System Organ Class Preferred Term Relationship	All Subjects (N=17) n (%)	E
General disorders and administration site conditions	3 (17.6)	5
Not Related	3 (17.6)	5
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Injection site swelling	1 (5.9)	3
Not Related	1 (5.9)	3
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Injection site erythema	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Injection site haemorrhage	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0

Note: Adverse Events are coded using MedDRA version 15.0. If a subject has multiple occurrences of an AE, the subject is presented only once at the maximum relationship in the respective subject count. Events are counted each time in the event (E) column. Treatment-emergent AEs are defined as AEs that started after the first dose of study treatment. Events with a missing relationship are considered related.

System Organ Class Preferred Term Relationship	All Subjects (N=17) n (%)	E
Nervous system disorders	4 (23.5)	4
Not Related	4 (23.5)	4
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Headache	3 (17.6)	3
Not Related	3 (17.6)	3
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Dizziness	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Eye disorders	2 (11.8)	2
Not Related	2 (11.8)	2
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0

Note: Adverse Events are coded using MedDRA version 15.0. If a subject has multiple occurrences of an AE, the subject is presented only once at the maximum relationship in the respective subject count. Events are counted each time in the event (E) column. Treatment-emergent AEs are defined as AEs that started after the first dose of study treatment. Events with a missing relationship are considered related.

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System Organ Class Preferred Term Relationship	All Subjects (N=17) n (%)	E
Conjunctivitis	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Eye pain	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Gastrointestinal disorders	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Dyspepsia	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0

Note: Adverse Events are coded using MedDRA version 15.0. If a subject has multiple occurrences of an AE, the subject is presented only once at the maximum relationship in the respective subject count. Events are counted each time in the event (E) column. Treatment-emergent AEs are defined as AEs that started after the first dose of study treatment. Events with a missing relationship are considered related.

System Organ Class Preferred Term Relationship	All Subjects (N=17) n (%)	E
Investigations	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Weight decreased	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Skin and subcutaneous tissue disorders	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0
Rash follicular	1 (5.9)	1
Not Related	1 (5.9)	1
Unlikely Related	0	0
Possibly Related	0	0
Probably Related	0	0
Related	0	0

Note: Adverse Events are coded using MedDRA version 15.0. If a subject has multiple occurrences of an AE, the subject is presented only once at the maximum relationship in the respective subject count. Events are counted each time in the event (E) column. Treatment-emergent AEs are defined as AEs that started after the first dose of study treatment. Events with a missing relationship are considered related.
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Source: Study 2004 CSR Table 14.3.2.3.

A.3 Study 3001

Table A.3-1 Study 3001: Annualized Spontaneous Bleeding Rate (Primary Efficacy Population)

	On-Demand Regimen (N=19)	Prophylaxis Regimen (N=19)	Prophylaxis Regimen/ On-demand Regimen
Annualized Spontaneous Bleeding Rate (Bleeds/Year/Subject)			
n	19	19	
Mean (SD)	14.57 (8.421)	0.73 (1.171)	
Median	15.43	0.00	
Q1, Q3	7.98, 17.96	0.00, 0.96	
Min, Max	2.0, 39.5	0.0, 4.2	
Percent Reduction in AsBR with prophylaxis treatment (%)			
n			19
Mean (SD)			95.96 (5.539)
Median			100.00
Q1, Q3			90.53, 100.00
Min, Max			82.8, 100.0
p-value [1]			<0.0001
Number of Spontaneous Bleeds per Year (95% CI) [2]	13.62 (11.001, 16.868)	0.55 (0.233, 1.322)	0.04 (0.019, 0.089)

[1] P-value is based on Wilcoxon Signed-rank test of H0: AsBR ratio (prophylaxis/on-demand) >= 0.50.
[2] Assuming Poisson distribution.
Source: Listing 16.2.6.1
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	On-Demand Regimen (N=19)	Prophylaxis Regimen (N=19)	Prophylaxis Regimen/ On-demand Regimen
Number of Subjects with No Spontaneous Bleeding Episodes (n (%))	0	10 (52.6)	
Number of Subjects with at Least 1 Spontaneous Bleeding Episode (n (%))	19 (100.0)	9 (47.4)	
Number of Subjects with at Least 1 Spontaneous Bleeding Episode Not Requiring Treatment (n (%))	0	2 (10.5)	
Number of Subjects with at Least 1 Spontaneous Bleeding Episode Requiring Treatment (n (%))	19 (100.0)	7 (36.8)	

[1] P-value is based on Wilcoxon Signed-rank test of H0: AsBR ratio (prophylaxis/on-demand) >= 0.50.
[2] Assuming Poisson distribution.
Source: Listing 16.2.6.1
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	On-Demand Regimen (N=19)	Prophylaxis Regimen (N=19)	Prophylaxis Regimen/ On-demand Regimen
Number of Spontaneous Bleeding Episodes Requiring Treatment			
n	19	19	
Mean (SD)	7.1 (3.38)	0.6 (0.90)	
Median	8.0	0.0	
Q1, Q3	4.0, 9.0	0.0, 1.0	
Min, Max	1, 13	0, 3	
Duration of Treatment Period (Days)			
n	19	19	
Mean (SD)	184.2 (20.55)	315.7 (176.66)	
Median	187.0	316.0	
Q1, Q3	183.0, 192.0	121.0, 518.0	
Min, Max	111, 213	14, 525	

[1] P-value is based on Wilcoxon Signed-rank test of H0: AsBR ratio (prophylaxis/on-demand) >= 0.50.
[2] Assuming Poisson distribution.
Source: Listing 16.2.6.1
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Source: Study 3001 CSR Table 14.2.1.1.

Table A.3-2 Study 3001: Annualized Spontaneous Bleeding Rate Compared Between 7-Day and 10-Day Prophylaxis Regimens (Efficacy Population)

Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Spontaneous Bleeds			
Annualized Bleeding Rate (Bleeds/Year/Subject)			
n	7	7	
Mean (SD)	0.00 (0.000)	0.13 (0.334)	
Median	0.00	0.00	
Q1, Q3	0.00, 0.00	0.00, 0.00	
Min, Max	0.0, 0.0	0.0, 0.9	
Mean Difference (95% CI) [1]			-0.13 (-0.435, 0.183)
Number of Bleeds Per Year (95% CI) [2]	NC	NC	NC

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Spontaneous Bleeds			
Number of Subjects with No Bleeding Episodes (n (%))	7 (100.0)	6 (85.7)	
Number of Subjects with at Least 1 Bleeding Episode (n (%))	0	1 (14.3)	
Number of Subjects with at Least 1 Bleeding Episode Not Requiring Treatment (n (%))	0	0	
Number of Subjects with at Least 1 Bleeding Episode Requiring Treatment (n (%))	0	1 (14.3)	

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Spontaneous Bleeds			
Number of Bleeding Episodes Requiring Treatment Per Subject			
n	7	7	
Mean (SD)	0.0 (0.00)	0.1 (0.38)	
Median	0.0	0.0	
Q1, Q3	0.0, 0.0	0.0, 0.0	
Min, Max	0, 0	0, 1	
Duration of Treatment Period (Days) Per Subject			
n	7	7	
Mean (SD)	284.4 (117.18)	267.1 (132.83)	
Median	238.0	240.0	
Q1, Q3	203.0, 350.0	149.0, 410.0	
Min, Max	197, 521	114, 413	

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Joint Bleeds			
Annualized Bleeding Rate (Bleeds/Year/Subject)			
n	7	7	
Mean (SD)	0.32 (0.596)	0.34 (0.615)	
Median	0.00	0.00	
Q1, Q3	0.00, 0.70	0.00, 0.88	
Min, Max	0.0, 1.5	0.0, 1.5	
Mean Difference (95% CI) [1]			-0.02 (-0.945, 0.896)
Number of Bleeds Per Year (95% CI) [2]	0.34 (0.113, 1.049)	0.40 (0.137, 1.152)	0.87 (0.143, 5.263)

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Joint Bleeds			
Number of Subjects with No Bleeding Episodes (n (%))	5 (71.4)	5 (71.4)	
Number of Subjects with at Least 1 Bleeding Episode (n (%))	2 (28.6)	2 (28.6)	
Number of Subjects with at Least 1 Bleeding Episode Not Requiring Treatment (n (%))	0	0	
Number of Subjects with at Least 1 Bleeding Episode Requiring Treatment (n (%))	2 (28.6)	2 (28.6)	

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Joint Bleeds			
Number of Bleeding Episodes Requiring Treatment Per Subject			
n	7	7	
Mean (SD)	0.3 (0.49)	0.3 (0.49)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 1.0	
Min, Max	0, 1	0, 1	
Duration of Treatment Period (Days) Per Subject			
n	7	7	
Mean (SD)	284.4 (117.18)	267.1 (132.83)	
Median	238.0	240.0	
Q1, Q3	203.0, 350.0	149.0, 410.0	
Min, Max	197, 521	114, 413	

