Dossier zur Nutzenbewertung gemäß § 35a SGB V

Concizumab (Alhemo®)

Novo Nordisk Pharma GmbH

Anhang 4-G

Routineprophylaxe von Blutungen bei Patienten mit einer Hämophilie A mit Faktor-VIII-Hemmkörpern oder einer Hämophilie B mit Faktor-IX-Hemmkörpern ab einem Alter von 12 Jahren

Analysen für das Nutzendossier

Stand: 01.05.2025

Inhaltsverzeichnis

Studie Explorer7

* Die Gesamtmortalität wurde in der Studie Explorer7 über den Studienzeitraum im Rahmen der Sicherheitsanalysen erfasst.

Studie Explorer7

Analysesets

Analyseset[a]	Beschreibung
On-treatment without data on initial regimen	Stellt das für die Nutzenbewertung relevante Analyseset dar. Umfasst den Beobachtungszeitraum, in dem die Patienten eine Bedarfsbehandlung (Arm 1) oder Routineprophylaxe mit Concizumab entsprechend der Fachinformation (Arm 2) erhalten haben (Zeitraum nach der Unterbrechung der Behandlung mit Concizumab). Der Beobachtungszeitraum, während dem die Probanden *nicht* mit einem Fachinformation entsprechenden Dosierungsschema behandelt wurden, wird ausgeschlossen (Zeitraum vor der Unterbrechung der Behandlung mit Concizumab).
On-treatment without ancillary therapy[b] excl. data on initial regimen	Wird im Rahmen der vorliegenden Nutzenbewertung als Sensitivitätsanalyse für den Endpunkt Blutungsepisoden dargestellt. Umfasst den Beobachtungszeitraum, in dem die Patienten eine Bedarfsbehandlung (Arm 1) oder Routineprophylaxe mit Concizumab entsprechend der Fachinformation (Arm 2) erhalten haben (Zeitraum nach der Unterbrechung der Behandlung mit Concizumab). **Zusätzlich** wurden Zeiträume, in denen Patienten Faktorpräparate nicht im Zusammenhang mit der Behandlung einer Blutungsepisode erhalten haben, ausgeschlossen. Der Beobachtungszeitraum, während dem die Probanden *nicht* mit einem Fachinformation entsprechenden Dosierungsschema behandelt wurden, wird ausgeschlossen (Zeitraum vor der Unterbrechung der Behandlung mit Concizumab).
On-treatment without ancillary therapy[b] excl. data on initial regimen for subjects exposed to both regimen	Stellt das relevante Analyseset für den Zulassungsantrag bei der Europäischen Arzneimittel-Agentur dar.

Analyseset[a]	**Beschreibung**
	Umfasst den Beobachtungszeitraum, in dem die Patienten eine Bedarfsbehandlung (Arm 1) oder Routineprophylaxe mit Concizumab entsprechend der Fachinformation (Arm 2) erhalten haben (Zeitraum nach der Unterbrechung der Behandlung mit Concizumab). **Falls Patienten nach der Unterbrechung der Behandlung mit Concizumab nicht weiterbehandelt wurden**, wurde der Beobachtungszeitraum berücksichtigt, in dem die Patienten eine Bedarfsbehandlung (Arm 1) oder Routineprophylaxe mit Concizumab entsprechend des initialen Dosierungsschemas (Arm 2) erhalten haben (Zeitraum vor der Unterbrechung der Behandlung mit Concizumab). **Zusätzlich** wurden Zeiträume, in denen Patienten Faktorpräparate nicht im Zusammenhang mit der Behandlung einer Blutungsepisode erhalten haben, ausgeschlossen. Wird im Rahmen der vorliegenden Nutzenbewertung nicht berücksichtigt, da es Patienten umfasst, die eine nicht mit der Fachinformation übereinstimmenden Concizumab-Dosierung erhielten.

a. Es wurden nur Analysesets dargestellt, die die in Anhang 4-G enthaltenen Outputs umfassen.

b. Der Begriff „ancillary therapy“ (Zusatztherapie) bezieht sich auf die Anwendung von Faktorpräparaten, die nicht im Zusammenhang mit der Behandlung einer Blutungsepisode eingesetzt wurden.

Table of contents

Page

14 Tables, figures and graphs referred to but not included in the text

14.1 Demographic data

14.1.1 Inhibitor test results at baseline – HAwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS and ADS	9	17	26
Inhibitor test result, N(%)			
Number of inhibitor test results, N (%)	9 (100)	17 (100)	26 (100)
Median BU (SD)	6.3 (35.3)	2.0 (19.5)	3.6 (26.6)
Min ; Max	0.3 ; 108.0	0.3 ; 82.4	0.3 ; 108.0
>= 0.6 and < 5BU, number of results (%)	2 (22.2)	9 (52.9)	11 (42.3)
>= 5BU, number of results (%)	6 (66.7)	5 (29.4)	11 (42.3)

HAwI: Haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen. N: number of subjects, SD: standard deviation, Min: minimum, Max: maximum.
Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

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14.1.2 Inhibitor test results at baseline – HBwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS and ADS	10	12	22
Inhibitor test result, N(%)			
Number of inhibitor test results, N (%)	8 (100)	11 (100)	19 (100)
Median BU (SD)	4.5 (6.4)	0.3 (6.9)	1.8 (6.7)
Min ; Max	0.3 ; 15.6	0.3 ; 23.8	0.3 ; 23.8
>= 0.6 and < 5BU, number of results (%)	1 (12.5)	4 (36.4)	5 (26.3)
>= 5BU, number of results (%)	4 (50.0)	1 (9.1)	5 (26.3)

HBwI: Haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen. N: number of subjects, SD: standard deviation, Min: minimum, Max: maximum.
Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

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14.1.3 Demographics and baseline characteristics - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	9	17	26
Age group (years)			
Adolescents (12-17 years)	1 (11.1)	10 (58.8)	11 (42.3)
Adults (18-64 years)	7 (77.8)	7 (41.2)	14 (53.8)
Elderly/very elderly (65-84 years)	1 (11.1)	0	1 (3.8)
Ethnicity			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	8 (88.9)	17 (100)	25 (96.2)
Not Reported	1 (11.1)	0	1 (3.8)
Race			
American Indian or Alaska Native	0	0	0
Asian	2 (22.2)	9 (52.9)	11 (42.3)
Black or African American	0	3 (17.6)	3 (11.5)
Native Hawaiian or Other Pacific Islander	0	0	0
White	6 (66.7)	5 (29.4)	11 (42.3)
Not Reported	1 (11.1)	0	1 (3.8)
Country			
Australia	0	1 (5.9)	1 (3.8)
Croatia	1 (11.1)	0	1 (3.8)
France	1 (11.1)	0	1 (3.8)
India	0	8 (47.1)	8 (30.8)
Italy	2 (22.2)	1 (5.9)	3 (11.5)
Malaysia	1 (11.1)	0	1 (3.8)
Poland	1 (11.1)	0	1 (3.8)
Russian Federation	0	1 (5.9)	1 (3.8)

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

Demographics and baseline characteristics - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
South Africa	0	3 (17.6)	3 (11.5)
Korea, Republic of	1 (11.1)	1 (5.9)	2 (7.7)
Ukraine	2 (22.2)	2 (11.8)	4 (15.4)
OECD membership			
Non-OECD country	4 (44.4)	14 (82.4)	18 (69.2)
OECD country	5 (55.6)	3 (17.6)	8 (30.8)

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

14.1.4 Demographics and baseline characteristics - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	10	12	22
Age group (years)			
Adolescents (12-17 years)	5 (50.0)	6 (50.0)	11 (50.0)
Adults (18-64 years)	5 (50.0)	6 (50.0)	11 (50.0)
Elderly/very elderly (65-84 years)	0	0	0
Ethnicity			
Hispanic or Latino	1 (10.0)	3 (25.0)	4 (18.2)
Not Hispanic or Latino	8 (80.0)	8 (66.7)	16 (72.7)
Not Reported	1 (10.0)	1 (8.3)	2 (9.1)
Race			
American Indian or Alaska Native	1 (10.0)	1 (8.3)	2 (9.1)
Asian	4 (40.0)	4 (33.3)	8 (36.4)
Black or African American	1 (10.0)	1 (8.3)	2 (9.1)
Native Hawaiian or Other Pacific Islander	0	0	0
White	3 (30.0)	4 (33.3)	7 (31.8)
Not Reported	1 (10.0)	2 (16.7)	3 (13.6)
Country			
France	1 (10.0)	1 (8.3)	2 (9.1)
India	2 (20.0)	2 (16.7)	4 (18.2)
Italy	1 (10.0)	1 (8.3)	2 (9.1)
Japan	1 (10.0)	1 (8.3)	2 (9.1)
Malaysia	0	1 (8.3)	1 (4.5)
Mexico	1 (10.0)	1 (8.3)	2 (9.1)
Poland	0	1 (8.3)	1 (4.5)
Russian Federation	1 (10.0)	0	1 (4.5)

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

Demographics and baseline characteristics - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
South Africa	1 (10.0)	1 (8.3)	2 (9.1)
Spain	0	1 (8.3)	1 (4.5)
Ukraine	1 (10.0)	0	1 (4.5)
United States of America	1 (10.0)	2 (16.7)	3 (13.6)
OECD membership			
Non-OECD country	5 (50.0)	4 (33.3)	9 (40.9)
OECD country	5 (50.0)	8 (66.7)	13 (59.1)

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

14.1.5 Demographics and baseline characteristics - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	6	17	23
Age group (years)			
Adolescents (12-17 years)	1 (16.7)	10 (58.8)	11 (47.8)
Adults (18-64 years)	4 (66.7)	7 (41.2)	11 (47.8)
Elderly/very elderly (65-84 years)	1 (16.7)	0	1 (4.3)
Ethnicity			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5 (83.3)	17 (100)	22 (95.7)
Not Reported	1 (16.7)	0	1 (4.3)
Race			
American Indian or Alaska Native	0	0	0
Asian	1 (16.7)	9 (52.9)	10 (43.5)
Black or African American	0	2 (11.8)	2 (8.7)
Native Hawaiian or Other Pacific Islander	0	0	0
White	4 (66.7)	6 (35.3)	10 (43.5)
Not Reported	1 (16.7)	0	1 (4.3)
Country			
Australia	0	1 (5.9)	1 (4.3)
Bulgaria	0	1 (5.9)	1 (4.3)
France	1 (16.7)	0	1 (4.3)
India	0	8 (47.1)	8 (34.8)
Italy	2 (33.3)	1 (5.9)	3 (13.0)
Russian Federation	0	1 (5.9)	1 (4.3)
South Africa	0	2 (11.8)	2 (8.7)
Korea, Republic of	1 (16.7)	1 (5.9)	2 (8.7)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

Demographics and baseline characteristics - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Ukraine	2 (33.3)	2 (11.8)	4 (17.4)
OECD membership			
Non-OECD country	2 (33.3)	14 (82.4)	16 (69.6)
OECD country	4 (66.7)	3 (17.6)	7 (30.4)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

14.1.6 Demographics and baseline characteristics - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	7	11	18
Age group (years)			
Adolescents (12-17 years)	3 (42.9)	4 (36.4)	7 (38.9)
Adults (18-64 years)	4 (57.1)	7 (63.6)	11 (61.1)
Elderly/very elderly (65-84 years)	0	0	0
Ethnicity			
Hispanic or Latino	0	1 (9.1)	1 (5.6)
Not Hispanic or Latino	6 (85.7)	9 (81.8)	15 (83.3)
Not Reported	1 (14.3)	1 (9.1)	2 (11.1)
Race			
American Indian or Alaska Native	0	0	0
Asian	2 (28.6)	5 (45.5)	7 (38.9)
Black or African American	1 (14.3)	1 (9.1)	2 (11.1)
Native Hawaiian or Other Pacific Islander	0	0	0
White	3 (42.9)	3 (27.3)	6 (33.3)
Not Reported	1 (14.3)	2 (18.2)	3 (16.7)
Country			
France	1 (14.3)	1 (9.1)	2 (11.1)
India	0	3 (27.3)	3 (16.7)
Italy	1 (14.3)	0	1 (5.6)
Japan	1 (14.3)	1 (9.1)	2 (11.1)
Malaysia	0	1 (9.1)	1 (5.6)
Poland	0	1 (9.1)	1 (5.6)
Russian Federation	1 (14.3)	0	1 (5.6)
South Africa	1 (14.3)	1 (9.1)	2 (11.1)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

Demographics and baseline characteristics - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Sweden	0	1 (9.1)	1 (5.6)
Ukraine	1 (14.3)	0	1 (5.6)
United States of America	1 (14.3)	2 (18.2)	3 (16.7)
OECD membership			
Non-OECD country	3 (42.9)	5 (45.5)	8 (44.4)
OECD country	4 (57.1)	6 (54.5)	10 (55.6)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

14.1.7 Demographics and baseline characteristics - subjects enrolled after the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	3	1	4
Age group (years)			
Adolescents (12-17 years)	0	1 (100)	1 (25.0)
Adults (18-64 years)	3 (100)	0	3 (75.0)
Elderly/very elderly (65-84 years)	0	0	0
Ethnicity			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3 (100)	1 (100)	4 (100)
Not Reported	0	0	0
Race			
American Indian or Alaska Native	0	0	0
Asian	1 (33.3)	0	1 (25.0)
Black or African American	0	1 (100)	1 (25.0)
Native Hawaiian or Other Pacific Islander	0	0	0
White	2 (66.7)	0	2 (50.0)
Not Reported	0	0	0
Country			
Croatia	1 (33.3)	0	1 (25.0)
Malaysia	1 (33.3)	0	1 (25.0)
Poland	1 (33.3)	0	1 (25.0)
South Africa	0	1 (100)	1 (25.0)
OECD membership			
Non-OECD country	2 (66.7)	1 (100)	3 (75.0)
OECD country	1 (33.3)	0	1 (25.0)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

14.1.8 Demographics and baseline characteristics - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	3	4	7
Age group (years)			
Adolescents (12-17 years)	2 (66.7)	3 (75.0)	5 (71.4)
Adults (18-64 years)	1 (33.3)	1 (25.0)	2 (28.6)
Elderly/very elderly (65-84 years)	0	0	0
Ethnicity			
Hispanic or Latino	1 (33.3)	2 (50.0)	3 (42.9)
Not Hispanic or Latino	2 (66.7)	2 (50.0)	4 (57.1)
Not Reported	0	0	0
Race			
American Indian or Alaska Native	1 (33.3)	1 (25.0)	2 (28.6)
Asian	2 (66.7)	0	2 (28.6)
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	0	3 (75.0)	3 (42.9)
Not Reported	0	0	0
Country			
India	2 (66.7)	0	2 (28.6)
Italy	0	1 (25.0)	1 (14.3)
Mexico	1 (33.3)	1 (25.0)	2 (28.6)
Spain	0	1 (25.0)	1 (14.3)
United States of America	0	1 (25.0)	1 (14.3)
OECD membership			
Non-OECD country	2 (66.7)	0	2 (28.6)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

Demographics and baseline characteristics - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
OECD country	1 (33.3)	4 (100)	5 (71.4)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Note: information on age, ethnicity and race are according to local regulations.

