:30		481.250		75 IU/kg	60.1		
	Surgery PK	#35D :08:30		746.250		75 IU/kg	52.1		
7100001-2056	Screening	[redacted]:08:39					BLQ		
	RFIXPK	#9D :08:55		-0.167			BLQ	0.0	
	RFIXPK	#9D :09:45	0.5	0.667	0.167		113.4	113.4	
	RFIXPK	#11D :09:20	72.0	48.250	-23.750		61.8	61.8	

Chiltern • [redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_concen.sas • ZScott
Notes: BLQ = Below Limit of Quantification.

Source: Study 3003 aCSR Listing 16.2.5.1.

#新薬承認情報提供時に置き換え

Table A.5-3 Study 3003: FIX Activity Concentrations from Local Laboratory (All Subjects)

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 1					
0360014-2020	[redacted]:09:00	24	%		
0400001-0020	[redacted]:12:30	4	%		
0400002-2004	[redacted]:09:34	36	%	Other: roomtemperature	
1240021-2018	[redacted]:10:00	32	%	Other: room temp sample	
2030006-2022	[redacted]:08:59	114	%	Not Done	
	#0D :12:35	116	%	Not Done	
2500001-0055	[redacted]:11:45	8	%	Other: normal	
2500015-0042	[redacted]:13:46	36	%		
2500017-0053	[redacted]:10:48	19	%		
2500026-2006	[redacted]:12:00	5	%		
2500026-2008	[redacted]:11:45	4	%		

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted] 4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

Page 1 of 11

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 1					
2500029-2012	[redacted]20[redacted]:11:28	10.0	%	Other: plasma is normal	
2760001-0017	[redacted]20[redacted]:15:45	53.1	%		
2760065-0018	[redacted]20[redacted]:12:15	30	%		
2760079-2024	[redacted]20[redacted]:10:30	20	%		
3760001-0026	[redacted]20[redacted]:11:25	42	%		
	#128D :10:42	24	%		185.5
3760001-0027	[redacted]20[redacted]:12:10	95	%		
	#191D :09:48	34	%		256.4
	#238D :12:41	14	%		12.7
3760001-0028	[redacted]20[redacted]:12:20	61	%		
	#182D :11:00	29	%		213.0
3760001-0029	[redacted]20[redacted]:12:15	25	%		
	#176D 12:34	25	%		134.5

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20[redacted]:4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 1					
3760001-0031	[redacted]20[redacted]:08:25	13	%		
	#168D :11:40	14	%		311.1
	#240D :11:51	123	%		0.6
	#243D :09:23	52	%		70.2
	#247D :09:06	27	%		165.9
	#254D :08:55	14	%		333.7
	#259D :08:55	10	%		453.7
3760001-0032	[redacted]20[redacted]:09:05	34	%		
	#188D :08:55	19	%		201.9
3760001-0034	[redacted]20[redacted]:10:05	13	%		
	#142D :12:00	10	%		338.7
3760001-0035	[redacted]20[redacted]:11:20	29	%		
	#148D :11:02	28	%		251.0

Notes: BLQ = Below Limit of Quantification ND=Not Done.

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 1					
3760001-0036	[redacted]20[redacted]:10:25	31	%		
	#57D 10:45	63	%	Not Done	59.0
	#64D 07:12	22	%	Not Done	223.5
	#64D 07:40	104	%	Not Done	0.4
	#67D 09:35	46	%	Not Done	74.3
	#67D 12:25	105	%	Not Done	0.5
	#71D 09:50	40	%		93.9
	#80D 10:12	27	%		142.5
3760001-0037	[redacted]20[redacted]:12:35	70	%		
3760001-0039	[redacted]20[redacted]:12:50	44	%		
	:12:30	9	%		351.3
	#197D :09:48	11	%		349.5
	#244D :10:32	130	%		0.7
	#244D :11:14	54	%		73.4
	#247D :11:52	27	%		170.1
	#251D :11:52	12	%		338.1
	#258D :11:16	8	%		505.5
	#265D				

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20[redacted]:4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 1					
3800015-0056	[redacted]20[redacted]:09:28	11	%		
	#182D :09:12	19	%		204.6
3800025-0025	[redacted]20[redacted]:12:00	52.1	%		
3920026-0030	[redacted]20[redacted]:14:15	16	%		162.0
3920028-0038	[redacted]20[redacted]:11:33	12	%		160.6
3920029-0023	[redacted]20[redacted]:11:18	25	%		132.5
	#28D :11:23	16	%		228.2
	#48D :11:14	16	%		232.2
	#74D :12:03	13	%		228.7
	#102D :10:15	18	%		323.3
3920030-0001	[redacted]20[redacted]:11:58	9	%		307.2
	:12:55	70	%		0.5
	#0D :08:10	50	%		19.8
	#1D				
3920031-0040	[redacted]20[redacted]:09:15	23	%		154.3