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Total Bleeds			
Annualized Bleeding Rate (Bleeds/Year/Subject)			
n	7	7	
Mean (SD)	0.57 (0.776)	0.82 (1.195)	
Median	0.00	0.00	
Q1, Q3	0.00, 1.53	0.00, 1.78	
Min, Max	0.0, 1.7	0.0, 3.0	
Mean Difference (95% CI) [1]			-0.25 (-1.321, 0.825)
Number of Bleeds Per Year (95% CI) [2]	0.59 (0.287, 1.206)	0.98 (0.429, 2.243)	0.60 (0.216, 1.660)

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Total Bleeds			
Number of Subjects with No Bleeding Episodes (n (%))	4 (57.1)	4 (57.1)	
Number of Subjects with at Least 1 Bleeding Episode (n (%))	3 (42.9)	3 (42.9)	
Number of Subjects with at Least 1 Bleeding Episode Not Requiring Treatment (n (%))	0	0	
Number of Subjects with at Least 1 Bleeding Episode Requiring Treatment (n (%))	3 (42.9)	3 (42.9)	

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Bleeding Type	7-Day Regimen (N=7)	10-Day Regimen (N=7)	7-Day - 10-Day Regimen
Total Bleeds			
Number of Bleeding Episodes Requiring Treatment Per Subject			
n	7	7	
Mean (SD)	0.4 (0.53)	0.7 (0.95)	
Median	0.0	0.0	
Q1, Q3	0.0, 1.0	0.0, 2.0	
Min, Max	0, 1	0, 2	
Duration of Treatment Period (Days) Per Subject			
n	7	7	
Mean (SD)	284.4 (117.18)	267.1 (132.83)	
Median	238.0	240.0	
Q1, Q3	203.0, 350.0	149.0, 410.0	
Min, Max	197, 521	114, 413	

Note: The table only includes subjects with at least 12 weeks of treatment on more than one regimen.
[1] 95% CI based on t-test from matched pairs design. NC=Not Calculable.
[2] Assuming Poisson distribution. NC=Not Calculable.
Source: Listing 16.2.6.1
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Source: Study 3001 CSR Table 14.2.6.2.

Table A.3-3 Study 3001: Number of rIX-FP Infusions Required to Achieve Hemostasis by Cause (Efficacy Population)

	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Cause: Spontaneous				
Number of Bleeding Episodes	76	149	15	240
Number of Bleeding Episodes Requiring Treatment	48	145	11	204
Number of Infusions Required to Achieve Hemostasis (n (%))				
1 Infusion	46 (95.8)	139 (95.9)	10 (90.9)	195 (95.6)
2 Infusions	2 (4.2)	4 (2.8)	0	6 (2.9)
>2 Infusions	0	2 (1.4)	1 (9.1)	3 (1.5)
1 or 2 Infusions	48 (100.0)	143 (98.6)	10 (90.9)	201 (98.5)
Probability of Success [1]	NC	98.6	90.9	98.5
95% CI for Probability of Success	NC	(94.4, 99.7)	(59.0, 98.6)	(95.6, 99.5)

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Cause: Spontaneous				
First Dose of rIX-FP Used to Treat Bleed (IU/kg)				
n	47	145	11	203
Mean (SD)	53.063 (14.0815)	42.185 (10.0069)	50.132 (16.4493)	45.134 (12.3356)
Median	51.724	38.197	48.390	38.784
Q1, Q3	40.043, 60.600	36.877, 48.646	37.500, 57.602	37.360, 51.297
Min, Max	24.40, 75.00	16.86, 82.01	32.59, 81.28	16.86, 82.01

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Cause: Traumatic				
Number of Bleeding Episodes	81	68	26	175
Number of Bleeding Episodes Requiring Treatment	48	67	25	140
Number of Infusions Required to Achieve Hemostasis (n (%))				
1 Infusion	44 (91.7)	63 (94.0)	23 (92.0)	130 (92.9)
2 Infusions	4 (8.3)	4 (6.0)	1 (4.0)	9 (6.4)
>2 Infusions	0	0	1 (4.0)	1 (0.7)
1 or 2 Infusions	48 (100.0)	67 (100.0)	24 (96.0)	139 (99.3)
Probability of Success [1]	NC	NC	96.0	99.3
95% CI for Probability of Success	NC	NC	(71.7, 99.6)	(95.0, 99.9)

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Cause: Traumatic				
First Dose of rIX-FP Used to Treat Bleed (IU/kg)				
n	48	67	25	140
Mean (SD)	57.755 (14.1867)	47.142 (11.2409)	48.444 (15.9151)	51.013 (13.9960)
Median	55.398	47.351	49.238	50.000
Q1, Q3	49.220, 74.125	38.145, 52.957	39.551, 51.983	39.276, 56.164
Min, Max	25.01, 79.23	25.27, 78.25	13.31, 99.87	13.31, 99.87

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Cause: Unknown				
Number of Bleeding Episodes	9	8	1	18
Number of Bleeding Episodes Requiring Treatment	5	8	1	14
Number of Infusions Required to Achieve Hemostasis (n (%))				
1 Infusion	3 (60.0)	6 (75.0)	1 (100.0)	10 (71.4)
2 Infusions	2 (40.0)	1 (12.5)	0	3 (21.4)
>2 Infusions	0	1 (12.5)	0	1 (7.1)
1 or 2 Infusions	5 (100.0)	7 (87.5)	1 (100.0)	13 (92.9)
Probability of Success [1]	NC	87.5	NC	92.9
95% CI for Probability of Success	NC	(59.0, 97.2)	NC	(68.6, 98.7)

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Cause: Unknown				
First Dose of rIX-FP Used to Treat Bleed (IU/kg)				
n	5	8	1	14
Mean (SD)	50.993 (14.1355)	54.862 (14.9672)	37.037	52.207 (14.3078)
Median	50.000	57.692	37.037	50.000
Q1, Q3	40.137, 50.000	40.839, 65.444	37.037, 37.037	40.137, 61.647
Min, Max	40.14, 74.69	34.81, 76.13	37.04, 37.04	34.81, 76.13

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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Source: Study 3001 CSR Table 14.2.2.3.

Table A.3-4 Study 3001: Number of rIX-FP Infusions Required to Achieve Hemostasis by Location (Efficacy Population)

	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Location: Joint				
Number of Bleeding Episodes	79	163	31	273
Number of Bleeding Episodes Requiring Treatment	70	163	31	264
Number of Infusions Required to Achieve Hemostasis (n (%))				
1 Infusion	67 (95.7)	160 (98.2)	28 (90.3)	255 (96.6)
2 Infusions	3 (4.3)	3 (1.8)	1 (3.2)	7 (2.7)
>2 Infusions	0	0	2 (6.5)	2 (0.8)
1 or 2 Infusions	70 (100.0)	163 (100.0)	29 (93.5)	262 (99.2)
Probability of Success [1]	NC	NC	93.5	99.2
95% CI for Probability of Success	NC	NC	(74.4, 98.6)	(97.1, 99.8)

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Location: Joint				
First Dose of rIX-FP Used to Treat Bleed (IU/kg)				
n	70	163	31	264
Mean (SD)	55.471 (14.4527)	42.893 (10.0990)	49.217 (16.7258)	46.970 (13.4041)
Median	52.494	38.301	49.238	41.169
Q1, Q3	48.843, 72.554	37.500, 50.000	37.500, 52.522	37.500, 53.015
Min, Max	24.40, 75.04	16.86, 78.25	13.31, 99.87	13.31, 99.87

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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Table A.3-5 Study 3001: Hemoglobin Levels Relative to Surgery Time (Surgical Population)

	Overall (N=4)
Baseline	
Number of Events	5
Mean (SD)	129.60 (22.143)
Median	135.00
Q1, Q3	130.00, 143.00
Min, Max	92.0, 148.0
Lowest Intraoperative Hemoglobin Level	
Number of Events	3
Mean (SD)	116.00 (31.000)
Median	127.00
Q1, Q3	81.00, 140.00
Min, Max	81.0, 140.0
Lowest Postoperative Hemoglobin Level	
Number of Events	5
Mean (SD)	107.60 (27.961)
Median	121.00
Q1, Q3	94.00, 125.00
Min, Max	65.0, 133.0

Source: Listing 16.2.8.1
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Source: Study 3001 CSR Table 14.2.12.