14.1.9 Demographics and baseline characteristics - descriptive statistics - HAwI - OTexIR - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of subjects	9	17	26
Age(years)			
N	9	17	26
Median	43.0	17.0	22.5
P25 ; P75	27.0 ; 60.0	14.0 ; 41.0	15.0 ; 50.0
Mean (SD)	42.3 (18.5)	25.9 (16.9)	31.6 (18.9)
Min ; Max	15.0 ; 67.0	12.0 ; 61.0	12.0 ; 67.0
Height (m)			
N	9	17	26
Median	1.8	1.7	1.7
P25 ; P75	1.7 ; 1.8	1.6 ; 1.7	1.6 ; 1.8
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Min ; Max	1.6 ; 1.9	1.5 ; 1.9	1.5 ; 1.9
Body weight (kg)			
N	9	17	26
Median	69.0	61.1	63.8
P25 ; P75	62.3 ; 77.8	51.0 ; 69.3	53.0 ; 74.8
Mean (SD)	73.4 (18.9)	60.7 (13.3)	65.1 (16.3)
Min ; Max	44.1 ; 107.0	39.3 ; 84.5	39.3 ; 107.0
BMI, (kg/m^2)			
N	9	17	26
Median	25.1	21.7	22.3
P25 ; P75	20.3 ; 26.2	20.1 ; 24.0	20.1 ; 25.4
Mean (SD)	24.2 (5.5)	22.1 (4.2)	22.8 (4.7)
Min ; Max	16.3 ; 33.9	15.8 ; 32.5	15.8 ; 33.9

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, BMI: body mass index. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.10 Demographics and baseline characteristics - descriptive statistics - HBwI - OTexIR - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of subjects	10	12	22
Age(years)			
N	10	12	22
Median	17.5	19.0	17.5
P25 ; P75	15.0 ; 27.0	15.5 ; 32.0	15.0 ; 30.0
Mean (SD)	23.3 (11.1)	23.3 (10.4)	23.3 (10.5)
Min ; Max	15.0 ; 46.0	12.0 ; 41.0	12.0 ; 46.0
Height (m)			
N	10	12	22
Median	1.7	1.6	1.6
P25 ; P75	1.6 ; 1.8	1.6 ; 1.7	1.6 ; 1.7
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Min ; Max	1.5 ; 1.9	1.4 ; 1.8	1.4 ; 1.9
Body weight (kg)			
N	10	12	22
Median	56.2	71.2	59.0
P25 ; P75	45.8 ; 99.0	48.9 ; 92.3	48.8 ; 94.0
Mean (SD)	65.9 (25.1)	71.9 (24.8)	69.2 (24.5)
Min ; Max	40.0 ; 103.0	40.0 ; 115.3	40.0 ; 115.3
BMI, (kg/m^2)			
N	10	12	22
Median	21.2	25.8	21.5
P25 ; P75	18.7 ; 28.3	19.8 ; 29.5	19.7 ; 28.7
Mean (SD)	23.1 (6.9)	26.1 (8.0)	24.8 (7.5)
Min ; Max	15.1 ; 36.5	15.1 ; 42.4	15.1 ; 42.4

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, BMI: body mass index. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.11 Demographics and baseline characteristics - subjects enrolled before the pause - descriptive statistics - HAwI - OT - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of subjects	6	17	23
Age(years)			
N	6	17	23
Median	51.5	17.0	21.0
P25 ; P75	21.0 ; 60.0	13.0 ; 41.0	14.0 ; 50.0
Mean (SD)	44.3 (22.0)	25.8 (17.0)	30.6 (19.7)
Min ; Max	15.0 ; 67.0	12.0 ; 61.0	12.0 ; 67.0
Height (m)			
N	6	17	23
Median	1.8	1.7	1.7
P25 ; P75	1.6 ; 1.8	1.6 ; 1.7	1.6 ; 1.8
Mean (SD)	1.7 (0.1)	1.6 (0.1)	1.7 (0.1)
Min ; Max	1.6 ; 1.8	1.5 ; 1.9	1.5 ; 1.9
Body weight (kg)			
N	6	17	23
Median	64.7	61.1	61.6
P25 ; P75	60.0 ; 77.8	51.0 ; 69.3	51.0 ; 73.0
Mean (SD)	64.9 (12.7)	60.2 (13.9)	61.4 (13.5)
Min ; Max	44.1 ; 77.8	38.3 ; 84.5	38.3 ; 84.5
BMI, (kg/m^2)			
N	6	17	23
Median	22.7	21.7	21.7
P25 ; P75	18.7 ; 25.4	20.1 ; 24.0	18.7 ; 25.1
Mean (SD)	22.0 (4.1)	22.1 (4.2)	22.1 (4.1)
Min ; Max	16.3 ; 26.2	15.8 ; 32.5	15.8 ; 32.5

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, BMI: body mass index. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.12 Demographics and baseline characteristics - subjects enrolled before the pause - descriptive statistics - HBwI - OT - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of subjects	7	11	18
Age(years)			
N	7	11	18
Median	19.0	28.0	26.5
P25 ; P75	16.0 ; 39.0	15.0 ; 39.0	16.0 ; 39.0
Mean (SD)	25.4 (12.5)	27.6 (11.8)	26.8 (11.8)
Min ; Max	15.0 ; 46.0	13.0 ; 47.0	13.0 ; 47.0
Height (m)			
N	7	11	18
Median	1.7	1.7	1.7
P25 ; P75	1.6 ; 1.8	1.6 ; 1.7	1.6 ; 1.7
Mean (SD)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Min ; Max	1.5 ; 1.9	1.4 ; 1.8	1.4 ; 1.9
Body weight (kg)			
N	7	11	18
Median	58.0	69.0	63.5
P25 ; P75	45.8 ; 101.4	49.0 ; 90.5	49.0 ; 99.0
Mean (SD)	72.3 (27.3)	71.3 (25.5)	71.7 (25.4)
Min ; Max	44.8 ; 103.0	40.0 ; 115.3	40.0 ; 115.3
BMI, (kg/m^2)			
N	7	11	18
Median	21.5	23.8	22.6
P25 ; P75	18.7 ; 32.1	19.7 ; 30.2	19.7 ; 30.2
Mean (SD)	25.0 (7.3)	25.6 (8.3)	25.4 (7.7)
Min ; Max	17.1 ; 36.5	15.1 ; 42.4	15.1 ; 42.4

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, BMI: body mass index. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.13 Demographics and baseline characteristics - subjects enrolled after the pause - descriptive statistics - HAwI - OT - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of subjects	3	1	4
Age(years)			
N	3	1	4
Median	38.0	15.0	32.5
P25 ; P75	27.0 ; 50.0	15.0 ; 15.0	21.0 ; 44.0
Mean (SD)	38.3 (11.5)	15.0 (.)	32.5 (15.0)
Min ; Max	27.0 ; 50.0	15.0 ; 15.0	15.0 ; 50.0
Height (m)			
N	3	1	4
Median	1.8	1.6	1.7
P25 ; P75	1.7 ; 1.9	1.6 ; 1.6	1.6 ; 1.8
Mean (SD)	1.8 (0.1)	1.6 (.)	1.7 (0.1)
Min ; Max	1.7 ; 1.9	1.6 ; 1.6	1.6 ; 1.9
Body weight (kg)			
N	3	1	4
Median	95.1	45.9	82.1
P25 ; P75	69.0 ; 107.0	45.9 ; 45.9	57.5 ; 101.1
Mean (SD)	90.4 (19.4)	45.9 (.)	79.3 (27.3)
Min ; Max	69.0 ; 107.0	45.9 ; 45.9	45.9 ; 107.0
BMI, (kg/m^2)			
N	3	1	4
Median	29.6	17.5	26.1
P25 ; P75	22.5 ; 33.9	17.5 ; 17.5	20.0 ; 31.8
Mean (SD)	28.7 (5.7)	17.5 (.)	25.9 (7.3)
Min ; Max	22.5 ; 33.9	17.5 ; 17.5	17.5 ; 33.9

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, BMI: body mass index. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.14 Demographics and baseline characteristics - subjects enrolled after the pause - descriptive statistics - HBwI - OT - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of subjects	3	4	7
Age(years)			
N	3	4	7
Median	15.0	16.0	16.0
P25 ; P75	15.0 ; 25.0	14.0 ; 19.0	15.0 ; 22.0
Mean (SD)	18.3 (5.8)	16.5 (4.1)	17.3 (4.5)
Min ; Max	15.0 ; 25.0	12.0 ; 22.0	12.0 ; 25.0
Height (m)			
N	3	4	7
Median	1.6	1.6	1.6
P25 ; P75	1.6 ; 1.7	1.6 ; 1.7	1.6 ; 1.7
Mean (SD)	1.6 (0.0)	1.7 (0.1)	1.7 (0.1)
Min ; Max	1.6 ; 1.7	1.6 ; 1.8	1.6 ; 1.8
Body weight (kg)			
N	3	4	7
Median	53.0	83.7	60.0
P25 ; P75	40.0 ; 60.0	61.1 ; 99.5	48.8 ; 94.0
Mean (SD)	51.0 (10.1)	80.3 (24.7)	67.7 (24.2)
Min ; Max	40.0 ; 60.0	48.8 ; 105.0	40.0 ; 105.0
BMI, (kg/m^2)			
N	3	4	7
Median	19.7	28.6	21.5
P25 ; P75	15.1 ; 21.5	24.1 ; 33.0	19.7 ; 28.7
Mean (SD)	18.8 (3.3)	28.6 (7.1)	24.4 (7.5)
Min ; Max	15.1 ; 21.5	19.8 ; 37.2	15.1 ; 37.2

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, BMI: body mass index. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.15 Electrocardiography (ECG) at baseline - overall interpretation - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	9	17	26
ECG			
N	4	15	19
Normal	3 (75.0)	15 (100)	18 (94.7)
Abnormal, NCS	1 (25.0)	0	1 (5.3)
Abnormal, CS	0	0	0

HAwI: haemophilia A with inhibitors,OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis, CS: clinically significant, NCS: not clinically significant, ECG: electrocardiography. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.16 Electrocardiography (ECG) at baseline - overall interpretation - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	10	12	22
ECG			
N	6	11	17
Normal	5 (83.3)	9 (81.8)	14 (82.4)
Abnormal, NCS	1 (16.7)	2 (18.2)	3 (17.6)
Abnormal, CS	0	0	0

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis, CS: clinically significant, NCS: not clinically significant, ECG: electrocardiography. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.17 Electrocardiography (ECG) at baseline - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	6	17	23
ECG			
N	2	15	17
Normal	2 (100)	15 (100)	17 (100)
Abnormal, NCS	0	0	0
Abnormal, CS	0	0	0

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis, CS: clinically significant, NCS: not clinically significant, ECG: electrocardiography. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.18 Electrocardiography (ECG) at baseline - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	7	11	18
ECG			
N	3	10	13
Normal	2 (66.7)	7 (70.0)	9 (69.2)
Abnormal, NCS	1 (33.3)	3 (30.0)	4 (30.8)
Abnormal, CS	0	0	0

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis, CS: clinically significant, NCS: not clinically significant, ECG: electrocardiography. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.19 Electrocardiography (ECG) at baseline - subjects enrolled after the pause - summary - HAwI- OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	3	1	4
ECG			
N	2	1	3
Normal	1 (50.0)	1 (100)	2 (66.7)
Abnormal, NCS	1 (50.0)	0	1 (33.3)
Abnormal, CS	0	0	0

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis, CS: clinically significant, NCS: not clinically significant, ECG: electrocardiography. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.20 Electrocardiography (ECG) at baseline - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of subjects	3	4	7
ECG			
N	3	4	7
Normal	3 (100)	4 (100)	7 (100)
Abnormal, NCS	0	0	0
Abnormal, CS	0	0	0