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20[redacted]:4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 1					
7240009-0005	[redacted]:12:20	27.6	%	Updated Result	
	#336D :12:20	18.9	%	Updated Result	71.9
7240009-0043	[redacted]:13:22	9.1	%	Updated Result	
	#56D :11:54	20.2	%	Updated Result	73.4
	#58D :11:48	31.3	%	Updated Result	47.9
	#89D :13:51	33.2	%	Updated Result	42.2
	#91D :14:09	40.3	%	Updated Result	48.3
	#113D :12:42	20.2	%	Updated Result	121.7
	#138D :10:36	31.6	%	Updated Result	66.1
	#142D :11:50	46	%	Updated Result	45.4
	#150D :13:20	43.4	%	Updated Result	68.3
	#165D :14:47	16.6	%	Updated Result	240.8
8400160-0021	[redacted]:15:07	12	%		132.4

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]:4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 2					
2500001-0019	[redacted]20[redacted]:16:32	47	%	Other: Normal	
2500002-0063	[redacted]20[redacted]:10:10	16	%	Not Done	
	#82D :09:25	8	%	Not Done	143.4
	#131D :09:35	8	%	Not Done	145.6
2500002-0066	[redacted]20[redacted]:10:36	12	%	Not Done	
	:10:40	18	%	Not Done	49.9
	#90D :09:30	4	%	Not Done	337.0
	#116D				
2500002-0068	[redacted]20[redacted]:11:43	13	%	Not Done	
2500002-0069	[redacted]20[redacted]:12:35	19	%	Not Done	
3800015-0033	[redacted]20[redacted]:11:55	18	%		
	#151D 12:09	10	%		325.1

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20 :4:51 PM • [redacted]:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 2					
3920025-0047	[redacted]:14:06	5.1	%		332.1
	#42D :12:37	7.9	%		330.6
	#82D :13:11	18.8	%		163.2
	#119D :13:08	19.1	%		163.1
7240007-0061	[redacted]:10:00	29.7	%		
7240008-0011	[redacted]:11:50	18.8	%	Other: Good	
8400191-0045	[redacted]:11:47	26	%	Hemolytic Sample	112.5
	#0D :12:59	79	%	Hemolytic Sample	0.7
	#14D :09:59	60	%	Hemolytic Sample	110.6
	#42D :11:56	17	%	Hemolytic Sample	124.8

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted] 4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 3					
0400001-2057	[redacted]2015:10:40	<1.0	%		
3800023-2054	[redacted]20[redacted]:08:25	23	%	Other	168.4
	#0D :09:00	131	%	Other	0.6
	#0D :14:15	114	%	Other	5.8
	#0D :16:15	109	%	Other	7.8
	#1D :07:30	83	%	Other	23.1
	#1D :10:15	78	%	Other	25.8
	#1D :10:50	134	%	Other	0.6
	#2D :12:00	132	%	Other	25.7
	#2D :12:35	221	%	Other	0.6
	#3D :14:00	107	%	Other	26.0
	#4D :08:00	94	%	Other	44.0
	#5D :08:00	79	%	Other	68.0
	#5D :08:35	118	%	Other	0.6
	#28D :10:50	25.0	%		170.3
4580001-2051	[redacted]20[redacted]:13:30	2.0	%		
	#28D :15:06	4.4	%		
	#33D :10:40	50.5	%		67.5

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20[redacted]:4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

#新薬承認情報提供時に置き換え

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 3					
4580001-2051	[redacted]20[redacted] 12:00	25.9	%		164.8
	#8D 11:20	8.9	%		356.2
	#16D 09:57	4.4	%		498.8
	#17D 10:00	86.6	%	Other	24.0
	#18D 10:10	58.2	%	Other	48.2
	#18D 10:45	121.3	%	Other	0.5
	#19D 12:55	87.6	%	Other	26.7
	#20D 11:20	67.4	%	Other	49.1
	#20D 11:55	136.3	%	Other	0.6
	#21D 12:06	86.6	%	Other	24.7
	#22D 11:30	70.5	%	Other	48.1
	#23D 10:35	51.7	%	Other	71.2
	#23D 11:10	119.9	%	Other	0.5
	#30D 11:05	48.4	%	Other	68.9
	#30D 11:38	115.7	%	Other	0.5
	#40D 09:00	46.8	%	Other	71.3
	#50D 11:50	28.9	%	Other	146.2
	#50D 13:28	99.5	%	Other	0.6