	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Location: Muscle				
Number of Bleeding Episodes	31	48	7	86
Number of Bleeding Episodes Requiring Treatment	17	46	5	68
Number of Infusions Required to Achieve Hemostasis (n (%))				
1 Infusion	13 (76.5)	38 (82.6)	5 (100.0)	56 (82.4)
2 Infusions	4 (23.5)	6 (13.0)	0	10 (14.7)
>2 Infusions	0	2 (4.3)	0	2 (2.9)
1 or 2 Infusions	17 (100.0)	44 (95.7)	5 (100.0)	66 (97.1)
Probability of Success [1]	NC	95.7	NC	97.1
95% CI for Probability of Success	NC	(77.8, 99.3)	NC	(83.5, 99.5)

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Location: Muscle				
First Dose of rIX-FP Used to Treat Bleed (IU/kg)				
n	16	46	5	67
Mean (SD)	54.202 (12.3146)	47.112 (12.2211)	49.637 (1.5655)	48.994 (12.0633)
Median	50.000	41.092	48.854	48.854
Q1, Q3	49.026, 62.685	37.979, 52.957	48.854, 49.807	38.784, 52.632
Min, Max	37.05, 75.00	34.05, 82.01	48.39, 52.28	34.05, 82.01

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Location: Other				
Number of Bleeding Episodes	51	14	4	69
Number of Bleeding Episodes Requiring Treatment	14	11	1	26
Number of Infusions Required to Achieve Hemostasis (n (%))				
1 Infusion	13 (92.9)	10 (90.9)	1 (100.0)	24 (92.3)
2 Infusions	1 (7.1)	0	0	1 (3.8)
>2 Infusions	0	1 (9.1)	0	1 (3.8)
1 or 2 Infusions	14 (100.0)	10 (90.9)	1 (100.0)	25 (96.2)
Probability of Success [1]	NC	90.9	NC	96.2
95% CI for Probability of Success	NC	(53.0, 98.9)	NC	(76.6, 99.5)

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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	Treatment Arm 1: Prophylaxis (N=40)	Treatment Arm 2: On-demand		
		On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)	Total (N=63)
Location: Other				
First Dose of rIX-FP Used to Treat Bleed (IU/kg)				
n	14	11	1	26
Mean (SD)	55.066 (15.9021)	50.503 (14.3401)	25.679	52.005 (15.7389)
Median	54.288	50.000	25.679	50.289
Q1, Q3	38.961, 74.069	38.760, 54.054	25.679, 25.679	38.760, 59.816
Min, Max	36.48, 79.23	35.05, 76.84	25.68, 25.68	25.68, 79.23

[1] Probability of success is derived from a repeated measures model (expressed as percentages) and is defined as the probability of achieving hemostasis with 1 or 2 infusions.
Source: Listing 16.2.6.1
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Source: Study 3001 CSR Table 14.2.2.5.

Table A.3-6 Study 3001: Summary of Dose Assignment and Dose Adjustment (Safety Population)

	Treatment Arm 1: Prophylaxis			Treatment Arm 2: On-Demand	
	7-Day Regimen (N=40)	10-Day Regimen (N=7)	14-Day Regimen (N=21)	On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)
Assigned Prophylaxis Dose (IU/kg)					
n	40	6	20	N/A	12
Mean (SD)	48.20 (10.395)	70.56 (10.868)	72.50 (7.695)		43.74 (12.205)
Median	50.00	75.00	75.00		37.48
Q1, Q3	40.00, 50.00	75.00, 75.00	75.00, 75.00		36.20, 48.75
Min, Max	35.0, 75.0	48.4, 75.0	50.0, 75.0		35.0, 75.0
Assigned On-demand Dose Joint/Muscle (IU/kg)					
n	40	6	20	23	12
Mean (SD)	48.60 (12.070)	47.50 (5.206)	43.75 (7.461)	43.57 (9.685)	39.74 (6.559)
Median	50.00	50.00	45.50	38.00	37.43
Q1, Q3	40.00, 50.00	48.00, 50.00	40.00, 50.00	37.00, 50.00	35.60, 45.00
Min, Max	26.0, 75.0	37.0, 50.0	26.0, 52.0	31.0, 75.0	31.0, 50.0

Source: Listing 16.2.5.4
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	Treatment Arm 1: Prophylaxis			Treatment Arm 2: On-Demand	
	7-Day Regimen (N=40)	10-Day Regimen (N=7)	14-Day Regimen (N=21)	On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)
Assigned On-demand Dose Deep Muscle (IU/kg)					
n	40	6	20	23	12
Mean (SD)	50.58 (10.636)	47.50 (5.206)	47.65 (8.689)	52.96 (12.404)	43.33 (11.506)
Median	50.00	50.00	50.00	50.00	39.15
Q1, Q3	43.00, 50.00	48.00, 50.00	40.00, 50.00	50.00, 51.00	36.72, 48.00
Min, Max	35.0, 75.0	37.0, 50.0	35.0, 70.0	31.0, 75.0	31.0, 75.0
Weekly Prophylaxis Dose (IU/kg)					
n	40	7	21	N/A	19
Mean (SD)	46.61 (11.021)	46.34 (9.787)	36.21 (3.759)		44.08 (8.356)
Median	44.78	51.17	37.32		39.85
Q1, Q3	38.50, 49.46	34.27, 51.68	36.49, 37.77		37.74, 51.39
Min, Max	32.2, 73.9	30.3, 54.9	25.7, 41.2		33.9, 60.5

Source: Listing 16.2.5.4
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	Treatment Arm 1: Prophylaxis			Treatment Arm 2: On-Demand	
	7-Day Regimen (N=40)	10-Day Regimen (N=7)	14-Day Regimen (N=21)	On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)
Number of Prophylaxis Dose Adjustments per Subject [n (%)]					
0	12 (30.0)	6 (85.7)	18 (85.7)	N/A	16 (84.2)
1	14 (35.0)	1 (14.3)	3 (14.3)	N/A	3 (15.8)
2	9 (22.5)	0	0	N/A	0
>2	5 (12.5)	0	0	N/A	0
Reason for Prophylaxis Dose Adjustment [n (%)]					
Planned Dose/Regimen Change	31 (59.6)	0	0	N/A	0
Bleeding	1 (1.9)	0	1 (33.3)	N/A	0
Lack of Efficacy	0	0	0	N/A	0
Physician Decision	19 (36.5)	1 (100.0)	2 (66.7)	N/A	3 (100.0)
Other	1 (1.9)	0	0	N/A	0

Source: Listing 16.2.5.4
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	Treatment Arm 1: Prophylaxis			Treatment Arm 2: On-Demand	
	7-Day Regimen (N=40)	10-Day Regimen (N=7)	14-Day Regimen (N=21)	On-Demand Regimen (N=23)	Prophylaxis Regimen (N=19)
Number of On-demand Dose Adjustments per Subject [n (%)]					
0	40 (100.0)	7 (100.0)	20 (95.2)	16 (69.6)	18 (94.7)
1	0	0	1 (4.8)	1 (4.3)	1 (5.3)
2	0	0	0	1 (4.3)	0
>2	0	0	0	5 (21.7)	0
Reason for On-demand Dose Adjustment [n (%)]					
Planned Dose/Regimen Change	0	0	0	0	0
Bleeding	0	0	0	0	0
Lack of Efficacy	0	0	0	0	0
Physician Decision	0	0	1 (100.0)	29 (93.5)	1 (100.0)
Other	0	0	0	2 (6.5)	0

Source: Listing 16.2.5.4
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Source: Study 3001 CSR Table 14.2.5.2.

Table A.3-7 Study 3001: Inhibitors and Antibodies (Safety Population)

Parameter	Total (N=63) n (%)	95% CI [1] (N=63)	95% CI [2] (N=49)
Inhibitors to rIX-FP			
Yes	0	(0.0,5.7)	(0.0,7.3)
Antibodies Against rIX-FP			
Yes	0		
No	63 (100.0)		
Antibodies Against pDFIX			
Not Done			
Antibodies Against rFIX			
Not Done			
Antibodies Against Albumin			
Not Done			
Antibodies Against CHO Cell Proteins			
Yes	0		
No	63 (100.0)		

Notes: Proportions are based on the number of subjects in the respective group.
[1] Exact Clopper-Pearson 95% CI based on subjects in the Safety Population.
[2] Exact Clopper-Pearson 95% CI based on subjects with >=50 EDs from all CSL studies.
Source: Listing 16.2.8.6
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Source: Study 3001 CSR Table 14.4.3.