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis, CS: clinically significant, NCS: not clinically significant, ECG: electrocardiography. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.21 Haemophilia details - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N in FAS	9	18	27
N in FAS and ADS	9	17	26
Classification of haemophilia type			
N	9 (100.0)	17 (100.0)	26 (100.0)
Haemophilia A	9 (100.0)	17 (100.0)	26 (100.0)
Inhibitor test result [1]			
N	9 (100.0)	15 (100.0)	24 (100.0)
< 0.6 BU	1 (11.1)	1 (6.7)	2 (8.3)
>= 0.6 and < 5 BU	2 (22.2)	7 (46.7)	9 (37.5)
>= 5 BU	6 (66.7)	8 (53.3)	14 (58.3)
Family history of haemophilia			
N	9 (100.0)	17 (100.0)	26 (100.0)
Yes	4 (44.4)	4 (23.5)	8 (30.8)
No	2 (22.2)	11 (64.7)	13 (50.0)
Unknown	3 (33.3)	2 (11.8)	5 (19.2)
Family history of prothrombotic disorders			
N	9 (100.0)	17 (100.0)	26 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	3 (33.3)	3 (17.6)	6 (23.1)
Unknown	6 (66.7)	14 (82.4)	20 (76.9)
Family history of thromboembolism			
N	9 (100.0)	17 (100.0)	26 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	3 (33.3)	3 (17.6)	6 (23.1)
Unknown	6 (66.7)	14 (82.4)	20 (76.9)
Family history of inhibitors			

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 05, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

Haemophilia details - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N	9 (100.0)	17 (100.0)	26 (100.0)
Yes	1 (11.1)	2 (11.8)	3 (11.5)
No	4 (44.4)	13 (76.5)	17 (65.4)
Unknown	4 (44.4)	2 (11.8)	6 (23.1)

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 05, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

14.1.22 Haemophilia details - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N in FAS	10	15	25
N in FAS and ADS	10	12	22
Classification of haemophilia type			
N	10 (100.0)	12 (100.0)	22 (100.0)
Haemophilia B	10 (100.0)	12 (100.0)	22 (100.0)
Inhibitor test result [1]			
N	7 (100.0)	11 (100.0)	18 (100.0)
< 0.6 BU	2 (28.6)	2 (18.2)	4 (22.2)
>= 0.6 and < 5 BU	2 (28.6)	4 (36.4)	6 (33.3)
>= 5 BU	4 (57.1)	5 (45.5)	9 (50.0)
Family history of haemophilia			
N	10 (100.0)	12 (100.0)	22 (100.0)
Yes	4 (40.0)	8 (66.7)	12 (54.5)
No	6 (60.0)	1 (8.3)	7 (31.8)
Unknown	0 (0.0)	3 (25.0)	3 (13.6)
Family history of prothrombotic disorders			
N	10 (100.0)	12 (100.0)	22 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	5 (50.0)	5 (41.7)	10 (45.5)
Unknown	5 (50.0)	7 (58.3)	12 (54.5)
Family history of thromboembolism			
N	10 (100.0)	12 (100.0)	22 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	5 (50.0)	5 (41.7)	10 (45.5)
Unknown	5 (50.0)	7 (58.3)	12 (54.5)
Family history of inhibitors			

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 05, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

Haemophilia details - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N	10 (100.0)	12 (100.0)	22 (100.0)
Yes	2 (20.0)	2 (16.7)	4 (18.2)
No	7 (70.0)	4 (33.3)	11 (50.0)
Unknown	1 (10.0)	6 (50.0)	7 (31.8)

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 05, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

14.1.23 Haemophilia details - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N in FAS	6	17	23
N in FAS and ADS	6	17	23
Classification of haemophilia type			
N	6 (100.0)	17 (100.0)	23 (100.0)
Haemophilia A	6 (100.0)	17 (100.0)	23 (100.0)
Inhibitor test result [1]			
N	6 (100.0)	15 (100.0)	21 (100.0)
< 0.6 BU	1 (16.7)	1 (6.7)	2 (9.5)
>= 0.6 and < 5 BU	1 (16.7)	6 (40.0)	7 (33.3)
>= 5 BU	4 (66.7)	9 (60.0)	13 (61.9)
Family history of haemophilia			
N	6 (100.0)	17 (100.0)	23 (100.0)
Yes	2 (33.3)	5 (29.4)	7 (30.4)
No	1 (16.7)	10 (58.8)	11 (47.8)
Unknown	3 (50.0)	2 (11.8)	5 (21.7)
Family history of prothrombotic disorders			
N	6 (100.0)	17 (100.0)	23 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	0 (0.0)	3 (17.6)	3 (13.0)
Unknown	6 (100.0)	14 (82.4)	20 (87.0)
Family history of thromboembolism			
N	6 (100.0)	17 (100.0)	23 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	0 (0.0)	3 (17.6)	3 (13.0)
Unknown	6 (100.0)	14 (82.4)	20 (87.0)
Family history of inhibitors			

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

Haemophilia details - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N	6 (100.0)	17 (100.0)	23 (100.0)
Yes	0 (0.0)	2 (11.8)	2 (8.7)
No	2 (33.3)	13 (76.5)	15 (65.2)
Unknown	4 (66.7)	2 (11.8)	6 (26.1)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

14.1.24 Haemophilia details - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N in FAS	7	11	18
N in FAS and ADS	7	11	18
Classification of haemophilia type			
N	7 (100.0)	11 (100.0)	18 (100.0)
Haemophilia B	7 (100.0)	11 (100.0)	18 (100.0)
Inhibitor test result [1]			
N	7 (100.0)	11 (100.0)	18 (100.0)
< 0.6 BU	2 (28.6)	1 (9.1)	3 (16.7)
>= 0.6 and < 5 BU	2 (28.6)	5 (45.5)	7 (38.9)
>= 5 BU	4 (57.1)	6 (54.5)	10 (55.6)
Family history of haemophilia			
N	7 (100.0)	11 (100.0)	18 (100.0)
Yes	3 (42.9)	5 (45.5)	8 (44.4)
No	4 (57.1)	3 (27.3)	7 (38.9)
Unknown	0 (0.0)	3 (27.3)	3 (16.7)
Family history of prothrombotic disorders			
N	7 (100.0)	11 (100.0)	18 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	3 (42.9)	2 (18.2)	5 (27.8)
Unknown	4 (57.1)	9 (81.8)	13 (72.2)
Family history of thromboembolism			
N	7 (100.0)	11 (100.0)	18 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	3 (42.9)	2 (18.2)	5 (27.8)
Unknown	4 (57.1)	9 (81.8)	13 (72.2)
Family history of inhibitors			

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

Haemophilia details - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N	7 (100.0)	11 (100.0)	18 (100.0)
Yes	1 (14.3)	2 (18.2)	3 (16.7)
No	6 (85.7)	3 (27.3)	9 (50.0)
Unknown	0 (0.0)	6 (54.5)	6 (33.3)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

14.1.25 Haemophilia details - subjects enrolled after the pause - summary - HAwI- OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N in FAS	3	1	4
N in FAS and ADS	3	1	4
Classification of haemophilia type			
N	3 (100.0)	1 (100.0)	4 (100.0)
Haemophilia A	3 (100.0)	1 (100.0)	4 (100.0)
Inhibitor test result [1]			
N	3 (100.0)	1 (100.0)	4 (100.0)
>= 0.6 and < 5 BU	1 (33.3)	1 (100.0)	2 (50.0)
>= 5 BU	2 (66.7)	0	2 (50.0)
Family history of haemophilia			
N	3 (100.0)	1 (100.0)	4 (100.0)
Yes	2 (66.7)	0 (0.0)	2 (50.0)
No	1 (33.3)	1 (100.0)	2 (50.0)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Family history of prothrombotic disorders			
N	3 (100.0)	1 (100.0)	4 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	3 (100.0)	0 (0.0)	3 (75.0)
Unknown	0 (0.0)	1 (100.0)	1 (25.0)
Family history of thromboembolism			
N	3 (100.0)	1 (100.0)	4 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	3 (100.0)	0 (0.0)	3 (75.0)
Unknown	0 (0.0)	1 (100.0)	1 (25.0)
Family history of inhibitors			
N	3 (100.0)	1 (100.0)	4 (100.0)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

Haemophilia details - subjects enrolled after the pause - summary - HAwI- OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Yes	1 (33.3)	0 (0.0)	1 (25.0)
No	2 (66.7)	1 (100.0)	3 (75.0)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

14.1.26 Haemophilia details - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N in FAS	3	4	7
N in FAS and ADS	3	4	7
Classification of haemophilia type			
N	3 (100.0)	4 (100.0)	7 (100.0)
Haemophilia B	3 (100.0)	4 (100.0)	7 (100.0)
Inhibitor test result [1]			
N	0	3 (100.0)	3 (100.0)
< 0.6 BU	0	1 (33.3)	1 (33.3)
>= 0.6 and < 5 BU	0	1 (33.3)	1 (33.3)
>= 5 BU	0	1 (33.3)	1 (33.3)
Family history of haemophilia			
N	3 (100.0)	4 (100.0)	7 (100.0)
Yes	1 (33.3)	4 (100.0)	5 (71.4)
No	2 (66.7)	0 (0.0)	2 (28.6)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Family history of prothrombotic disorders			
N	3 (100.0)	4 (100.0)	7 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	2 (66.7)	4 (100.0)	6 (85.7)
Unknown	1 (33.3)	0 (0.0)	1 (14.3)
Family history of thromboembolism			
N	3 (100.0)	4 (100.0)	7 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	2 (66.7)	4 (100.0)	6 (85.7)
Unknown	1 (33.3)	0 (0.0)	1 (14.3)
Family history of inhibitors			

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

Haemophilia details - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
N	3 (100.0)	4 (100.0)	7 (100.0)
Yes	1 (33.3)	1 (25.0)	2 (28.6)
No	1 (33.3)	2 (50.0)	3 (42.9)
Unknown	1 (33.3)	1 (25.0)	2 (28.6)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, 04, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
[1] Subjects can have more than one inhibitor test result, therefore percentage do not add upto 100%.

14.1.27 Haemophilia treatment and bleed history - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS	9	18	27
N in FAS and ADS	9	17	26
Type of previous treatment, N (%)			
N	8 (100.0)	17 (100.0)	25 (100.0)
On demand	8 (100.0)	16 (94.1)	24 (96.0)
Prophylaxis	1 (12.5)	2 (11.8)	3 (12.0)
Time on prophylaxis, (months)			
N	1	2	3
Median	7.7	12.3	12.0
P25 ; P75	7.7 ; 7.7	12.0 ; 12.5	7.7 ; 12.5
Mean (SD)	7.7	12.3 (0.3)	10.7 (2.6)
Min ; Max	7.7 ; 7.7	12.0 ; 12.5	7.7 ; 12.5
Time on on demand, (months)			
N	3	14	17
Median	19.8	10.7	11.6
P25 ; P75	11.7 ; 24.1	7.9 ; 12.0	9.0 ; 12.0
Mean (SD)	18.5 (6.3)	10.2 (5.3)	11.7 (6.2)
Min ; Max	11.7 ; 24.1	1.4 ; 24.0	1.4 ; 24.1
Number of bleeding episodes during the prophylaxis treatment period			
N	1	2	3
Median	56.0	27.5	32.0
P25 ; P75	56.0 ; 56.0	23.0 ; 32.0	23.0 ; 56.0
Mean (SD)	56.0	27.5 (6.4)	37.0 (17.1)
Min ; Max	56 ; 56	23 ; 32	23 ; 56
ABR during the prophylaxis treatment period			
N	1	2	3
Median	87.4	26.9	30.8
P25 ; P75	87.4 ; 87.4	23.0 ; 30.8	23.0 ; 87.4
Mean (SD)	87.4	26.9 (5.5)	47.0 (35.2)

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate

Haemophilia treatment and bleed history - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Min ; Max	87.4 ; 87.4	23.0 ; 30.8	23.0 ; 87.4
Number of spontaneous bleeding episodes during the prophylaxis treatment period			
N	1	2	3
Median	56.0	10.5	12.0
P25 ; P75	56.0 ; 56.0	9.0 ; 12.0	9.0 ; 56.0
Mean (SD)	56.0	10.5 (2.1)	25.7 (26.3)
Min ; Max	56 ; 56	9 ; 12	9 ; 56
Type of factor product during the prophylaxis treatment period, N (%)			
N	1 (100.0)	2 (100.0)	3 (100.0)
BAY 1093884	1 (100.0)	0	1 (33.3)
FEIBA	0	2 (100.0)	2 (66.7)
Approximate number of doses to treat a bleed, during the prophylaxis treatment period			
N	1	2	3
Median	1.0	1.5	1.0
P25 ; P75	1.0 ; 1.0	0.0 ; 3.0	0.0 ; 3.0
Mean (SD)	1.0	1.5 (2.1)	1.3 (1.5)
Min ; Max	1 ; 1	0 ; 3	0 ; 3
Number of bleeding episodes during the on demand treatment period			
N	8	16	24
Median	16.5	18.5	18.5
P25 ; P75	12.5 ; 37.0	10.0 ; 30.0	12.0 ; 34.5
Mean (SD)	29.8 (28.9)	32.3 (44.4)	31.5 (39.3)
Min ; Max	10 ; 96	6 ; 180	6 ; 180
ABR during the on demand treatment period			
N	3	14	17
Median	10.0	25.6	24.4
P25 ; P75	7.9 ; 38.1	13.5 ; 36.9	10.0 ; 36.9
Mean (SD)	18.6 (16.9)	32.2 (30.2)	29.8 (28.4)
Min ; Max	7.9 ; 38.1	8.0 ; 123.7	7.9 ; 123.7