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20 :4:51 PM • K[redacted]CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

Page 10 of 11

Site - Subject ID	Sample Date:Time	FIX Concentration	Unit	Specimen Condition	Time from Last Dose to Sample Time (hr)
Treatment Arm 3					
6080001-2053	[redacted]20[redacted]:10:35	<3	%	Updated Result	
	#0D :11:35	108	%	Updated Result	0.8
	#0D :12:05	106.2	%	Updated Result	1.3
	#3D :11:10	30.6	%	Updated Result	72.3
	#4D :06:55	108	%	Updated Result	0.7

Notes: BLQ = Below Limit of Quantification ND=Not Done.
Chiltern • [redacted]20 :4:51 PM • [redacted]K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_factixa.sas • ZScott

Page 11 of 11

Source: Study 3003 aCSR Listing 16.2.5.2.

Table A.5-4 Study 3003: Listing of Predicted and Intraoperative Estimated Blood Loss (Surgical Population)

		Predicted Assessment (Pre-Surgery)			Actual Assessment (During Surgery)	
Site - Subject ID	Surgery Start Date: Time/ End Time	Assessment Date:Time	Average Blood Loss (mL)	Maximum Blood Loss (mL)	Assessment Date:Time	Estimated Blood Loss (mL)
Treatment Arm 1						
2030006-2022	[redacted]20[redacted]: 11:40/ 11:52	#0D :10:00	0	0	#0D :12:20	0
3760001-0036	[redacted]20[redacted]: 10:30/ 12:30	#0D :11:00	20	30	#0D :11:00	5
3920030-0001	[redacted]20[redacted]: 15:25/ 15:36	#0D :11:59	0	300	#0D :15:36	0

Chiltern • [redacted]20[redacted]:4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_bld_loss.sas • RValchev

Page 1 of 2

#新薬承認情報提供時に置き換え

Site - Subject ID	Surgery Start Date: Time/ End Time	Predicted Assessment (Pre-Surgery) Assessment Date:Time	Average Blood Loss (mL)	Maximum Blood Loss (mL)	Actual Assessment (During Surgery) Assessment Date:Time	Estimated Blood Loss (mL)
Treatment Arm 3						
3800023-2054	[redacted] 14:20/ 16:15	#0D :08:00	250	300	#0D 16:15	250
4580001-2051	[redacted] 14:40/ 16:00	#0D :16:42	200	200	#0D 17:00	200
6080001-2053	[redacted] 08:18/ 09:58	#0D :13:00	30	100	#0D 10:00	50

Chiltern • [redacted] 4:50 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_bld_loss.sas • RValchev

Page 2 of 2

Source: Study 3003 aCSR Listing 16.2.6.1.

Table A.5-5 Study 3003: Listing of Predicted and Actual Transfusion Requirement (Surgical Population)

Site - Subject ID	Surgery Start Date:Time	Transfusion Requirement	Predicted Assessment (Pre-Surgery) Assessment Date:Time	Predicted Assessment (Pre-Surgery) Amount (unit)	Actual Assessment (During Surgery) Assessment Date:Time	Actual Assessment (During Surgery) Amount (unit)
Treatment Arm 1						
3760001-0036	[redacted]:10:30	NONE	#0D 10:30			
3920030-0001	[redacted]:15:25	NONE	#0D 15:25	280 (ml)		

Chiltern • [redacted] 4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_tranfus.sas • RValchev

Page 1 of 2

Site - Subject ID	Surgery Start Date:Time	Transfusion Requirement	Predicted Assessment (Pre-Surgery) Assessment Date:Time	Predicted Assessment (Pre-Surgery) Amount (unit)	Actual Assessment (During Surgery) Assessment Date:Time	Actual Assessment (During Surgery) Amount (unit)
Treatment Arm 3						
3800023-2054	[redacted]:14:20	NONE	#0D :14:20	0 (ml)		
6080001-2053	[redacted]:08:18	RBC	#0D :08:18	500 (ml)	#1D :16:30	280 (ml)

Chiltern • [redacted] 4:51 PM • K:\CSL_Behring\32670\21_Stat\Programs\Listings\l_tranfus.sas • RValchev

Page 2 of 2

Source: Study 3003 aCSR Listing 16.2.6.2.

#新薬承認情報提供時におきかえ