Table A.3-8 Study 3001: Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
Any Treatment-Emergent AEs	36 (90.0)	278	18 (78.3)	69	54 (85.7)	347
INFECTIONS AND INFESTATIONS	28 (70.0)	74	12 (52.2)	23	40 (63.5)	97
NASOPHARYNGITIS	10 (25.0)	27	6 (26.1)	11	16 (25.4)	38
INFLUENZA	4 (10.0)	7	3 (13.0)	3	7 (11.1)	10
UPPER RESPIRATORY TRACT INFECTION	5 (12.5)	7	0	0	5 (7.9)	7
BRONCHITIS	4 (10.0)	4	1 (4.3)	1	5 (7.9)	5
PHARYNGITIS	3 (7.5)	3	2 (8.7)	2	5 (7.9)	5
GASTROENTERITIS	3 (7.5)	4	0	0	3 (4.8)	4
FUNGAL INFECTION	2 (5.0)	3	0	0	2 (3.2)	3
ACUTE TONSILLITIS	0	0	2 (8.7)	2	2 (3.2)	2
SINUSITIS	2 (5.0)	2	0	0	2 (3.2)	2
URINARY TRACT INFECTION	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
ORAL HERPES	1 (2.5)	2	0	0	1 (1.6)	2
ABSCESS LIMB	1 (2.5)	1	0	0	1 (1.6)	1
CELLULITIS	1 (2.5)	1	0	0	1 (1.6)	1
EAR INFECTION	1 (2.5)	1	0	0	1 (1.6)	1
FOLLICULITIS	1 (2.5)	1	0	0	1 (1.6)	1
GASTROENTERITIS VIRAL	1 (2.5)	1	0	0	1 (1.6)	1
GENITOURINARY TRACT INFECTION	1 (2.5)	1	0	0	1 (1.6)	1
HELICOBACTER GASTRITIS	1 (2.5)	1	0	0	1 (1.6)	1
HELICOBACTER INFECTION	1 (2.5)	1	0	0	1 (1.6)	1
HEPATITIS C	0	0	1 (4.3)	1	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
HERPES ZOSTER	1 (2.5)	1	0	0	1 (1.6)	1
PRIMARY SYPHILIS	1 (2.5)	1	0	0	1 (1.6)	1
SKIN BACTERIAL INFECTION	0	0	1 (4.3)	1	1 (1.6)	1
TONSILLITIS	1 (2.5)	1	0	0	1 (1.6)	1
TOOTH ABSCESS	1 (2.5)	1	0	0	1 (1.6)	1
TRACHEOBRONCHITIS	0	0	1 (4.3)	1	1 (1.6)	1
VIRAL RASH	1 (2.5)	1	0	0	1 (1.6)	1
VIRAL RHINITIS	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	24 (60.0)	61	4 (17.4)	7	28 (44.4)	68
ARTHRALGIA	9 (22.5)	19	0	0	9 (14.3)	19
BACK PAIN	4 (10.0)	5	2 (8.7)	3	6 (9.5)	8
SYNOVITIS	3 (7.5)	6	1 (4.3)	1	4 (6.3)	7
PAIN IN EXTREMITY	3 (7.5)	4	0	0	3 (4.8)	4
JOINT SWELLING	3 (7.5)	3	0	0	3 (4.8)	3
TENDONITIS	3 (7.5)	3	0	0	3 (4.8)	3
HAEMOPHILIC ARTHROPATHY	1 (2.5)	2	1 (4.3)	1	2 (3.2)	3
GROIN PAIN	2 (5.0)	2	0	0	2 (3.2)	2
MYALGIA	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
PERIARTHRITIS	1 (2.5)	3	0	0	1 (1.6)	3
ARTHRITIS	1 (2.5)	2	0	0	1 (1.6)	2
MUSCULOSKELETAL CHEST PAIN	1 (2.5)	2	0	0	1 (1.6)	2
AXILLARY MASS	1 (2.5)	1	0	0	1 (1.6)	1
FLANK PAIN	1 (2.5)	1	0	0	1 (1.6)	1
HAEMARTHROSIS	1 (2.5)	1	0	0	1 (1.6)	1
JOINT CONTRACTURE	1 (2.5)	1	0	0	1 (1.6)	1
MUSCLE TIGHTNESS	1 (2.5)	1	0	0	1 (1.6)	1
MUSCULOSKELETAL PAIN	1 (2.5)	1	0	0	1 (1.6)	1
MUSCULOSKELETAL STIFFNESS	1 (2.5)	1	0	0	1 (1.6)	1
NECK PAIN	1 (2.5)	1	0	0	1 (1.6)	1
ROTATOR CUFF SYNDROME	0	0	1 (4.3)	1	1 (1.6)	1
TENOSYNOVITIS	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
NERVOUS SYSTEM DISORDERS	16 (40.0)	38	6 (26.1)	10	22 (34.9)	48
HEADACHE	11 (27.5)	26	4 (17.4)	8	15 (23.8)	34
DIZZINESS	4 (10.0)	5	0	0	4 (6.3)	5
MIGRAINE	2 (5.0)	3	1 (4.3)	1	3 (4.8)	4
ACQUIRED EPILEPTIC APHASIA	0	0	1 (4.3)	1	1 (1.6)	1
DISTURBANCE IN ATTENTION	1 (2.5)	1	0	0	1 (1.6)	1
HYPOAESTHESIA	1 (2.5)	1	0	0	1 (1.6)	1
NEURALGIA	1 (2.5)	1	0	0	1 (1.6)	1
SPINAL CORD COMPRESSION	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (40.0)	30	6 (26.1)	10	22 (34.9)	40
LIMB INJURY	5 (12.5)	5	1 (4.3)	1	6 (9.5)	6
CONTUSION	3 (7.5)	5	1 (4.3)	3	4 (6.3)	8
LACERATION	1 (2.5)	1	2 (8.7)	2	3 (4.8)	3
ARTHROPOD BITE	2 (5.0)	3	0	0	2 (3.2)	3
INJURY	2 (5.0)	3	0	0	2 (3.2)	3
JOINT INJURY	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
LIGAMENT SPRAIN	2 (5.0)	2	0	0	2 (3.2)	2
ROAD TRAFFIC ACCIDENT	1 (2.5)	2	0	0	1 (1.6)	2
ANIMAL BITE	1 (2.5)	1	0	0	1 (1.6)	1
EAR INJURY	0	0	1 (4.3)	1	1 (1.6)	1
FACE INJURY	1 (2.5)	1	0	0	1 (1.6)	1
FALL	1 (2.5)	1	0	0	1 (1.6)	1
FIBULA FRACTURE	1 (2.5)	1	0	0	1 (1.6)	1
MUSCLE INJURY	0	0	1 (4.3)	1	1 (1.6)	1
MUSCLE STRAIN	0	0	1 (4.3)	1	1 (1.6)	1
PERIORBITAL HAEMATOMA	1 (2.5)	1	0	0	1 (1.6)	1
SUNBURN	1 (2.5)	1	0	0	1 (1.6)	1
TENDON INJURY	1 (2.5)	1	0	0	1 (1.6)	1
TOOTH FRACTURE	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
GASTROINTESTINAL DISORDERS	16 (40.0)	21	5 (21.7)	8	21 (33.3)	29
DIARRHOEA	2 (5.0)	2	3 (13.0)	4	5 (7.9)	6
TOOTHACHE	4 (10.0)	4	1 (4.3)	1	5 (7.9)	5
DENTAL CARIES	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
FOOD POISONING	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
GINGIVITIS	2 (5.0)	2	0	0	2 (3.2)	2
HAEMORRHOIDS	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
VOMITING	2 (5.0)	2	0	0	2 (3.2)	2
ABDOMINAL PAIN	1 (2.5)	1	0	0	1 (1.6)	1
ABDOMINAL PAIN UPPER	1 (2.5)	1	0	0	1 (1.6)	1
ANAL FISSURE	1 (2.5)	1	0	0	1 (1.6)	1
DYSPEPSIA	1 (2.5)	1	0	0	1 (1.6)	1
GASTROOESOPHAGEAL REFLUX DISEASE	1 (2.5)	1	0	0	1 (1.6)	1
HAEMORRHOIDAL HAEMORRHAGE	1 (2.5)	1	0	0	1 (1.6)	1
NAUSEA	1 (2.5)	1	0	0	1 (1.6)	1
ODYNOPHAGIA	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9 (22.5)	16	1 (4.3)	1	10 (15.9)	17
ACNE	3 (7.5)	3	0	0	3 (4.8)	3
ECZEMA	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
RASH	2 (5.0)	7	0	0	2 (3.2)	7
ECCHYMOSIS	2 (5.0)	2	0	0	2 (3.2)	2
ECZEMA ASTEATOTIC	1 (2.5)	1	0	0	1 (1.6)	1
SKIN STRIAE	1 (2.5)	1	0	0	1 (1.6)	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	9 (22.5)	13	1 (4.3)	1	10 (15.9)	14
INJECTION SITE HAEMATOMA	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
INJECTION SITE PAIN	2 (5.0)	2	0	0	2 (3.2)	2
HYPERPYREXIA	1 (2.5)	2	0	0	1 (1.6)	2
INJECTION SITE ERYTHEMA	1 (2.5)	2	0	0	1 (1.6)	2
ASTHENIA	1 (2.5)	1	0	0	1 (1.6)	1
FATIGUE	1 (2.5)	1	0	0	1 (1.6)	1
INJECTION SITE EROSION	1 (2.5)	1	0	0	1 (1.6)	1
INJECTION SITE PARAESTHESIA	1 (2.5)	1	0	0	1 (1.6)	1
NON-CARDIAC CHEST PAIN	1 (2.5)	1	0	0	1 (1.6)	1
PYREXIA	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (17.5)	8	2 (8.7)	2	9 (14.3)	10
COUGH	3 (7.5)	3	0	0	3 (4.8)	3
OROPHARYNGEAL PAIN	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
RHINITIS ALLERGIC	2 (5.0)	2	0	0	2 (3.2)	2
ASTHMA	0	0	1 (4.3)	1	1 (1.6)	1
NASAL SEPTUM ULCERATION	1 (2.5)	1	0	0	1 (1.6)	1
INVESTIGATIONS	1 (2.5)	1	3 (13.0)	3	4 (6.3)	4
BLOOD CREATINE PHOSPHOKINASE INCREASED	0	0	1 (4.3)	1	1 (1.6)	1
GAMMA-GLUTAMYLTRANSFERASE INCREASED	0	0	1 (4.3)	1	1 (1.6)	1
HAEMOGLOBIN DECREASED	1 (2.5)	1	0	0	1 (1.6)	1
MEAN CELL VOLUME INCREASED	0	0	1 (4.3)	1	1 (1.6)	1
PSYCHIATRIC DISORDERS	3 (7.5)	3	1 (4.3)	1	4 (6.3)	4
ANXIETY	1 (2.5)	1	0	0	1 (1.6)	1
DEPRESSION	0	0	1 (4.3)	1	1 (1.6)	1
PSYCHOSOMATIC DISEASE	1 (2.5)	1	0	0	1 (1.6)	1
SLEEP DISORDER	1 (2.5)	1	0	0	1 (1.6)	1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
ANAEMIA	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
EYE DISORDERS	3 (7.5)	3	0	0	3 (4.8)	3
CONJUNCTIVITIS	1 (2.5)	1	0	0	1 (1.6)	1
GLAUCOMA	1 (2.5)	1	0	0	1 (1.6)	1
VISION BLURRED	1 (2.5)	1	0	0	1 (1.6)	1
VASCULAR DISORDERS	3 (7.5)	3	0	0	3 (4.8)	3
HYPERTENSION	2 (5.0)	2	0	0	2 (3.2)	2
HYPERAEMIA	1 (2.5)	1	0	0	1 (1.6)	1
RENAL AND URINARY DISORDERS	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
DYSURIA	1 (2.5)	1	0	0	1 (1.6)	1
URINARY RETENTION	0	0	1 (4.3)	1	1 (1.6)	1
HEPATOBILIARY DISORDERS	0	0	1 (4.3)	1	1 (1.6)	1
ALCOHOLIC LIVER DISEASE	0	0	1 (4.3)	1	1 (1.6)	1
IMMUNE SYSTEM DISORDERS	1 (2.5)	1	0	0	1 (1.6)	1
HYPERSENSITIVITY	1 (2.5)	1	0	0	1 (1.6)	1
METABOLISM AND NUTRITION DISORDERS	1 (2.5)	1	0	0	1 (1.6)	1
ABNORMAL WEIGHT GAIN	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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System Organ Class Preferred Term	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (2.5)	1	0	0	1 (1.6)	1
MELANOCYTIC NAEVUS	1 (2.5)	1	0	0	1 (1.6)	1
SURGICAL AND MEDICAL PROCEDURES	1 (2.5)	1	0	0	1 (1.6)	1
TOOTH EXTRACTION	1 (2.5)	1	0	0	1 (1.6)	1