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate

Haemophilia treatment and bleed history - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Number of spontaneous bleeding episodes during the on demand treatment period			
N	8	15	23
Median	12.5	12.0	12.0
P25 ; P75	9.5 ; 22.5	7.0 ; 28.0	8.0 ; 27.0
Mean (SD)	23.4 (30.2)	29.3 (47.3)	27.3 (41.5)
Min ; Max	2 ; 96	0 ; 180	0 ; 180
Type of factor product during the on demand treatment period, N (%)			
N	8 (100.0)	16 (100.0)	24 (100.0)
BIOSTATE	0	1 (6.3)	1 (4.2)
COAGIL-VII	1 (12.5)	0	1 (4.2)
COAGIL-VII FVII PREPARATION	1 (12.5)	0	1 (4.2)
FEEBA	0	1 (6.3)	1 (4.2)
FEIBA	4 (50.0)	7 (43.8)	11 (45.8)
FEIBA (APCC)	0	1 (6.3)	1 (4.2)
FIEBA	0	2 (12.5)	2 (8.3)
HAEMOSOLVATE	0	1 (6.3)	1 (4.2)
INJ.NOVOSEVEN OR INJ. FEIBA	0	1 (6.3)	1 (4.2)
NOVO NORDISK FVII PREPARATION	1 (12.5)	0	1 (4.2)
NOVO SEVEN	0	2 (12.5)	2 (8.3)
NOVOSENEN	1 (12.5)	0	1 (4.2)
NOVOSEVEN	4 (50.0)	7 (43.8)	11 (45.8)
NOVOSEVEN FVII PREPARATION	0	1 (6.3)	1 (4.2)
Approximate number of doses to treat a bleed, during the on demand treatment period			
N	8	16	24
Median	3.0	2.0	2.5
P25 ; P75	1.5 ; 4.5	1.0 ; 3.5	1.0 ; 4.0
Mean (SD)	4.4 (4.9)	7.4 (12.5)	6.4 (10.6)
Min ; Max	1 ; 16	1 ; 40	1 ; 40

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate

14.1.28 Haemophilia treatment and bleed history - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS	10	15	25
N in FAS and ADS	10	12	22
Type of previous treatment, N (%)			
N	9 (100.0)	11 (100.0)	20 (100.0)
On demand	9 (100.0)	11 (100.0)	20 (100.0)
Prophylaxis	0	1 (9.1)	1 (5.0)
Time on prophylaxis, (months)			
N	0	1	1
Median		2.3	2.3
P25 ; P75		2.3 ; 2.3	2.3 ; 2.3
Mean (SD)		2.3	2.3
Min ; Max		2.3 ; 2.3	2.3 ; 2.3
Time on on demand, (months)			
N	5	8	13
Median	12.0	31.7	18.7
P25 ; P75	8.2 ; 27.6	12.0 ; 83.6	12.0 ; 56.8
Mean (SD)	22.0 (32.1)	48.4 (47.5)	38.2 (42.9)
Min ; Max	-11.7 ; 73.7	4.5 ; 128.3	-11.7 ; 128.3
Number of bleeding episodes during the prophylaxis treatment period			
N	0	1	1
Median		5.0	5.0
P25 ; P75		5.0 ; 5.0	5.0 ; 5.0
Mean (SD)		5.0	5.0
Min ; Max		5 ; 5	5 ; 5
ABR during the prophylaxis treatment period			
N	0	1	1
Median		26.1	26.1
P25 ; P75		26.1 ; 26.1	26.1 ; 26.1

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.
The negative duration of on-demand treatment is caused by a reporting of the end date prior to the start date.

Haemophilia treatment and bleed history - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Mean (SD)		26.1	26.1
Min ; Max		26.1 ; 26.1	26.1 ; 26.1
Number of spontaneous bleeding episodes during the prophylaxis treatment period			
N	0	1	1
Median		2.0	2.0
P25 ; P75		2.0 ; 2.0	2.0 ; 2.0
Mean (SD)		2.0	2.0
Min ; Max		2 ; 2	2 ; 2
Type of factor product during the prophylaxis treatment period, N (%)			
N	0	1 (100.0)	1 (100.0)
FEIBA	0	1 (100.0)	1 (100.0)
Approximate number of doses to treat a bleed, during the prophylaxis treatment period			
N	0	1	1
Median		1.0	1.0
P25 ; P75		1.0 ; 1.0	1.0 ; 1.0
Mean (SD)		1.0	1.0
Min ; Max		1 ; 1	1 ; 1
Number of bleeding episodes during the on demand treatment period			
N	9	11	20
Median	12.0	10.0	10.5
P25 ; P75	10.0 ; 21.0	3.0 ; 27.0	6.5 ; 21.0
Mean (SD)	13.6 (7.1)	13.6 (11.8)	13.6 (9.7)
Min ; Max	5 ; 25	1 ; 36	1 ; 36
ABR during the on demand treatment period			
N	5	8	13
Median	10.9	7.4	9.7
P25 ; P75	2.0 ; 17.6	1.0 ; 14.8	1.4 ; 17.6
Mean (SD)	8.2 (12.6)	9.2 (9.5)	8.8 (10.3)
Min ; Max	-10.3 ; 21.0	0.3 ; 27.0	-10.3 ; 27.0

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.
The negative duration of on-demand treatment is caused by a reporting of the end date prior to the start date.

Haemophilia treatment and bleed history - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Number of spontaneous bleeding episodes during the on demand treatment period			
N	9	11	20
Median	12.0	7.0	8.0
P25 ; P75	7.0 ; 15.0	1.0 ; 11.0	5.5 ; 13.5
Mean (SD)	11.3 (5.2)	8.5 (7.9)	9.8 (6.8)
Min ; Max	5 ; 19	0 ; 27	0 ; 27
Type of factor product during the on demand treatment period, N (%)			
N	9 (100.0)	11 (100.0)	20 (100.0)
BYCLOT	0	1 (9.1)	1 (5.0)
COAGIL-VII (EPTACOG ALFA)	1 (11.1)	0	1 (5.0)
FEIBA	2 (22.2)	1 (9.1)	3 (15.0)
FEIBA NF INTRAVENOUS	1 (11.1)	0	1 (5.0)
NOVO SEVEN	1 (11.1)	2 (18.2)	3 (15.0)
NOVO SEVEN HI SYRINGE,	1 (11.1)	0	1 (5.0)
NOVOSEVEN	4 (44.4)	8 (72.7)	12 (60.0)
Approximate number of doses to treat a bleed, during the on demand treatment period			
N	9	11	20
Median	5.0	2.0	3.0
P25 ; P75	3.0 ; 7.0	1.0 ; 3.0	2.0 ; 5.0
Mean (SD)	6.4 (5.7)	2.5 (1.4)	4.3 (4.4)
Min ; Max	1 ; 20	1 ; 6	1 ; 20

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.
The negative duration of on-demand treatment is caused by a reporting of the end date prior to the start date.

14.1.29 Haemophilia treatment and bleed history - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS	6	17	23
N in FAS and ADS	6	17	23
Type of previous treatment, N (%)			
N	5 (100.0)	17 (100.0)	22 (100.0)
On demand	5 (100.0)	16 (94.1)	21 (95.5)
Prophylaxis	1 (20.0)	2 (11.8)	3 (13.6)
Time on prophylaxis, (months)			
N	1	2	3
Median	7.7	12.3	12.0
P25 ; P75	7.7 ; 7.7	12.0 ; 12.5	7.7 ; 12.5
Mean (SD)	7.7	12.3 (0.3)	10.7 (2.6)
Min ; Max	7.7 ; 7.7	12.0 ; 12.5	7.7 ; 12.5
Time on on demand, (months)			
N	1	14	15
Median	11.7	10.0	10.7
P25 ; P75	11.7 ; 11.7	7.5 ; 12.0	7.5 ; 12.0
Mean (SD)	11.7	9.5 (5.7)	9.6 (5.5)
Min ; Max	11.7 ; 11.7	1.4 ; 24.0	1.4 ; 24.0
Number of bleeding episodes during the prophylaxis treatment period			
N	1	2	3
Median	56.0	27.5	32.0
P25 ; P75	56.0 ; 56.0	23.0 ; 32.0	23.0 ; 56.0
Mean (SD)	56.0	27.5 (6.4)	37.0 (17.1)
Min ; Max	56 ; 56	23 ; 32	23 ; 56
ABR during the prophylaxis treatment period			
N	1	2	3
Median	87.4	26.9	30.8
P25 ; P75	87.4 ; 87.4	23.0 ; 30.8	23.0 ; 87.4
Mean (SD)	87.4	26.9 (5.5)	47.0 (35.2)

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

Haemophilia treatment and bleed history - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Min ; Max	87.4 ; 87.4	23.0 ; 30.8	23.0 ; 87.4
Number of spontaneous bleeding episodes during the prophylaxis treatment period			
N	1	2	3
Median	56.0	10.5	12.0
P25 ; P75	56.0 ; 56.0	9.0 ; 12.0	9.0 ; 56.0
Mean (SD)	56.0	10.5 (2.1)	25.7 (26.3)
Min ; Max	56 ; 56	9 ; 12	9 ; 56
Type of factor product during the prophylaxis treatment period, N (%)			
N	1 (100.0)	2 (100.0)	3 (100.0)
BAY 1093884	1 (100.0)	0	1 (33.3)
FEIBA	0	2 (100.0)	2 (66.7)
Approximate number of doses to treat a bleed, during the prophylaxis treatment period			
N	1	2	3
Median	1.0	1.5	1.0
P25 ; P75	1.0 ; 1.0	0.0 ; 3.0	0.0 ; 3.0
Mean (SD)	1.0	1.5 (2.1)	1.3 (1.5)
Min ; Max	1 ; 1	0 ; 3	0 ; 3
Number of bleeding episodes during the on demand treatment period			
N	5	16	21
Median	13.0	20.0	19.0
P25 ; P75	12.0 ; 37.0	10.0 ; 30.0	12.0 ; 32.0
Mean (SD)	33.6 (36.6)	32.8 (44.2)	33.0 (41.7)
Min ; Max	10 ; 96	6 ; 180	6 ; 180
ABR during the on demand treatment period			
N	1	14	15
Median	38.1	27.9	28.9
P25 ; P75	38.1 ; 38.1	13.5 ; 45.4	13.5 ; 45.4
Mean (SD)	38.1	39.6 (37.4)	39.5 (36.0)
Min ; Max	38.1 ; 38.1	8.0 ; 123.7	8.0 ; 123.7

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

Haemophilia treatment and bleed history - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Number of spontaneous bleeding episodes during the on demand treatment period			
N	5	16	21
Median	10.0	13.5	12.0
P25 ; P75	9.0 ; 12.0	7.5 ; 25.0	8.0 ; 22.0
Mean (SD)	25.8 (39.4)	28.8 (45.8)	28.1 (43.4)
Min ; Max	2 ; 96	0 ; 180	0 ; 180
Type of factor product during the on demand treatment period, N (%)			
N	5 (100.0)	16 (100.0)	21 (100.0)
BIOSTATE	0	1 (6.3)	1 (4.8)
COAGIL-VII	1 (20.0)	0	1 (4.8)
COAGIL-VII FVII PREPARATION	1 (20.0)	0	1 (4.8)
FEEBA	0	1 (6.3)	1 (4.8)
FEIBA	2 (40.0)	8 (50.0)	10 (47.6)
FEIBA (APCC)	0	1 (6.3)	1 (4.8)
FIEBA	0	2 (12.5)	2 (9.5)
INJ.NOVOSEVEN OR INJ. FEIBA	0	1 (6.3)	1 (4.8)
NOVO NORDISK FVII PREPARATION	1 (20.0)	0	1 (4.8)
NOVO SEVEN	0	2 (12.5)	2 (9.5)
NOVOSENEN	1 (20.0)	0	1 (4.8)
NOVOSEVEN	1 (20.0)	8 (50.0)	9 (42.9)
NOVOSEVEN FVII PREPARATION	0	1 (6.3)	1 (4.8)
Approximate number of doses to treat a bleed, during the on demand treatment period			
N	5	16	21
Median	3.0	2.0	2.0
P25 ; P75	2.0 ; 5.0	1.0 ; 11.0	1.0 ; 5.0
Mean (SD)	5.4 (6.1)	8.4 (12.7)	7.7 (11.4)
Min ; Max	1 ; 16	1 ; 40	1 ; 40

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

14.1.30 Haemophilia treatment and bleed history - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS	7	11	18
N in FAS and ADS	7	11	18
Type of previous treatment, N (%)			
N	6 (100.0)	11 (100.0)	17 (100.0)
On demand	6 (100.0)	11 (100.0)	17 (100.0)
Prophylaxis	0	2 (18.2)	2 (11.8)
Time on prophylaxis, (months)			
N	0	2	2
Median		5.4	5.4
P25 ; P75		2.3 ; 8.5	2.3 ; 8.5
Mean (SD)		5.4 (4.4)	5.4 (4.4)
Min ; Max		2.3 ; 8.5	2.3 ; 8.5
Time on on demand, (months)			
N	3	9	12
Median	12.0	12.0	12.0
P25 ; P75	-11.7 ; 27.6	10.5 ; 18.7	8.5 ; 23.1
Mean (SD)	9.3 (19.8)	25.7 (33.9)	21.6 (31.0)
Min ; Max	-11.7 ; 27.6	4.5 ; 110.4	-11.7 ; 110.4
Number of bleeding episodes during the prophylaxis treatment period			
N	0	2	2
Median		2.5	2.5
P25 ; P75		0.0 ; 5.0	0.0 ; 5.0
Mean (SD)		2.5 (3.5)	2.5 (3.5)
Min ; Max		0 ; 5	0 ; 5
ABR during the prophylaxis treatment period			
N	0	2	2
Median		13.0	13.0
P25 ; P75		0.0 ; 26.1	0.0 ; 26.1
Mean (SD)		13.0 (18.4)	13.0 (18.4)

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

Haemophilia treatment and bleed history - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Min ; Max		0.0 ; 26.1	0.0 ; 26.1
Number of spontaneous bleeding episodes during the prophylaxis treatment period			
N	0	2	2
Median		2.0	2.0
P25 ; P75		2.0 ; 2.0	2.0 ; 2.0
Mean (SD)		2.0 (0.0)	2.0 (0.0)
Min ; Max		2 ; 2	2 ; 2
Type of factor product during the prophylaxis treatment period, N (%)			
N	0	2 (100.0)	2 (100.0)
ALPROLIX	0	1 (50.0)	1 (50.0)
FEIBA	0	2 (100.0)	2 (100.0)
NANOFIX	0	1 (50.0)	1 (50.0)
Approximate number of doses to treat a bleed, during the prophylaxis treatment period			
N	0	1	1
Median		1.0	1.0
P25 ; P75		1.0 ; 1.0	1.0 ; 1.0
Mean (SD)		1.0	1.0
Min ; Max		1 ; 1	1 ; 1
Number of bleeding episodes during the on demand treatment period			
N	6	11	17
Median	15.5	10.0	10.0
P25 ; P75	10.0 ; 21.0	7.0 ; 27.0	8.0 ; 21.0
Mean (SD)	15.5 (7.8)	14.3 (11.4)	14.7 (10.0)
Min ; Max	6 ; 25	1 ; 36	1 ; 36
ABR during the on demand treatment period			
N	3	9	12
Median	10.9	9.7	10.3
P25 ; P75	-10.3 ; 21.0	5.1 ; 18.5	3.1 ; 19.7
Mean (SD)	7.2 (15.9)	12.4 (10.6)	11.1 (11.6)
Min ; Max	-10.3 ; 21.0	0.3 ; 29.8	-10.3 ; 29.8

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

Haemophilia treatment and bleed history - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Number of spontaneous bleeding episodes during the on demand treatment period			
N	6	11	17
Median	13.5	9.0	10.0
P25 ; P75	7.0 ; 18.0	7.0 ; 16.0	7.0 ; 16.0
Mean (SD)	12.8 (5.5)	11.0 (6.9)	11.6 (6.3)
Min ; Max	6 ; 19	1 ; 27	1 ; 27
Type of factor product during the on demand treatment period, N (%)			
N	6 (100.0)	11 (100.0)	17 (100.0)
BYCLOT	0	1 (9.1)	1 (5.9)
COAGIL-VII (EPTACOG ALFA)	1 (16.7)	0	1 (5.9)
FEIBA	1 (16.7)	1 (9.1)	2 (11.8)
FEIBA NF INTRAVENOUS	1 (16.7)	0	1 (5.9)
NOVO SEVEN	1 (16.7)	3 (27.3)	4 (23.5)
NOVO SEVEN HI SYRINGE,	1 (16.7)	0	1 (5.9)
NOVOSEVEN	2 (33.3)	7 (63.6)	9 (52.9)
Approximate number of doses to treat a bleed, during the on demand treatment period			
N	6	11	17
Median	6.0	2.0	3.0
P25 ; P75	4.0 ; 10.0	2.0 ; 3.0	2.0 ; 6.0
Mean (SD)	8.2 (6.3)	4.4 (6.3)	5.7 (6.4)
Min ; Max	3 ; 20	1 ; 23	1 ; 23

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

14.1.31 Haemophilia treatment and bleed history - subjects enrolled after the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS	3	1	4
N in FAS and ADS	3	1	4
Type of previous treatment, N (%)			
N	3 (100.0)	1 (100.0)	4 (100.0)
On demand	3 (100.0)	1 (100.0)	4 (100.0)
Time on on demand, (months)			
N	2	1	3
Median	22.0	12.0	19.8
P25 ; P75	19.8 ; 24.1	12.0 ; 12.0	12.0 ; 24.1
Mean (SD)	22.0 (3.0)	12.0	18.7 (6.1)
Min ; Max	19.8 ; 24.1	12.0 ; 12.0	12.0 ; 24.1
Number of bleeding episodes during the on demand treatment period			
N	3	1	4
Median	20.0	14.0	17.0
P25 ; P75	13.0 ; 37.0	14.0 ; 14.0	13.5 ; 28.5
Mean (SD)	23.3 (12.3)	14.0	21.0 (11.1)
Min ; Max	13 ; 37	14 ; 14	13 ; 37
ABR during the on demand treatment period			
N	2	1	3
Median	8.9	14.0	10.0
P25 ; P75	7.9 ; 10.0	14.0 ; 14.0	7.9 ; 14.0
Mean (SD)	8.9 (1.5)	14.0	10.6 (3.1)
Min ; Max	7.9 ; 10.0	14.0 ; 14.0	7.9 ; 14.0
Number of spontaneous bleeding episodes during the on demand treatment period			
N	3	0	3
Median	18.0		18.0
P25 ; P75	13.0 ; 27.0		13.0 ; 27.0
Mean (SD)	19.3 (7.1)		19.3 (7.1)
Min ; Max	13 ; 27		13 ; 27

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

Haemophilia treatment and bleed history - subjects enrolled after the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Type of factor product during the on demand treatment period, N (%)			
N	3 (100.0)	1 (100.0)	4 (100.0)
FEIBA	2 (66.7)	0	2 (50.0)
HAEMOSOLVATE	0	1 (100.0)	1 (25.0)
NOVOSEVEN	3 (100.0)	0	3 (75.0)
Approximate number of doses to treat a bleed, during the on demand treatment period			
N	3	1	4
Median	3.0	3.0	3.0
P25 ; P75	1.0 ; 4.0	3.0 ; 3.0	2.0 ; 3.5
Mean (SD)	2.7 (1.5)	3.0	2.8 (1.3)
Min ; Max	1 ; 4	3 ; 3	1 ; 4

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

14.1.32 Haemophilia treatment and bleed history - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N in FAS	3	4	7
N in FAS and ADS	3	4	7
Type of previous treatment, N (%)			
N	3 (100.0)	3 (100.0)	6 (100.0)
On demand	3 (100.0)	3 (100.0)	6 (100.0)
Time on on demand, (months)			
N	2	2	4
Median	40.9	92.6	65.2
P25 ; P75	8.2 ; 73.7	56.8 ; 128.3	32.5 ; 101.0
Mean (SD)	40.9 (46.3)	92.6 (50.6)	66.7 (49.6)
Min ; Max	8.2 ; 73.7	56.8 ; 128.3	8.2 ; 128.3
Number of bleeding episodes during the on demand treatment period			
N	3	3	6
Median	12.0	3.0	8.5
P25 ; P75	5.0 ; 12.0	1.0 ; 15.0	3.0 ; 12.0
Mean (SD)	9.7 (4.0)	6.3 (7.6)	8.0 (5.7)
Min ; Max	5 ; 12	1 ; 15	1 ; 15
ABR during the on demand treatment period			
N	2	2	4
Median	9.8	1.0	1.7
P25 ; P75	2.0 ; 17.6	0.6 ; 1.4	1.0 ; 9.8
Mean (SD)	9.8 (11.1)	1.0 (0.5)	5.4 (8.2)
Min ; Max	2.0 ; 17.6	0.6 ; 1.4	0.6 ; 17.6
Number of spontaneous bleeding episodes during the on demand treatment period			
N	3	3	6
Median	8.0	1.0	5.0
P25 ; P75	5.0 ; 12.0	0.0 ; 5.0	1.0 ; 8.0
Mean (SD)	8.3 (3.5)	2.0 (2.6)	5.2 (4.4)
Min ; Max	5 ; 12	0 ; 5	0 ; 12

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

Haemophilia treatment and bleed history - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Type of factor product during the on demand treatment period, N (%)			
N	3 (100.0)	3 (100.0)	6 (100.0)
FEIBA	1 (33.3)	0	1 (16.7)
NOVOSEVEN	2 (66.7)	3 (100.0)	5 (83.3)
Approximate number of doses to treat a bleed, during the on demand treatment period			
N	3	3	6
Median	3.0	3.0	3.0
P25 ; P75	1.0 ; 5.0	1.0 ; 3.0	1.0 ; 3.0
Mean (SD)	3.0 (2.0)	2.3 (1.2)	2.7 (1.5)
Min ; Max	1 ; 5	1 ; 3	1 ; 5

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum, ABR: annualised bleeding rate.

14.1.33 Target joints at baseline - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
N in FAS	9		18		27	
N in FAS and ADS	9		17		26	
Number of subjects having at least one target joint, N (%)	3 (33.3)		6 (35.3)		9 (34.6)	
Target joint location, N (%) E						
Ankle	0		2 (11.8)	2	2 (7.7)	2
Elbow	2 (22.2)	2	2 (11.8)	3	4 (15.4)	5
Hip	1 (11.1)	1	0		1 (3.8)	1
Knee	3 (33.3)	3	4 (23.5)	4	7 (26.9)	7
Shoulder	1 (11.1)	1	1 (5.9)	1	2 (7.7)	2
Body position of joint, N (%) E						
Left	1 (11.1)	1	4 (23.5)	5	5 (19.2)	6
Right	3 (33.3)	6	4 (23.5)	5	7 (26.9)	11
Number of bleeds in specified joint within 12 months						
e	7		10		17	
Median	8.0		6.0		6.0	
P25 ; P75	4.0 ; 16.0		3.0 ; 7.0		4.0 ; 8.0	
Mean (SD)	10.0 (7.0)		5.6 (2.3)		7.4 (5.2)	
Min ; Max	3.0 ; 22.0		3.0 ; 10.0		3.0 ; 22.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
3	1 (11.1)	1	3 (17.6)	3	4 (15.4)	4
4	1 (11.1)	1	1 (5.9)	1	2 (7.7)	2
5	1 (11.1)	1	0		1 (3.8)	1
6	0		2 (11.8)	2	2 (7.7)	2
7	0		2 (11.8)	3	2 (7.7)	3
8	1 (11.1)	1	0		1 (3.8)	1

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

Target joints at baseline - summary - HAwI - OTexIR - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
10	0		1 (5.9)	1	1 (3.8)	1
12	1 (11.1)	1	0		1 (3.8)	1
16	1 (11.1)	1	0		1 (3.8)	1
22	1 (11.1)	1	0		1 (3.8)	1

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one target joint, thus the percentage do not add up to 100.

14.1.34 Target joints at baseline - summary - HBwI - OTexIR - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
N in FAS	10		15		25	
N in FAS and ADS	10		12		22	
Number of subjects having at least one target joint, N (%)	7 (70.0)		6 (50.0)		13 (59.1)	
Target joint location, N (%) E						
Ankle	0		1 (8.3)	1	1 (4.5)	1
Elbow	2 (20.0)	2	2 (16.7)	3	4 (18.2)	5
Knee	6 (60.0)	7	4 (33.3)	4	10 (45.5)	11
Shoulder	0		1 (8.3)	1	1 (4.5)	1
Body position of joint, N (%) E						
Left	6 (60.0)	6	3 (25.0)	3	9 (40.9)	9
Right	3 (30.0)	3	6 (50.0)	6	9 (40.9)	9
Number of bleeds in specified joint within 12 months						
e	9		9		18	
Median	5.0		5.0		5.0	
P25 ; P75	4.0 ; 6.0		4.0 ; 6.0		4.0 ; 6.0	
Mean (SD)	5.0 (1.5)		5.1 (1.5)		5.1 (1.4)	
Min ; Max	3.0 ; 7.0		3.0 ; 7.0		3.0 ; 7.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
3	1 (10.0)	2	1 (8.3)	1	2 (9.1)	3
4	1 (10.0)	1	3 (25.0)	3	4 (18.2)	4
5	3 (30.0)	3	1 (8.3)	1	4 (18.2)	4
6	1 (10.0)	1	1 (8.3)	2	2 (9.1)	3
7	2 (20.0)	2	2 (16.7)	2	4 (18.2)	4

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

14.1.35 Target joints at baseline - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
N in FAS	6		17		23	
N in FAS and ADS	6		17		23	
Number of subjects having at least one target joint, N (%)	1 (16.7)		11 (64.7)		12 (52.2)	
Target joint location, N (%) E						
Ankle	0		4 (23.5)	4	4 (17.4)	4
Elbow	1 (16.7)	1	7 (41.2)	9	8 (34.8)	10
Knee	1 (16.7)	1	5 (29.4)	6	6 (26.1)	7
Shoulder	1 (16.7)	1	0		1 (4.3)	1
Body position of joint, N (%) E						
Left	1 (16.7)	1	8 (47.1)	10	9 (39.1)	11
Right	1 (16.7)	2	6 (35.3)	9	7 (30.4)	11
Number of bleeds in specified joint within 12 months						
e	3		19		22	
Median	16.0		6.0		7.0	
P25 ; P75	12.0 ; 22.0		4.0 ; 11.0		4.0 ; 12.0	
Mean (SD)	16.7 (5.0)		10.4 (13.2)		11.3 (12.5)	
Min ; Max	12.0 ; 22.0		3.0 ; 60.0		3.0 ; 60.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
3	0		3 (17.6)	3	3 (13.0)	3
4	0		3 (17.6)	3	3 (13.0)	3
5	0		1 (5.9)	1	1 (4.3)	1
6	0		4 (23.5)	4	4 (17.4)	4
8	0		1 (5.9)	1	1 (4.3)	1
9	0		2 (11.8)	2	2 (8.7)	2
11	0		1 (5.9)	1	1 (4.3)	1

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

Target joints at baseline - subjects enrolled before the pause - summary - HAwI - OT - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
12	1 (16.7)	1	1 (5.9)	1	2 (8.7)	2
13	0		1 (5.9)	1	1 (4.3)	1
16	1 (16.7)	1	0		1 (4.3)	1
22	1 (16.7)	1	0		1 (4.3)	1
26	0		1 (5.9)	1	1 (4.3)	1
60	0		1 (5.9)	1	1 (4.3)	1