Note: 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
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Source: Study 3001 Table 14.4.1.3.

Table A.3-9 Study 3001: Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Relationship (Safety Population)

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
Any Treatment-Emergent AEs	36 (90.0)	278	18 (78.3)	69	54 (85.7)	347
Related	4 (10.0)	8	1 (4.3)	3	5 (7.9)	11
Not Related	32 (80.0)	270	17 (73.9)	66	49 (77.8)	336
Missing	0	0	0	0	0	0
INFECTIONS AND INFESTATIONS	28 (70.0)	74	12 (52.2)	23	40 (63.5)	97
Related	0	0	0	0	0	0
Not Related	28 (70.0)	74	12 (52.2)	23	40 (63.5)	97
Missing	0	0	0	0	0	0
NASOPHARYNGITIS	10 (25.0)	27	6 (26.1)	11	16 (25.4)	38
Related	0	0	0	0	0	0
Not Related	10 (25.0)	27	6 (26.1)	11	16 (25.4)	38
Missing	0	0	0	0	0	0
INFLUENZA	4 (10.0)	7	3 (13.0)	3	7 (11.1)	10
Related	0	0	0	0	0	0
Not Related	4 (10.0)	7	3 (13.0)	3	7 (11.1)	10
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
UPPER RESPIRATORY TRACT INFECTION	5 (12.5)	7	0	0	5 (7.9)	7
Related	0	0	0	0	0	0
Not Related	5 (12.5)	7	0	0	5 (7.9)	7
Missing	0	0	0	0	0	0
BRONCHITIS	4 (10.0)	4	1 (4.3)	1	5 (7.9)	5
Related	0	0	0	0	0	0
Not Related	4 (10.0)	4	1 (4.3)	1	5 (7.9)	5
Missing	0	0	0	0	0	0
PHARYNGITIS	3 (7.5)	3	2 (8.7)	2	5 (7.9)	5
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	2 (8.7)	2	5 (7.9)	5
Missing	0	0	0	0	0	0
GASTROENTERITIS	3 (7.5)	4	0	0	3 (4.8)	4
Related	0	0	0	0	0	0
Not Related	3 (7.5)	4	0	0	3 (4.8)	4
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
FUNGAL INFECTION	2 (5.0)	3	0	0	2 (3.2)	3
Related	0	0	0	0	0	0
Not Related	2 (5.0)	3	0	0	2 (3.2)	3
Missing	0	0	0	0	0	0
ACUTE TONSILLITIS	0	0	2 (8.7)	2	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	0	0	2 (8.7)	2	2 (3.2)	2
Missing	0	0	0	0	0	0
SINUSITIS	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0
URINARY TRACT INFECTION	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
ORAL HERPES	1 (2.5)	2	0	0	1 (1.6)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
ABSCESS LIMB	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
CELLULITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
EAR INFECTION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
FOLLICULITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
GASTROENTERITIS VIRAL	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
GENITOURINARY TRACT INFECTION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
HELICOBACTER GASTRITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
HELICOBACTER INFECTION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
HEPATITIS C	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
HERPES ZOSTER	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
PRIMARY SYPHILIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
SKIN BACTERIAL INFECTION	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
TONSILLITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
TOOTH ABSCESS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
TRACHEOBRONCHITIS	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
VIRAL RASH	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
VIRAL RHINITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	24 (60.0)	61	4 (17.4)	7	28 (44.4)	68
Related	0	0	0	0	0	0
Not Related	24 (60.0)	61	4 (17.4)	7	28 (44.4)	68
Missing	0	0	0	0	0	0
ARTHRALGIA	9 (22.5)	19	0	0	9 (14.3)	19
Related	0	0	0	0	0	0
Not Related	9 (22.5)	19	0	0	9 (14.3)	19
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
BACK PAIN	4 (10.0)	5	2 (8.7)	3	6 (9.5)	8
Related	0	0	0	0	0	0
Not Related	4 (10.0)	5	2 (8.7)	3	6 (9.5)	8
Missing	0	0	0	0	0	0
SYNOVITIS	3 (7.5)	6	1 (4.3)	1	4 (6.3)	7
Related	0	0	0	0	0	0
Not Related	3 (7.5)	6	1 (4.3)	1	4 (6.3)	7
Missing	0	0	0	0	0	0
PAIN IN EXTREMITY	3 (7.5)	4	0	0	3 (4.8)	4
Related	0	0	0	0	0	0
Not Related	3 (7.5)	4	0	0	3 (4.8)	4
Missing	0	0	0	0	0	0
JOINT SWELLING	3 (7.5)	3	0	0	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	0	0	3 (4.8)	3
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
TENDONITIS	3 (7.5)	3	0	0	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	0	0	3 (4.8)	3
Missing	0	0	0	0	0	0
HAEMOPHILIC ARTHROPATHY	1 (2.5)	2	1 (4.3)	1	2 (3.2)	3
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	1 (4.3)	1	2 (3.2)	3
Missing	0	0	0	0	0	0
GROIN PAIN	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0
MYALGIA	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
PERIARTHRITIS	1 (2.5)	3	0	0	1 (1.6)	3
Related	0	0	0	0	0	0
Not Related	1 (2.5)	3	0	0	1 (1.6)	3
Missing	0	0	0	0	0	0
ARTHRITIS	1 (2.5)	2	0	0	1 (1.6)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
MUSCULOSKELETAL CHEST PAIN	1 (2.5)	2	0	0	1 (1.6)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
AXILLARY MASS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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]:3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
FLANK PAIN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
HAEMARTHROSIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
JOINT CONTRACTURE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
MUSCLE TIGHTNESS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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]:3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
MUSCULOSKELETAL PAIN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
MUSCULOSKELETAL STIFFNESS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
NECK PAIN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
ROTATOR CUFF SYNDROME	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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] 3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
TENOSYNOVITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	16 (40.0)	38	6 (26.1)	10	22 (34.9)	48
Related	1 (2.5)	1	1 (4.3)	2	2 (3.2)	3
Not Related	15 (37.5)	37	5 (21.7)	8	20 (31.7)	45
Missing	0	0	0	0	0	0
HEADACHE	11 (27.5)	26	4 (17.4)	8	15 (23.8)	34
Related	0	0	1 (4.3)	2	1 (1.6)	2
Not Related	11 (27.5)	26	3 (13.0)	6	14 (22.2)	32
Missing	0	0	0	0	0	0
DIZZINESS	4 (10.0)	5	0	0	4 (6.3)	5
Related	1 (2.5)	1	0	0	1 (1.6)	1
Not Related	3 (7.5)	4	0	0	3 (4.8)	4
Missing	0	0	0	0	0	0