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

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14.1.36 Target joints at baseline - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
N in FAS	7		11		18	
N in FAS and ADS	7		11		18	
Number of subjects having at least one target joint, N (%)	4 (57.1)		9 (81.8)		13 (72.2)	
Target joint location, N (%) E						
Ankle	0		2 (18.2)	2	2 (11.1)	2
Elbow	2 (28.6)	2	6 (54.5)	8	8 (44.4)	10
Knee	3 (42.9)	4	6 (54.5)	7	9 (50.0)	11
Shoulder	0		1 (9.1)	1	1 (5.6)	1
Body position of joint, N (%) E						
Left	4 (57.1)	4	6 (54.5)	9	10 (55.6)	13
Right	2 (28.6)	2	7 (63.6)	9	9 (50.0)	11
Number of bleeds in specified joint within 12 months						
e	6		18		24	
Median	5.5		5.5		5.5	
P25 ; P75	3.0 ; 7.0		4.0 ; 8.0		4.0 ; 7.0	
Mean (SD)	5.2 (1.8)		6.4 (3.4)		6.1 (3.1)	
Min ; Max	3.0 ; 7.0		3.0 ; 14.0		3.0 ; 14.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
3	1 (14.3)	2	3 (27.3)	3	4 (22.2)	5
4	0		2 (18.2)	3	2 (11.1)	3
5	1 (14.3)	1	3 (27.3)	3	4 (22.2)	4
6	1 (14.3)	1	3 (27.3)	3	4 (22.2)	4
7	2 (28.6)	2	1 (9.1)	1	3 (16.7)	3
8	0		2 (18.2)	2	2 (11.1)	2
10	0		1 (9.1)	1	1 (5.6)	1

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

Target joints at baseline - subjects enrolled before the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)		Total	
14	0	2 (18.2)	2	2 (11.1)	2

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

14.1.37 Target joints at baseline - subjects enrolled after the pause - summary - HAwI- OT - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
N in FAS	3		1		4	
N in FAS and ADS	3		1		4	
Number of subjects having at least one target joint, N (%)	2 (66.7)		0		2 (50.0)	
Target joint location, N (%) E						
Elbow	1 (33.3)	1	0		1 (25.0)	1
Hip	1 (33.3)	1	0		1 (25.0)	1
Knee	2 (66.7)	2	0		2 (50.0)	2
Body position of joint, N (%) E						
Right	2 (66.7)	4	0		2 (50.0)	4
Number of bleeds in specified joint within 12 months						
e	4		0		4	
Median	4.5		0		4.5	
P25 ; P75	3.5 ; 6.5		0		3.5 ; 6.5	
Mean (SD)	5.0 (2.2)		0		5.0 (2.2)	
Min ; Max	3.0 ; 8.0		0		3.0 ; 8.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
3	1 (33.3)	1	0		1 (25.0)	1
4	1 (33.3)	1	0		1 (25.0)	1
5	1 (33.3)	1	0		1 (25.0)	1
8	1 (33.3)	1	0		1 (25.0)	1

HAwI: haemophilia A with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

14.1.38 Target joints at baseline - subjects enrolled after the pause - summary - HBwI - OT - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
N in FAS	3		4		7	
N in FAS and ADS	3		4		7	
Number of subjects having at least one target joint, N (%)	3 (100.0)		2 (50.0)		5 (71.4)	
Target joint location, N (%) E						
Knee	3 (100.0)	3	2 (50.0)	2	5 (71.4)	5
Shoulder	0		1 (25.0)	1	1 (14.3)	1
Body position of joint, N (%) E						
Left	2 (66.7)	2	1 (25.0)	1	3 (42.9)	3
Right	1 (33.3)	1	2 (50.0)	2	3 (42.9)	3
Number of bleeds in specified joint within 12 months						
e	3		3		6	
Median	5.0		4.0		4.5	
P25 ; P75	4.0 ; 5.0		3.0 ; 7.0		4.0 ; 5.0	
Mean (SD)	4.7 (0.6)		4.7 (2.1)		4.7 (1.4)	
Min ; Max	4.0 ; 5.0		3.0 ; 7.0		3.0 ; 7.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
3	0		1 (25.0)	1	1 (14.3)	1
4	1 (33.3)	1	1 (25.0)	1	2 (28.6)	2
5	2 (66.7)	2	0		2 (28.6)	2
7	0		1 (25.0)	1	1 (14.3)	1

HBwI: haemophilia B with inhibitors, OT: On-treatment.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis, E: number of target joints, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum.
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1 Patients can have more than one targ et joint, thus the percentage do not add up to 100.

14.1.39 Target joints at baseline and bleeding in the last 24 weeks before study entry - HAwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Totals N (%)
N in FAS	9	18	27
N in FAS and ADS	9	17	26
Target joints at baseline			
Subjects with zero target joints, N (%)	6 (66.7)	11 (64.7)	17 (65.4)
Subjects with one target joint, N (%)	0 (0.0)	3 (17.6)	3 (11.5)
Subjects with > 1 target joints, N (%)	3 (33.3)	3 (17.6)	6 (23.1)
Bleeding episodes in the last 24 weeks before study entry			
< 9 bleeding episodes, N (%)	3 (33.3)	4 (23.5)	7 (26.9)
>= 9 bleeding episodes, N (%)	6 (66.7)	13 (76.5)	19 (73.1)

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

14.1.40 Target joints at baseline and bleeding in the last 24 weeks before study entry - HBwI - OTexIR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Totals N (%)
N in FAS	10	15	25
N in FAS and ADS	10	12	22
Target joints at baseline			
Subjects with zero target joints, N (%)	3 (30.0)	6 (50.0)	9 (40.9)
Subjects with one target joint, N (%)	5 (50.0)	3 (25.0)	8 (36.4)
Subjects with > 1 target joints, N (%)	2 (20.0)	3 (25.0)	5 (22.7)
Bleeding episodes in the last 24 weeks before study entry			
< 9 bleeding episodes, N (%)	4 (40.0)	5 (41.7)	9 (40.9)
>= 9 bleeding episodes, N (%)	6 (60.0)	7 (58.3)	13 (59.1)

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis
Target joint is defined as having three or more spontaneous bleeds into a single joint within a consecutive 6-month period. Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.

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14.1.41 Haemophilia patient preference questionnaire (H-PPQ) - week 24 - descriptive statistics - HAwI - OTexIR - full analysis set

	No PPX	Concizumab PPX
	Arm 1 N (%)	Arm 2 N (%)
N in FAS	9	18
N in FAS and ADS	9	17
1. Overall, which treatment do you prefer?		
Current treatment	3 (33.3)	12 (70.6)
Previous treatment	0	1 (5.9)
No preference	2 (22.2)	1 (5.9)
Missing	4 (44.4)	3 (17.6)
For subjects preferring current treatment:		
N preferring current treatment	3 (100)	12 (100)
2. How strong is this treatment preference (indicated in question 1)?		
Very strong	1 (33.3)	8 (66.7)
Fairly strong	1 (33.3)	4 (33.3)
Not very strong	1 (33.3)	0
3. What are the TWO main reasons for this treatment preference?		
Easier to remember to inject	1 (33.3)	3 (25.0)
Feels less emotionally distressing	1 (33.3)	5 (41.7)
Less painful to inject	0	5 (41.7)
How often do you have to inject	0	0
Fewer bleeds	0	9 (75.0)
Require less time	1 (33.3)	6 (50.0)
Other reason	1 (33.3)	1 (8.3)
For subjects preferring previous treatment:		
N preferring previous treatment	0	1 (100)

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis
Patients in arm 1 also responded to the questionnaire at week 24 even though they had not received any trial drug at that point in time. These arm 1 data should therefore be interpreted with caution.

Haemophilia patient preference questionnaire (H-PPQ) - week 24 - descriptive statistics - HAwI - OTexIR - full analysis set

	No PPX	Concizumab PPX
	Arm 1 N (%)	Arm 2 N (%)
2. How strong is this treatment preference (indicated in question 1)?		
Very strong	0	1 (100)
Fairly strong	0	0
Not very strong	0	0
3. What are the TWO main reasons for this treatment preference?		
Easier to remember to inject	0	0
Feels less emotionally distressing	0	1 (100)
Less painful to inject	0	1 (100)
How often do you have to inject	0	0
Fewer bleeds	0	0
Require less time	0	0
Other reason	0	0

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, FAS: Full analysis set, PPX: Prophylaxis
Patients in arm 1 also responded to the questionnaire at week 24 even though they had not received any trial drug at that point in time. These arm 1 data should therefore be interpreted with caution.

14.1.42 Haemophilia patient preference questionnaire (H-PPQ) - week 24 - descriptive statistics - HBwI - OTexIR - full analysis set

	No PPX	Concizumab PPX
	Arm 1 N (%)	Arm 2 N (%)
N in FAS	10	15
N in FAS and ADS	10	12
1. Overall, which treatment do you prefer?		
Current treatment	2 (20.0)	9 (75.0)
No preference	4 (40.0)	0
Missing	4 (40.0)	3 (25.0)
For subjects preferring current treatment:		
N preferring current treatment	2 (100)	9 (100)
2. How strong is this treatment preference (indicated in question 1)?		
Very strong	1 (50.0)	6 (66.7)
Fairly strong	1 (50.0)	3 (33.3)
3. What are the TWO main reasons for this treatment preference?		
Easier to remember to inject	1 (50.0)	1 (11.1)
Feels less emotionally distressing	1 (50.0)	2 (22.2)
Less painful to inject	1 (50.0)	2 (22.2)
How often do you have to inject	1 (50.0)	0
Fewer bleeds	2 (100)	8 (88.9)
Require less time	1 (50.0)	4 (44.4)
Other reason	1 (50.0)	0
For subjects preferring previous treatment:		
2. How strong is this treatment preference (indicated in question 1)?	0	0

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis
Patients in arm 1 also responded to the questionnaire at week 24 even though they had not received any trial drug at that point in time. These arm 1 data should therefore be interpreted with caution.

Haemophilia patient preference questionnaire (H-PPQ) - week 24 - descriptive statistics - HBwI - OTexIR - full analysis set

	No PPX	Concizumab PPX
	Arm 1 N (%)	Arm 2 N (%)
Very strong	0	0
Fairly strong	0	0
3. What are the TWO main reasons for this treatment preference?		
	0	0
Easier to remember to inject	0	0
Feels less emotionally distressing	0	0
Less painful to inject	0	0
How often do you have to inject	0	0
Fewer bleeds	0	0
Require less time	0	0
Other reason	0	0

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen, %: percentage of subjects, FAS: Full analysis set, ADS: Analysis data set, PPX: Prophylaxis
Patients in arm 1 also responded to the questionnaire at week 24 even though they had not received any trial drug at that point in time. These arm 1 data should therefore be interpreted with caution.

Table of contents

Page

14.2 Efficacy data

14.2.1 Subject disposition - summary - HAwI - all subjects

	Previous OnD treatment		Concizumab Non-naive	Concizumab Naive	
	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Concizumab PPX (arm 3) N (%)	Concizumab PPX (arm 4) N (%)	Total N (%)
Randomised/allocated	9 (100.0)	18 (100.0)	13 (100.0)	40 (100.0)	80 (100.0)
Exposed		18 (100.0)	13 (100.0)	40 (100.0)	71 (100.0)
Completed treatment at 24/32 weeks [a]	6 (66.7)	17 (94.4)	8 (61.5)	36 (90.0)	67 (83.8)
Discontinued treatment		1 (5.6)	5 (38.5)	4 (10.0)	10 (14.1)
Adverse Event		0	1 (7.7)	0	1 (1.4)
Protocol deviation		0	0	0	0
Lack of efficacy		0	0	0	0
Lost to follow-up		0	0	0	0
Technical problems		0	0	0	0
Discretion of Investigator		0	2 (15.4)	0	2 (2.8)
Other		1 (5.6)	2 (15.4)	4 (10.0)	7 (9.9)
Missing		0	0	0	0
Withdrawn from trial	4 (44.4)	1 (5.6)	5 (38.5)	4 (10.0)	14 (17.5)
Withdrawal of consent [b]	3 (33.3)	1 (5.6)	3 (23.1)	4 (10.0)	11 (13.8)
Lost to follow-up	0	0	0	0	0
Investigator decision	0	0	2 (15.4)	0	2 (2.5)
Death	1 (11.1)	0	0	0	1 (1.3)
Missing	0	0	0	0	0
Full analysis set	9 (100.0)	18 (100.0)	13 (100.0)	40 (100.0)	80 (100.0)
Safety analysis set	9 (100.0)	18 (100.0)	13 (100.0)	40 (100.0)	80 (100.0)

HAwI: haemophilia A with inhibitors.
N: number of subjects, %: Percentage of randomised/allocated subjects, PPX: Prophylaxis, OnD: on-demand.
[a]: Randomised/allocated subjects who did not discontinue treatment prior to week 24/32 (depending on arm).
[b]: withdrawal of consent by subject, subject’s parent or subject’s legally acceptable representative (LAR).
Subjects in arm 4 were previously on prophylaxis with by-passing agents or treated on-demand.

14.2.2 Subject disposition - summary - HBwI - all subjects

	Previous OnD treatment		Concizumab Non-naive	Concizumab Naive	
	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Concizumab PPX (arm 3) N (%)	Concizumab PPX (arm 4) N (%)	Total N (%)
Randomised/allocated	10 (100.0)	15 (100.0)	8 (100.0)	20 (100.0)	53 (100.0)
Exposed		15 (100.0)	8 (100.0)	20 (100.0)	43 (100.0)
Completed treatment at 24/32 weeks [a]	8 (80.0)	11 (73.3)	7 (87.5)	17 (85.0)	43 (81.1)
Discontinued treatment		5 (33.3)	1 (12.5)	3 (15.0)	9 (20.9)
Adverse Event		2 (13.3)	1 (12.5)	1 (5.0)	4 (9.3)
Protocol deviation		0	0	0	0
Lack of efficacy		0	0	0	0
Lost to follow-up		0	0	0	0
Technical problems		0	0	0	0
Discretion of Investigator		1 (6.7)	0	0	1 (2.3)
Other		2 (13.3)	0	2 (10.0)	4 (9.3)
Missing		0	0	0	0
Withdrawn from trial	2 (20.0)	5 (33.3)	1 (12.5)	3 (15.0)	11 (20.8)
Withdrawal of consent [b]	2 (20.0)	1 (6.7)	0	3 (15.0)	6 (11.3)
Lost to follow-up	0	0	0	0	0
Investigator decision	0	1 (6.7)	0	0	1 (1.9)
Death	0	3 (20.0)	1 (12.5)	0	4 (7.5)
Missing	0	0	0	0	0
Full analysis set	10 (100.0)	15 (100.0)	8 (100.0)	20 (100.0)	53 (100.0)
Safety analysis set	10 (100.0)	15 (100.0)	8 (100.0)	20 (100.0)	53 (100.0)

HBwI: haemophilia B with inhibitors.
N: number of subjects, %: Percentage of randomised/allocated subjects, PPX: Prophylaxis, OnD: on-demand.
[a]: Randomised/allocated subjects who did not discontinue treatment prior to week 24/32 (depending on arm).
[b]: withdrawal of consent by subject, subject’s parent or subject’s legally acceptable representative (LAR).
Subjects in arm 4 were previously on prophylaxis with by-passing agents or treated on-demand.