Note: 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] 3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
MIGRAINE	2 (5.0)	3	1 (4.3)	1	3 (4.8)	4
Related	0	0	0	0	0	0
Not Related	2 (5.0)	3	1 (4.3)	1	3 (4.8)	4
Missing	0	0	0	0	0	0
ACQUIRED EPILEPTIC APHASIA	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
DISTURBANCE IN ATTENTION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
HYPOAESTHESIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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]:3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
NEURALGIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
SPINAL CORD COMPRESSION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (40.0)	30	6 (26.1)	10	22 (34.9)	40
Related	0	0	0	0	0	0
Not Related	16 (40.0)	30	6 (26.1)	10	22 (34.9)	40
Missing	0	0	0	0	0	0
LIMB INJURY	5 (12.5)	5	1 (4.3)	1	6 (9.5)	6
Related	0	0	0	0	0	0
Not Related	5 (12.5)	5	1 (4.3)	1	6 (9.5)	6
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
CONTUSION	3 (7.5)	5	1 (4.3)	3	4 (6.3)	8
Related	0	0	0	0	0	0
Not Related	3 (7.5)	5	1 (4.3)	3	4 (6.3)	8
Missing	0	0	0	0	0	0
LACERATION	1 (2.5)	1	2 (8.7)	2	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	2 (8.7)	2	3 (4.8)	3
Missing	0	0	0	0	0	0
ARTHROPOD BITE	2 (5.0)	3	0	0	2 (3.2)	3
Related	0	0	0	0	0	0
Not Related	2 (5.0)	3	0	0	2 (3.2)	3
Missing	0	0	0	0	0	0
INJURY	2 (5.0)	3	0	0	2 (3.2)	3
Related	0	0	0	0	0	0
Not Related	2 (5.0)	3	0	0	2 (3.2)	3
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
JOINT INJURY	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0
LIGAMENT SPRAIN	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0
ROAD TRAFFIC ACCIDENT	1 (2.5)	2	0	0	1 (1.6)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
ANIMAL BITE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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] 3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
EAR INJURY	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
FACE INJURY	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
FALL	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
FIBULA FRACTURE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
MUSCLE INJURY	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
MUSCLE STRAIN	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
PERIORBITAL HAEMATOMA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
SUNBURN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

□

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
TENDON INJURY	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
TOOTH FRACTURE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
GASTROINTESTINAL DISORDERS	16 (40.0)	21	5 (21.7)	8	21 (33.3)	29
Related	0	0	0	0	0	0
Not Related	16 (40.0)	21	5 (21.7)	8	21 (33.3)	29
Missing	0	0	0	0	0	0
DIARRHOEA	2 (5.0)	2	3 (13.0)	4	5 (7.9)	6
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	3 (13.0)	4	5 (7.9)	6
Missing	0	0	0	0	0	0

Note: 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]:3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
TOOTHACHE	4 (10.0)	4	1 (4.3)	1	5 (7.9)	5
Related	0	0	0	0	0	0
Not Related	4 (10.0)	4	1 (4.3)	1	5 (7.9)	5
Missing	0	0	0	0	0	0
DENTAL CARIES	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0
FOOD POISONING	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0
GINGIVITIS	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
HAEMORRHOIDS	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0
VOMITING	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0
ABDOMINAL PAIN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
ABDOMINAL PAIN UPPER	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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]:3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
ANAL FISSURE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
DYSPEPSIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
HAEMORRHOIDAL HAEMORRHAGE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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] 3:13 PM • I:\CSL_Behring\33176\21_Stat\Programs\Tables\t_aerel.sas • BMoore

System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
NAUSEA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
ODYNOPHAGIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9 (22.5)	16	1 (4.3)	1	10 (15.9)	17
Related	1 (2.5)	5	1 (4.3)	1	2 (3.2)	6
Not Related	8 (20.0)	11	0	0	8 (12.7)	11
Missing	0	0	0	0	0	0
ACNE	3 (7.5)	3	0	0	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	0	0	3 (4.8)	3
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
ECZEMA	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Related	0	0	1 (4.3)	1	1 (1.6)	1
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0
RASH	2 (5.0)	7	0	0	2 (3.2)	7
Related	1 (2.5)	5	0	0	1 (1.6)	5
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
ECCHYMOSIS	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0
ECZEMA ASTEATOTIC	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
SKIN STRIAE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	9 (22.5)	13	1 (4.3)	1	10 (15.9)	14
Related	1 (2.5)	1	0	0	1 (1.6)	1
Not Related	8 (20.0)	12	1 (4.3)	1	9 (14.3)	13
Missing	0	0	0	0	0	0
INJECTION SITE HAEMATOMA	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	1 (2.5)	1	0	0	1 (1.6)	1
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
INJECTION SITE PAIN	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
HYPERPYREXIA	1 (2.5)	2	0	0	1 (1.6)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
INJECTION SITE ERYTHEMA	1 (2.5)	2	0	0	1 (1.6)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	2	0	0	1 (1.6)	2
Missing	0	0	0	0	0	0
ASTHENIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
FATIGUE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
INJECTION SITE EROSION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
INJECTION SITE PARAESTHESIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
NON-CARDIAC CHEST PAIN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
PYREXIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (17.5)	8	2 (8.7)	2	9 (14.3)	10
Related	0	0	0	0	0	0
Not Related	7 (17.5)	8	2 (8.7)	2	9 (14.3)	10
Missing	0	0	0	0	0	0
COUGH	3 (7.5)	3	0	0	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	0	0	3 (4.8)	3
Missing	0	0	0	0	0	0
OROPHARYNGEAL PAIN	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Missing	0	0	0	0	0	0
RHINITIS ALLERGIC	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
ASTHMA	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
NASAL SEPTUM ULCERATION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
INVESTIGATIONS	1 (2.5)	1	3 (13.0)	3	4 (6.3)	4
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	3 (13.0)	3	4 (6.3)	4
Missing	0	0	0	0	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
GAMMA-GLUTAMYLTRANSFERASE INCREASED	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
HAEMOGLOBIN DECREASED	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
MEAN CELL VOLUME INCREASED	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
PSYCHIATRIC DISORDERS	3 (7.5)	3	1 (4.3)	1	4 (6.3)	4
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	1 (4.3)	1	4 (6.3)	4
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
ANXIETY	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
DEPRESSION	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
PSYCHOSOMATIC DISEASE	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
SLEEP DISORDER	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Missing	0	0	0	0	0	0
ANAEMIA	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	1 (4.3)	1	3 (4.8)	3
Missing	0	0	0	0	0	0
EYE DISORDERS	3 (7.5)	3	0	0	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	0	0	3 (4.8)	3
Missing	0	0	0	0	0	0
CONJUNCTIVITIS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
GLAUCOMA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
VISION BLURRED	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
VASCULAR DISORDERS	3 (7.5)	3	0	0	3 (4.8)	3
Related	0	0	0	0	0	0
Not Related	3 (7.5)	3	0	0	3 (4.8)	3
Missing	0	0	0	0	0	0
HYPERTENSION	2 (5.0)	2	0	0	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	2 (5.0)	2	0	0	2 (3.2)	2
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
HYPERAEMIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
RENAL AND URINARY DISORDERS	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	1 (4.3)	1	2 (3.2)	2
Missing	0	0	0	0	0	0
DYSURIA	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
URINARY RETENTION	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
HEPATOBILIARY DISORDERS	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
ALCOHOLIC LIVER DISEASE	0	0	1 (4.3)	1	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	0	0	1 (4.3)	1	1 (1.6)	1
Missing	0	0	0	0	0	0
IMMUNE SYSTEM DISORDERS	1 (2.5)	1	0	0	1 (1.6)	1
Related	1 (2.5)	1	0	0	1 (1.6)	1
Not Related	0	0	0	0	0	0
Missing	0	0	0	0	0	0
HYPERSENSITIVITY	1 (2.5)	1	0	0	1 (1.6)	1
Related	1 (2.5)	1	0	0	1 (1.6)	1
Not Related	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
METABOLISM AND NUTRITION DISORDERS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
ABNORMAL WEIGHT GAIN	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
MELANOCYTIC NAEVUS	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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System Organ Class Preferred Term Relationship	Prophylaxis Arm (N=40) n (%)	E	On-demand Arm (N=23) n (%)	E	Total (N=63) n (%)	E
SURGICAL AND MEDICAL PROCEDURES	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0
TOOTH EXTRACTION	1 (2.5)	1	0	0	1 (1.6)	1
Related	0	0	0	0	0	0
Not Related	1 (2.5)	1	0	0	1 (1.6)	1
Missing	0	0	0	0	0	0

Note: 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
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Source: Study 3001 CSR Table 14.4.1.12.