14.2.3 Observation time in weeks - descriptive statistics - HAwI+HBwI - safety analysis set

	Arm 1 - No PPX	Arm 2 - Concizumab PPX
Patient weeks of observation / exposure		
ADS: On-treatment without data on initial regimen (OTexIR)		
For safety endpoints/assessments relating to events [a][b]		
N	19	29
Median	31.1	40.1
P25 ; P75	16.3 ; 44.0	39.9 ; 48.4
Mean (SD)	32.9 (19.9)	42.6 (11.1)
Min ; Max	3.9 ; 72.9	5.7 ; 56.3
For all other endpoint/assessments [c]		
N	19	29
Median	31.1	40.1
P25 ; P75	16.3 ; 44.0	39.9 ; 48.4
Mean (SD)	32.9 (19.9)	42.5 (11.2)
Min ; Max	3.9 ; 72.9	5.7 ; 56.3

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors.
N: number of subjects, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum. ADS: Analysis data set.
Arm 1 represents the patients in arm 1, showing both observation time in main phase (no PPX) and exposure time for those that starts concizumab PPX in the extension phase.
[a]: Covering number of thromboembolic events, number of hypersensitivity type reactions, number of injection site reactions, number of patients with antibodies to concizumab, number of adverse events.
[b]: End of period is defined as the first of 1) death, 2) withdrawal date, 3) last contact for LTFU patients, 4) date of discontinuation of concizumab + 7 weeks , 5) primary analysis cut-off.
[c]: End of period is defined as the first of 1) death, 2) withdrawal date, 3) last contact for LTFU patients, 4) date of discontinuation of concizumab + 1 day, 5) primary analysis cut-off.

14.2.4 Observation time in weeks - descriptive statistics - HAwI - safety analysis set

	Arm 1 - No PPX	Arm 2 - Concizumab PPX
Patient weeks of observation / exposure		
ADS: On-treatment without data on initial regimen (OTexIR)		
For safety endpoints/assessments relating to events [a][b]		
N	9	17
Median	24.0	48.1
P25 ; P75	16.1 ; 38.1	40.1 ; 56.1
Mean (SD)	31.1 (21.8)	47.6 (7.7)
Min ; Max	3.9 ; 72.9	32.1 ; 56.3
For all other endpoint/assessments [c]		
N	9	17
Median	24.0	48.1
P25 ; P75	16.1 ; 38.1	40.1 ; 56.1
Mean (SD)	31.1 (21.8)	47.6 (7.7)
Min ; Max	3.9 ; 72.9	32.1 ; 56.3

HAwI: haemophilia A with inhibitors.
N: number of subjects, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum. ADS: Analysis data set.
Arm 1 represents the patients in arm 1, showing both observation time in main phase (no PPX) and exposure time for those that starts concizumab PPX in the extension phase.
[a]: Covering number of thromboembolic events, number of hypersensitivity type reactions, number of injection site reactions, number of patients with antibodies to concizumab, number of adverse events.
[b]: End of period is defined as the first of 1) death, 2) withdrawal date, 3) last contact for LTFU patients, 4) date of discontinuation of concizumab + 7 weeks , 5) primary analysis cut-off.
[c]: End of period is defined as the first of 1) death, 2) withdrawal date, 3) last contact for LTFU patients, 4) date of discontinuation of concizumab + 1 day, 5) primary analysis cut-off.

14.2.5 Observation time in weeks - descriptive statistics - HBwI - safety analysis set

	Arm 1 - No PPX	Arm 2 - Concizumab PPX
Patient weeks of observation / exposure		
ADS: On-treatment without data on initial regimen (OTexIR)		
For safety endpoints/assessments relating to events [a][b]		
N	10	12
Median	34.3	37.6
P25 ; P75	24.1 ; 44.0	32.0 ; 40.1
Mean (SD)	34.5 (19.1)	35.4 (11.5)
Min ; Max	4.1 ; 72.6	5.7 ; 55.9
For all other endpoint/assessments [c]		
N	10	12
Median	34.3	36.9
P25 ; P75	24.1 ; 44.0	32.0 ; 40.1
Mean (SD)	34.5 (19.1)	35.3 (11.6)
Min ; Max	4.1 ; 72.6	5.7 ; 55.9

HBwI: haemophilia B with inhibitors.
N: number of subjects, SD: standard deviation, P25/P75 is the 25th/75th percentile, Min: minimum, Max: maximum. ADS: Analysis data set.
Arm 1 represents the patients in arm 1, showing both observation time in main phase (no PPX) and exposure time for those that starts concizumab PPX in the extension phase.
[a]: Covering number of thromboembolic events, number of hypersensitivity type reactions, number of injection site reactions, number of patients with antibodies to concizumab, number of adverse events.
[b]: End of period is defined as the first of 1) death, 2) withdrawal date, 3) last contact for LTFU patients, 4) date of discontinuation of concizumab + 7 weeks , 5) primary analysis cut-off.
[c]: End of period is defined as the first of 1) death, 2) withdrawal date, 3) last contact for LTFU patients, 4) date of discontinuation of concizumab + 1 day, 5) primary analysis cut-off.

14.2.6 Concizumab maintenance dose level - summary - HAwI - OTexIR - safety analysis set

	Concizumab PPX			Total
	(arm 2) N (%)	(arm 3) N (%)	(arm 4) N (%)	N (%)
Number of subjects	17	8	37	62
Maintenance dose level				
N	17	8	37	62
0.25 mg/kg	3 (17.6)	1 (12.5)	10 (27.0)	14 (22.6)
0.20 mg/kg	14 (82.4)	7 (87.5)	27 (73.0)	48 (77.4)

HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis.

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14.2.7 Concizumab maintenance dose level - summary - HBwI - OTexIR - safety analysis set

	Concizumab PPX			Total
	(arm 2) N (%)	(arm 3) N (%)	(arm 4) N (%)	N (%)
Number of subjects	12	7	18	37
Maintenance dose level				
N	11	7	17	35
0.15 mg/kg	0	1 (14.3)	0	1 (2.9)
0.25 mg/kg	5 (45.5)	1 (14.3)	4 (23.5)	10 (28.6)
0.20 mg/kg	6 (54.5)	5 (71.4)	13 (76.5)	24 (68.6)

HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
N: number of subjects, %: percentage of subjects, PPX: Prophylaxis.
The following subjects missed the maintenance dose: 721071, 923073.

Table of contents

Page

1: Treated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	18	18	1.58 [0.89 , 2.83]	9	9	18.30 [10.18 , 32.87]	0.09 [0.04 , 0.18]	< 0.0001	
Age									
< 18 years	11	11	1.94 [1.02 , 3.71]	1	1	17.50 [4.13 , 74.12]	0.11 [0.02 , 0.50]	0.0041	0.4335
>= 18 years	7	7	1.01 [0.42 , 2.44]	8	8	17.84 [9.91 , 32.11]	0.06 [0.02 , 0.15]	< 0.0001	
Disease severity									
high titer	5	5	1.81 [0.71 , 4.63]	6	6	25.47 [12.59 , 51.53]	0.07 [0.03 , 0.19]	< 0.0001	0.2757
low titer	12	12	1.80 [0.98 , 3.30]	3	3	9.28 [3.85 , 22.40]	0.19 [0.06 , 0.58]	0.0034	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

2: Treated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	15	15	2.23 [0.76 , 6.52]	10	10	7.24 [2.61 , 20.06]	0.31 [0.07 , 1.36]	0.1200	
Age									
< 18 years	7	7	0.56 [0.09 , 3.51]	5	5	8.81 [2.40 , 32.32]	0.06 [0.01 , 0.65]	0.0203	0.2382
>= 18 years	8	8	5.02 [1.15 , 21.90]	5	5	6.59 [1.79 , 24.28]	0.76 [0.11 , 5.28]	0.7828	
Region									
Non-OECD country	5	5	1.12 [0.15 , 8.31]	5	5	8.10 [1.96 , 33.42]	0.14 [0.01 , 1.71]	0.1228	0.7248
OECD country	10	10	3.16 [0.77 , 12.89]	5	5	6.44 [1.51 , 27.42]	0.49 [0.06 , 3.92]	0.5017	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

3: Treated spontaneous bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	18	18	0.79 [0.39 , 1.59]	9	9	13.67 [7.43 , 25.15]	0.06 [0.03 , 0.13]	< 0.0001	
Age									
< 18 years	11	11	0.83 [0.36 , 1.93]	1	1	16.76 [3.96 , 71.01]	0.05 [0.01 , 0.24]	0.0002	0.9294
>= 18 years	7	7	0.74 [0.27 , 2.01]	8	8	13.20 [7.04 , 24.77]	0.06 [0.02 , 0.16]	< 0.0001	
Disease severity									
high titer	5	5	0.51 [0.13 , 1.89]	6	6	18.28 [9.38 , 35.63]	0.03 [0.01 , 0.11]	< 0.0001	0.1147
low titer	12	12	1.00 [0.50 , 2.01]	3	3	6.51 [2.82 , 15.05]	0.15 [0.05 , 0.46]	0.0007	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

4: Treated spontaneous bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	15	15	2.24 [0.76 , 6.61]	10	10	5.81 [2.05 , 16.49]	0.39 [0.09 , 1.74]	0.2146	
Age									
< 18 years	7	7	0.56 [0.09 , 3.53]	5	5	6.66 [1.81 , 24.53]	0.08 [0.01 , 0.85]	0.0357	0.2378
>= 18 years	8	8	5.09 [1.15 , 22.49]	5	5	5.70 [1.48 , 21.99]	0.89 [0.13 , 6.06]	0.9082	
Region									
Non-OECD country	5	5	1.11 [0.15 , 8.28]	5	5	6.81 [1.64 , 28.34]	0.16 [0.01 , 1.99]	0.1557	0.6959
OECD country	10	10	3.21 [0.78 , 13.15]	5	5	4.85 [1.10 , 21.41]	0.66 [0.08 , 5.26]	0.6955	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

5: Treated spontaneous and traumatic joint bleeds - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	18	18	1.48 [0.75 , 2.92]	9	9	15.78 [7.32 , 34.05]	0.09 [0.04 , 0.23]	< 0.0001	
Age									
< 18 years	11	11	1.86 [0.87 , 3.96]	1	1	13.69 [2.03 , 92.15]	0.14 [0.02 , 0.98]	0.0478	0.4441
>= 18 years	7	7	0.84 [0.29 , 2.45]	8	8	15.24 [7.10 , 32.69]	0.06 [0.02 , 0.18]	< 0.0001	
Disease severity									
high titer	5	5	1.90 [0.64 , 5.59]	6	6	26.25 [11.20 , 61.53]	0.07 [0.02 , 0.23]	< 0.0001	0.0980
low titer	12	12	1.72 [0.88 , 3.38]	3	3	4.29 [1.39 , 13.26]	0.40 [0.10 , 1.55]	0.1859	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

6: Treated spontaneous and traumatic joint bleeds - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	15	15	1.61 [0.54 , 4.82]	10	10	5.28 [2.03 , 13.74]	0.31 [0.07 , 1.30]	0.1088	
Age									
< 18 years	7	7	0.27 [0.03 , 2.45]	5	5	6.39 [2.09 , 19.57]	0.04 [0.00 , 0.51]	0.0126	0.1188
>= 18 years	8	8	3.54 [0.87 , 14.34]	5	5	4.69 [1.41 , 15.57]	0.75 [0.13 , 4.50]	0.7571	
Region									
Non-OECD country	5	5	0.58 [0.06 , 5.99]	5	5	6.51 [1.80 , 23.55]	0.09 [0.01 , 1.32]	0.0783	0.5164
OECD country	10	10	2.44 [0.61 , 9.69]	5	5	4.08 [1.02 , 16.27]	0.60 [0.08 , 4.33]	0.6106	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

7: Treated spontaneous and traumatic target joint bleeds - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	18	18	0.00 [0.00 , Inf]	9	9	0.00 [0.00 , Inf]	0.04 [0.00 , 0.56]	0.0163	
Age									
< 18 years	11	11	0.00 [0.00 , Inf]	1	1	0.00 [0.00 , Inf]	15219080.96 [0.00 , Inf]	0.9976	0.1051
>= 18 years	7	7	0.00 [0.00 , Inf]	8	8	0.00 [0.00 , Inf]	0.00 [0.00 , Inf]	0.9928	
Disease severity									
high titer	5	5	0.00 [0.00 , Inf]	6	6	0.00 [0.00 , Inf]	0.02 [0.00 , 0.67]	0.0281	0.4408
low titer	12	12	0.00 [0.00 , Inf]	3	3	0.00 [0.00 , Inf]	11209383.01 [0.00 , Inf]	0.9973	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