Table A.3-10 Study 3001: Japanese Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Japanese Safety Population)

System Organ Class Preferred Term	Treatment Arm 1: Prophylaxis (N=6) n (%)	E	Treatment Arm 2: On-demand (N=4) n (%)	E	Total (N=10) n (%)	E
Any Treatment-Emergent AEs	6 (100.0)	32	4 (100.0)	23	10 (100.0)	55
INFECTIONS AND INFESTATIONS	4 (66.7)	9	4 (100.0)	7	8 (80.0)	16
NASOPHARYNGITIS	2 (33.3)	6	2 (50.0)	4	4 (40.0)	10
BRONCHITIS	0	0	1 (25.0)	1	1 (10.0)	1
CELLULITIS	1 (16.7)	1	0	0	1 (10.0)	1
HELICOBACTER GASTRITIS	1 (16.7)	1	0	0	1 (10.0)	1
HEPATITIS C	0	0	1 (25.0)	1	1 (10.0)	1
INFLUENZA	1 (16.7)	1	0	0	1 (10.0)	1
PHARYNGITIS	0	0	1 (25.0)	1	1 (10.0)	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (66.7)	6	1 (25.0)	1	5 (50.0)	7
BACK PAIN	2 (33.3)	3	1 (25.0)	1	3 (30.0)	4
HAEMOPHILIC ARTHROPATHY	1 (16.7)	2	0	0	1 (10.0)	2
TENOSYNOVITIS	1 (16.7)	1	0	0	1 (10.0)	1

Note: 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
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System Organ Class Preferred Term	Treatment Arm 1: Prophylaxis (N=6) n (%)	E	Treatment Arm 2: On-demand (N=4) n (%)	E	Total (N=10) n (%)	E
GASTROINTESTINAL DISORDERS	3 (50.0)	5	1 (25.0)	2	4 (40.0)	7
DIARRHOEA	1 (16.7)	1	1 (25.0)	1	2 (20.0)	2
GINGIVITIS	2 (33.3)	2	0	0	2 (20.0)	2
DENTAL CARIES	0	0	1 (25.0)	1	1 (10.0)	1
DYSPEPSIA	1 (16.7)	1	0	0	1 (10.0)	1
GASTROOESOPHAGEAL REFLUX DISEASE	1 (16.7)	1	0	0	1 (10.0)	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (50.0)	4	1 (25.0)	3	4 (40.0)	7
CONTUSION	1 (16.7)	1	1 (25.0)	3	2 (20.0)	4
INJURY	2 (33.3)	3	0	0	2 (20.0)	3
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (33.3)	2	1 (25.0)	1	3 (30.0)	3
ECZEMA	1 (16.7)	1	1 (25.0)	1	2 (20.0)	2
ECZEMA ASTEATOTIC	1 (16.7)	1	0	0	1 (10.0)	1
NERVOUS SYSTEM DISORDERS	0	0	2 (50.0)	3	2 (20.0)	3
HEADACHE	0	0	1 (25.0)	2	1 (10.0)	2
MIGRAINE	0	0	1 (25.0)	1	1 (10.0)	1

Note: Table presents number and percentage of subjects (n (%)) with at least one specified event and number of spe
events (E). Percentages are based on the number of subjects in the respective group. Adverse events are coded using
version 14.1.
Source: Listing 16.2.7.1

System Organ Class Preferred Term	Treatment Arm 1: Prophylaxis (N=6) n (%)	E	Treatment Arm 2: On-demand (N=4) n (%)	E	Total (N=10) n (%)	E
INVESTIGATIONS	1 (16.7)	1	1 (25.0)	1	2 (20.0)	2
GAMMA-GLUTAMYLTRANSFERASE INCREASED	0	0	1 (25.0)	1	1 (10.0)	1
HAEMOGLOBIN DECREASED	1 (16.7)	1	0	0	1 (10.0)	1
PSYCHIATRIC DISORDERS	1 (16.7)	1	1 (25.0)	1	2 (20.0)	2
DEPRESSION	0	0	1 (25.0)	1	1 (10.0)	1
PSYCHOSOMATIC DISEASE	1 (16.7)	1	0	0	1 (10.0)	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (16.7)	2	0	0	1 (10.0)	2
INJECTION SITE EROSION	1 (16.7)	1	0	0	1 (10.0)	1
PYREXIA	1 (16.7)	1	0	0	1 (10.0)	1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0	1 (25.0)	1	1 (10.0)	1
ANAEMIA	0	0	1 (25.0)	1	1 (10.0)	1
EYE DISORDERS	1 (16.7)	1	0	0	1 (10.0)	1
GLAUCOMA	1 (16.7)	1	0	0	1 (10.0)	1
HEPATOBILIARY DISORDERS	0	0	1 (25.0)	1	1 (10.0)	1
ALCOHOLIC LIVER DISEASE	0	0	1 (25.0)	1	1 (10.0)	1

Note: 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
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System Organ Class Preferred Term	Treatment Arm 1: Prophylaxis (N=6) n (%)	E	Treatment Arm 2: On-demand (N=4) n (%)	E	Total (N=10) n (%)	E
RENAL AND URINARY DISORDERS	0	0	1 (25.0)	1	1 (10.0)	1
URINARY RETENTION	0	0	1 (25.0)	1	1 (10.0)	1
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	0	1 (25.0)	1	1 (10.0)	1
ASTHMA	0	0	1 (25.0)	1	1 (10.0)	1
VASCULAR DISORDERS	1 (16.7)	1	0	0	1 (10.0)	1
HYPERTENSION	1 (16.7)	1	0	0	1 (10.0)	1

Note: 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
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Source: Study 3001 CSR Addendum 2 Table 14.4.1.3.1.

Table A.3-11 Study 3001: Japanese Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Japanese Safety Population)

System Organ Class Preferred Term	Treatment Arm 1: Prophylaxis (N=6) n (%)	E	Treatment Arm 2: On-demand (N=4) n (%)	E	Total (N=10) n (%)	E
Any Related Treatment-Emergent AEs	0	0	1 (25.0)	3	1 (10.0)	3
NERVOUS SYSTEM DISORDERS	0	0	1 (25.0)	2	1 (10.0)	2
HEADACHE	0	0	1 (25.0)	2	1 (10.0)	2
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0	1 (25.0)	1	1 (10.0)	1
ECZEMA	0	0	1 (25.0)	1	1 (10.0)	1

Note: 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
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Source: Study 3001 CSR Addendum 2 Table 14.4.1.4.1.

A.4 Study 3002

Table A.4-1 Study 3002: Summary of Bleeding Episodes Requiring Treatment by Bleeding Type (Efficacy Population)

Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Overall						
Number of Subjects with >=1 Bleed Requiring Treatment	11		12		23	
Location of Bleed (n (%) E)						
Total Number of Bleeding Episodes	45		61		106	
Chest	1 (9.1)	1	0	0	1 (4.3)	1
Left Ankle	2 (18.2)	3	4 (33.3)	4	6 (26.1)	7
Left Elbow	2 (18.2)	2	0	0	2 (8.7)	2
Left Foot	0	0	3 (25.0)	5	3 (13.0)	5
Left Gluteal Muscle (Buttocks)	0	0	1 (8.3)	1	1 (4.3)	1
Left Hand Back	1 (9.1)	1	1 (8.3)	1	2 (8.7)	2
Left Hand Front	0	0	1 (8.3)	1	1 (4.3)	1
Left Hip/Left Iliopsoas	1 (9.1)	1	0	0	1 (4.3)	1
Left Knee	2 (18.2)	2	2 (16.7)	5	4 (17.4)	7
Left Thigh	0	0	2 (16.7)	2	2 (8.7)	2
Lower Left Leg	0	0	1 (8.3)	1	1 (4.3)	1
Lower Right Leg	1 (9.1)	1	1 (8.3)	1	2 (8.7)	2
Multiple	3 (27.3)	3	3 (25.0)	3	6 (26.1)	6
Nasal	2 (18.2)	6	1 (8.3)	1	3 (13.0)	7
Oral	3 (27.3)	5	2 (16.7)	2	5 (21.7)	7
Right Ankle	0	0	2 (16.7)	5	2 (8.7)	5

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Overall						
Right Elbow	1 (9.1)	1	1 (8.3)	1	2 (8.7)	2
Right Foot	0	0	1 (8.3)	1	1 (4.3)	1
Right Forearm	0	0	1 (8.3)	1	1 (4.3)	1
Right Hand Front	0	0	1 (8.3)	1	1 (4.3)	1
Right Knee	2 (18.2)	2	1 (8.3)	2	3 (13.0)	4
Right Shoulder	0	0	1 (8.3)	1	1 (4.3)	1
Right Thigh	0	0	2 (16.7)	2	2 (8.7)	2
Right Wrist	0	0	2 (16.7)	2	2 (8.7)	2
Upper Left Arm	0	0	1 (8.3)	1	1 (4.3)	1
Upper Right Arm	1 (9.1)	1	0	0	1 (4.3)	1
Other	8 (72.7)	16	9 (75.0)	17	17 (73.9)	33
First Dose of rIX-FP Used to Treat Bleed (IU/kg)						
n	44		61		105	
Mean (SD)	49.456 (13.0623)		46.566 (9.3944)		47.777 (11.1138)	
Median	49.439		44.042		45.000	
Q1, Q3	37.205, 58.678		40.726, 49.800		40.000, 51.818	
Min, Max	25.83, 76.36		29.12, 75.00		25.83, 76.36	

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)	Age 6 to <12 years (N=15)	Total (N=27)
Overall			
Time from Start of Bleed to Treatment (hours)			
n	39	60	99
Mean (SD)	5.405 (12.3372)	6.260 (11.5698)	5.923 (11.8230)
Median	1.000	1.008	1.000
Q1, Q3	0.000, 3.667	0.000, 4.917	0.000, 4.833
Min, Max	0.00, 69.98	0.00, 46.92	0.00, 69.98

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Spontaneous						
Number of Subjects with >=1 Bleed Requiring Treatment	1		9		10	
Location of Bleed (n (%) E)						
Total Number of Bleeding Episodes	1		15		16	
Left Ankle	0	0	2 (22.2)	2	2 (20.0)	2
Left Foot	0	0	1 (11.1)	1	1 (10.0)	1
Left Hand Back	0	0	1 (11.1)	1	1 (10.0)	1
Left Knee	0	0	1 (11.1)	1	1 (10.0)	1
Multiple	1 (100.0)	1	1 (11.1)	1	2 (20.0)	2
Nasal	0	0	1 (11.1)	1	1 (10.0)	1
Right Ankle	0	0	2 (22.2)	4	2 (20.0)	4
Right Foot	0	0	1 (11.1)	1	1 (10.0)	1
Right Thigh	0	0	2 (22.2)	2	2 (20.0)	2
Right Wrist	0	0	1 (11.1)	1	1 (10.0)	1

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)	Age 6 to <12 years (N=15)	Total (N=27)
Spontaneous			
First Dose of rIX-FP Used to Treat Bleed (IU/kg)			
n	1	15	16
Mean (SD)	40.000	49.741 (10.9914)	49.132 (10.8944)
Median	40.000	47.980	46.968
Q1, Q3	40.000, 40.000	42.946, 59.760	41.473, 59.060
Min, Max	40.00, 40.00	29.28, 66.87	29.28, 66.87
Time from Start of Bleed to Treatment (hours)			
n	0	15	15
Mean (SD)		3.269 (4.5368)	3.269 (4.5368)
Median		2.367	2.367
Q1, Q3		0.133, 4.833	0.133, 4.833
Min, Max		0.00, 17.50	0.00, 17.50

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Traumatic						
Number of Subjects with >=1 Bleed Requiring Treatment	11		10		21	
Location of Bleed (n (%) E)						
Total Number of Bleeding Episodes	38		35		73	
Chest	1 (9.1)	1	0	0	1 (4.8)	1
Left Ankle	2 (18.2)	3	2 (20.0)	2	4 (19.0)	5
Left Elbow	2 (18.2)	2	0	0	2 (9.5)	2
Left Foot	0	0	2 (20.0)	3	2 (9.5)	3
Left Gluteal Muscle (Buttocks)	0	0	1 (10.0)	1	1 (4.8)	1
Left Hand Back	1 (9.1)	1	0	0	1 (4.8)	1
Left Hand Front	0	0	1 (10.0)	1	1 (4.8)	1
Left Knee	2 (18.2)	2	2 (20.0)	4	4 (19.0)	6
Left Thigh	0	0	1 (10.0)	1	1 (4.8)	1
Lower Left Leg	0	0	1 (10.0)	1	1 (4.8)	1
Lower Right Leg	1 (9.1)	1	0	0	1 (4.8)	1
Multiple	2 (18.2)	2	2 (20.0)	2	4 (19.0)	4
Nasal	2 (18.2)	2	0	0	2 (9.5)	2
Oral	3 (27.3)	5	1 (10.0)	1	4 (19.0)	6
Right Ankle	0	0	1 (10.0)	1	1 (4.8)	1
Right Elbow	1 (9.1)	1	0	0	1 (4.8)	1

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Traumatic						
Right Forearm	0	0	1 (10.0)	1	1 (4.8)	1
Right Knee	1 (9.1)	1	0	0	1 (4.8)	1
Right Shoulder	0	0	1 (10.0)	1	1 (4.8)	1
Right Wrist	0	0	1 (10.0)	1	1 (4.8)	1
Upper Left Arm	0	0	1 (10.0)	1	1 (4.8)	1
Upper Right Arm	1 (9.1)	1	0	0	1 (4.8)	1
Other	8 (72.7)	16	8 (80.0)	14	16 (76.2)	30
First Dose of rIX-FP Used to Treat Bleed (IU/kg)						
n	37		35		72	
Mean (SD)	49.589 (13.7773)		45.193 (8.9883)		47.452 (11.8249)	
Median	49.648		42.903		44.174	
Q1, Q3	36.944, 59.111		40.625, 46.261		39.868, 52.260	
Min, Max	25.83, 76.36		30.65, 75.00		25.83, 76.36	
Time from Start of Bleed to Treatment (hours)						
n	33		34		67	
Mean (SD)	4.926 (12.8920)		6.474 (11.3623)		5.712 (12.0724)	
Median	0.617		0.642		0.617	
Q1, Q3	0.000, 2.217		0.000, 9.017		0.000, 4.017	
Min, Max	0.00, 69.98		0.00, 45.03		0.00, 69.98	

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Post Surgery						
Number of Subjects with >=1 Bleed Requiring Treatment	0		1		1	
Location of Bleed (n (%) E)						
Total Number of Bleeding Episodes	0		1		1	
Oral	0	0	1 (100.0)	1	1 (100.0)	1
First Dose of rIX-FP Used to Treat Bleed (IU/kg)						
n	0		1		1	
Mean (SD)			48.984		48.984	
Median			48.984		48.984	
Q1, Q3			48.984, 48.984		48.984, 48.984	
Min, Max			48.98, 48.98		48.98, 48.98	
Time from Start of Bleed to Treatment (hours)						
n	0		1		1	
Mean (SD)			0.050		0.050	
Median			0.050		0.050	
Q1, Q3			0.050, 0.050		0.050, 0.050	
Min, Max			0.05, 0.05		0.05, 0.05	

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)		Age 6 to <12 years (N=15)		Total (N=27)	
Unknown						
Number of Subjects with >=1 Bleed Requiring Treatment	3		5		8	
Location of Bleed (n (%) E)						
Total Number of Bleeding Episodes	6		10		16	
Left Foot	0	0	1 (20.0)	1	1 (12.5)	1
Left Hip/Left Iliopsoas	1 (33.3)	1	0	0	1 (12.5)	1
Left Thigh	0	0	1 (20.0)	1	1 (12.5)	1
Lower Right Leg	0	0	1 (20.0)	1	1 (12.5)	1
Nasal	1 (33.3)	4	0	0	1 (12.5)	4
Right Elbow	0	0	1 (20.0)	1	1 (12.5)	1
Right Hand Front	0	0	1 (20.0)	1	1 (12.5)	1
Right Knee	1 (33.3)	1	1 (20.0)	2	2 (25.0)	3
Other	0	0	3 (60.0)	3	3 (37.5)	3
First Dose of rIX-FP Used to Treat Bleed (IU/kg)						
n	6		10		16	
Mean (SD)	50.214 (9.0557)		46.366 (8.3907)		47.809 (8.5603)	
Median	49.709		48.540		49.231	
Q1, Q3	49.231, 57.222		42.903, 49.800		43.472, 50.094	
Min, Max	34.55, 60.87		29.12, 61.38		29.12, 61.38	

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Bleeding Type	Age <6 years (N=12)	Age 6 to <12 years (N=15)	Total (N=27)
Unknown			
Time from Start of Bleed to Treatment (hours)			
n	6	10	16
Mean (SD)	8.036 (9.1240)	10.638 (18.2061)	9.663 (15.1102)
Median	4.408	3.292	3.292
Q1, Q3	1.000, 13.400	0.000, 4.583	1.000, 9.858
Min, Max	1.00, 24.00	0.00, 46.92	0.00, 46.92

Note: Location=Multiple indicates reported for more than one location. Percentages are based on the number of number of subjects with >=1 bleed requiring rIX-FP treatment.
Source: Listing 16.2.6.1
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Source: Study 3002 CSR Table 14.2.6.1.

Table A.4-2 Study 3002: QOL Questionnaire for Children and Teenager (Ages 8-12) (Safety Population)

	Screening (N=11)	End of Study (N=11)
Transformed Scale Score [1]		
n	8	7
Mean (SD)	27.94 (6.391)	20.35 (3.360)
Median	27.38	21.27
Q1, Q3	24.44, 29.24	19.05, 23.11
Min, Max	19.7, 41.7	14.0, 24.2
Transformed Scale Score [1] Change from Baseline		
n	--	7
Mean (SD)		-7.34 (7.124)
Median		-5.68
Q1, Q3		-14.86, -2.61
Min, Max		-18.6, 1.8
How frequent were your bleeds in the last 4 weeks?		
Number Assessed	8	7
No Bleeds	6 (75.0)	6 (85.7)
1	1 (12.5)	1 (14.3)
2	1 (12.5)	0
More Than 2	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
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	Screening (N=11)	End of Study (N=11)
How much were you troubled by bleeds during the last 4 weeks?		
Number Assessed	5	2
Not At All	3 (60.0)	1 (50.0)
Somewhat	1 (20.0)	1 (50.0)
Moderately	0	0
Quite a Bit	1 (20.0)	0
How severe were your bleeds during the last 4 weeks?		
Number Assessed	3	1
Slight	2 (66.7)	1 (100.0)
Moderate	1 (33.3)	0
Severe	0	0
Very Severe	0	0
Did you feel a strange sensation in your joints before you had a bleed?		
Number Assessed	5	1
Never	3 (60.0)	1 (100.0)
Seldom	0	0
Sometimes	0	0
Often	2 (40.0)	0
Always	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
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