8: Treated spontaneous and traumatic target joint bleeds - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	15	15	0.60 [0.11 , 3.37]	10	10	0.85 [0.17 , 4.27]	0.70 [0.08 , 5.79]	0.7413	
Age									
< 18 years	7	7	0.00 [0.00 , Inf]	5	5	1.06 [0.16 , 7.06]	0.00 [0.00 , Inf]	0.9999	0.1364
>= 18 years	8	8	1.29 [0.17 , 9.72]	5	5	0.91 [0.12 , 7.04]	1.42 [0.12 , 16.86]	0.7820	
Region									
Non-OECD country	5	5	0.00 [0.00 , Inf]	5	5	1.24 [0.16 , 9.43]	0.00 [0.00 , Inf]	0.9999	0.3773
OECD country	10	10	1.02 [0.14 , 7.48]	5	5	0.60 [0.05 , 6.60]	1.69 [0.09 , 30.58]	0.7216	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

9: Treated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	1.62 [0.91 , 2.90]	9	9	18.18 [10.17 , 32.47]	0.09 [0.04 , 0.18]	< 0.0001	
Age									
< 18 years	10	10	2.05 [1.07 , 3.93]	1	1	17.22 [4.13 , 71.67]	0.12 [0.03 , 0.53]	0.0052	0.3633
>= 18 years	7	7	1.00 [0.42 , 2.39]	8	8	17.68 [9.89 , 31.60]	0.06 [0.02 , 0.15]	< 0.0001	
Disease severity									
high titer	5	5	1.81 [0.71 , 4.63]	6	6	25.47 [12.59 , 51.53]	0.07 [0.03 , 0.19]	< 0.0001	0.2757
low titer	12	12	1.80 [0.98 , 3.30]	3	3	9.28 [3.85 , 22.40]	0.19 [0.06 , 0.58]	0.0034	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

10: Treated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	1.38 [0.55 , 3.52]	10	10	7.40 [3.23 , 16.97]	0.19 [0.06 , 0.63]	0.0071	
Age									
< 18 years	6	6	0.56 [0.11 , 3.03]	5	5	8.90 [3.11 , 25.48]	0.06 [0.01 , 0.48]	0.0076	0.4219
>= 18 years	6	6	2.38 [0.73 , 7.77]	5	5	6.78 [2.31 , 19.89]	0.35 [0.07 , 1.67]	0.1885	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

11: Treated spontaneous bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	0.81 [0.40 , 1.62]	9	9	13.61 [7.42 , 24.97]	0.06 [0.03 , 0.13]	< 0.0001	
Age									
< 18 years	10	10	0.87 [0.38 , 2.02]	1	1	16.59 [3.93 , 69.93]	0.05 [0.01 , 0.25]	0.0002	0.9112
>= 18 years	7	7	0.73 [0.27 , 1.99]	8	8	13.13 [7.02 , 24.55]	0.06 [0.02 , 0.16]	< 0.0001	
Disease severity									
high titer	5	5	0.51 [0.13 , 1.89]	6	6	18.28 [9.38 , 35.63]	0.03 [0.01 , 0.11]	< 0.0001	0.1147
low titer	12	12	1.00 [0.50 , 2.01]	3	3	6.51 [2.82 , 15.05]	0.15 [0.05 , 0.46]	0.0007	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

12: Treated spontaneous bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	1.39 [0.54 , 3.56]	10	10	5.93 [2.51 , 13.97]	0.23 [0.07 , 0.81]	0.0222	
Age									
< 18 years	6	6	0.56 [0.10 , 3.06]	5	5	6.70 [2.28 , 19.67]	0.08 [0.01 , 0.65]	0.0174	0.4361
>= 18 years	6	6	2.39 [0.71 , 8.02]	5	5	5.86 [1.89 , 18.15]	0.41 [0.08 , 1.97]	0.2637	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

13: Treated spontaneous and traumatic joint bleeds - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	1.53 [0.77 , 3.01]	9	9	15.62 [7.31 , 33.40]	0.10 [0.04 , 0.24]	< 0.0001	
Age									
< 18 years	10	10	1.97 [0.92 , 4.24]	1	1	13.35 [2.04 , 87.57]	0.15 [0.02 , 1.05]	0.0562	0.3752
>= 18 years	7	7	0.82 [0.29 , 2.38]	8	8	15.02 [7.08 , 31.85]	0.05 [0.02 , 0.18]	< 0.0001	
Disease severity									
high titer	5	5	1.90 [0.64 , 5.59]	6	6	26.25 [11.20 , 61.53]	0.07 [0.02 , 0.23]	< 0.0001	0.0980
low titer	12	12	1.72 [0.88 , 3.38]	3	3	4.29 [1.39 , 13.26]	0.40 [0.10 , 1.55]	0.1859	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

14: Treated spontaneous and traumatic joint bleeds - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	0.92 [0.38 , 2.26]	10	10	5.44 [2.72 , 10.88]	0.17 [0.06 , 0.50]	0.0014	
Age									
< 18 years	6	6	0.27 [0.03 , 2.09]	5	5	6.44 [2.92 , 14.21]	0.04 [0.00 , 0.38]	0.0047	0.2335
>= 18 years	6	6	1.60 [0.59 , 4.36]	5	5	4.94 [2.04 , 11.95]	0.32 [0.09 , 1.15]	0.0806	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

15: Treated spontaneous and traumatic target joint bleeds - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	0.00 [0.00 , Inf]	9	9	0.00 [0.00 , Inf]	0.04 [0.00 , 0.59]	0.0185	
Age									
< 18 years	10	10	0.00 [0.00 , Inf]	1	1	0.00 [0.00 , Inf]	37102024.62 [0.00 , Inf]	0.9983	0.0983
>= 18 years	7	7	0.00 [0.00 , Inf]	8	8	0.00 [0.00 , Inf]	0.00 [0.00 , Inf]	0.9943	
Disease severity									
high titer	5	5	0.00 [0.00 , Inf]	6	6	0.00 [0.00 , Inf]	0.02 [0.00 , 0.67]	0.0281	0.4408
low titer	12	12	0.00 [0.00 , Inf]	3	3	0.00 [0.00 , Inf]	11209383.01 [0.00 , Inf]	0.9973	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

16: Treated spontaneous and traumatic target joint bleeds - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	0.22 [0.05 , 1.03]	10	10	0.95 [0.28 , 3.29]	0.23 [0.05 , 1.11]	0.0671	
Age									
< 18 years	6	6	0.00 [0.00 , Inf]	5	5	0.94 [0.22 , 4.01]	0.00 [0.00 , Inf]	0.9999	0.2954
>= 18 years	6	6	0.38 [0.07 , 1.95]	5	5	1.14 [0.26 , 4.96]	0.33 [0.06 , 1.92]	0.2195	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

17: Treated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	1.62 [0.91 , 2.89]	9	9	18.13 [10.15 , 32.38]	0.09 [0.04 , 0.18]	< 0.0001	
Age									
< 18 years	10	10	2.04 [1.06 , 3.92]	1	1	17.18 [4.12 , 71.58]	0.12 [0.03 , 0.53]	0.0052	0.3631
>= 18 years	7	7	0.99 [0.41 , 2.39]	8	8	17.63 [9.87 , 31.51]	0.06 [0.02 , 0.15]	< 0.0001	
Disease severity									
high titer	5	5	1.81 [0.71 , 4.62]	6	6	25.45 [12.58 , 51.48]	0.07 [0.03 , 0.19]	< 0.0001	0.2730
low titer	12	12	1.80 [0.98 , 3.29]	3	3	9.25 [3.84 , 22.28]	0.19 [0.07 , 0.58]	0.0034	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

18: Treated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	1.37 [0.54 , 3.46]	10	10	7.04 [3.08 , 16.08]	0.19 [0.06 , 0.65]	0.0079	
Age									
< 18 years	6	6	0.57 [0.11 , 3.06]	5	5	8.73 [3.10 , 24.62]	0.07 [0.01 , 0.49]	0.0079	0.4259
>= 18 years	6	6	2.30 [0.71 , 7.43]	5	5	6.19 [2.12 , 18.12]	0.37 [0.08 , 1.73]	0.2068	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

19: Treated spontaneous bleeding episodes - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	0.80 [0.40 , 1.62]	9	9	13.57 [7.40 , 24.88]	0.06 [0.03 , 0.13]	< 0.0001	
Age									
< 18 years	10	10	0.87 [0.37 , 2.02]	1	1	16.55 [3.93 , 69.78]	0.05 [0.01 , 0.25]	0.0002	0.9108
>= 18 years	7	7	0.73 [0.27 , 1.99]	8	8	13.09 [7.01 , 24.47]	0.06 [0.02 , 0.16]	< 0.0001	
Disease severity									
high titer	5	5	0.50 [0.13 , 1.89]	6	6	18.26 [9.37 , 35.58]	0.03 [0.01 , 0.11]	< 0.0001	0.1133
low titer	12	12	1.00 [0.50 , 2.01]	3	3	6.49 [2.81 , 14.97]	0.15 [0.05 , 0.46]	0.0007	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

20: Treated spontaneous bleeding episodes - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	1.38 [0.54 , 3.53]	10	10	5.71 [2.42 , 13.51]	0.24 [0.07 , 0.84]	0.0249	
Age									
< 18 years	6	6	0.57 [0.10 , 3.12]	5	5	6.62 [2.25 , 19.51]	0.09 [0.01 , 0.67]	0.0188	0.4507
>= 18 years	6	6	2.33 [0.69 , 7.85]	5	5	5.47 [1.74 , 17.18]	0.43 [0.09 , 2.05]	0.2871	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

21: Treated spontaneous and traumatic joint bleeds - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	1.52 [0.77 , 3.00]	9	9	15.60 [7.29 , 33.37]	0.10 [0.04 , 0.24]	< 0.0001	
Age									
< 18 years	10	10	1.97 [0.91 , 4.24]	1	1	13.34 [2.03 , 87.61]	0.15 [0.02 , 1.05]	0.0564	0.3752
>= 18 years	7	7	0.82 [0.28 , 2.38]	8	8	15.00 [7.07 , 31.81]	0.05 [0.02 , 0.18]	< 0.0001	
Disease severity									
high titer	5	5	1.89 [0.64 , 5.58]	6	6	26.24 [11.19 , 61.51]	0.07 [0.02 , 0.23]	< 0.0001	0.0974
low titer	12	12	1.72 [0.87 , 3.38]	3	3	4.28 [1.39 , 13.22]	0.40 [0.10 , 1.55]	0.1863	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

22: Treated spontaneous and traumatic joint bleeds - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	0.91 [0.37 , 2.24]	10	10	5.25 [2.61 , 10.58]	0.17 [0.06 , 0.52]	0.0017	
Age									
< 18 years	6	6	0.27 [0.03 , 2.11]	5	5	6.36 [2.85 , 14.19]	0.04 [0.00 , 0.39]	0.0051	0.2387
>= 18 years	6	6	1.55 [0.56 , 4.27]	5	5	4.58 [1.87 , 11.26]	0.34 [0.09 , 1.21]	0.0963	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

23: Treated spontaneous and traumatic target joint bleeds - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	0.00 [0.00 , Inf]	9	9	0.00 [0.00 , Inf]	0.04 [0.00 , 0.59]	0.0185	
Age									
< 18 years	10	10	0.00 [0.00 , Inf]	1	1	0.00 [0.00 , Inf]	37096677.23 [0.00 , Inf]	0.9983	0.0984
>= 18 years	7	7	0.00 [0.00 , Inf]	8	8	0.00 [0.00 , Inf]	0.00 [0.00 , Inf]	0.9943	
Disease severity									
high titer	5	5	0.00 [0.00 , Inf]	6	6	0.00 [0.00 , Inf]	0.02 [0.00 , 0.67]	0.0281	0.4409
low titer	12	12	0.00 [0.00 , Inf]	3	3	0.00 [0.00 , Inf]	11342034.42 [0.00 , Inf]	0.9973	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

24: Treated spontaneous and traumatic target joint bleeds - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	0.21 [0.04 , 1.01]	10	10	0.92 [0.26 , 3.20]	0.23 [0.05 , 1.13]	0.0704	
Age									
< 18 years	6	6	0.00 [0.00 , Inf]	5	5	0.91 [0.21 , 4.04]	0.00 [0.00 , Inf]	0.9999	0.3042
>= 18 years	6	6	0.36 [0.07 , 1.89]	5	5	1.07 [0.25 , 4.65]	0.34 [0.06 , 2.00]	0.2336	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

Table of contents

Page

1: All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	18	18	4.84 [2.81 , 8.33]	9	9	19.99 [9.61 , 41.58]	0.24 [0.11 , 0.56]	0.0008	
Age									
< 18 years	11	11	4.11 [2.14 , 7.88]	1	1	23.09 [3.34 , 159.46]	0.18 [0.02 , 1.33]	0.0928	0.7132
>= 18 years	7	7	6.34 [2.68 , 14.96]	8	8	20.58 [9.54 , 44.37]	0.31 [0.11 , 0.87]	0.0261	
Disease severity									
high titer	5	5	12.13 [4.92 , 29.90]	6	6	33.97 [14.62 , 78.94]	0.36 [0.12 , 1.02]	0.0549	0.0293
low titer	12	12	3.47 [1.96 , 6.17]	3	3	9.39 [3.31 , 26.62]	0.37 [0.11 , 1.22]	0.1019	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

2: All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	15	15	4.56 [2.07 , 10.04]	10	10	8.62 [3.79 , 19.61]	0.53 [0.17 , 1.64]	0.2711	
Age									
< 18 years	7	7	3.02 [0.91 , 10.02]	5	5	10.90 [3.48 , 34.18]	0.28 [0.05 , 1.59]	0.1503	0.6486
>= 18 years	8	8	6.63 [1.93 , 22.70]	5	5	7.26 [2.26 , 23.27]	0.91 [0.18 , 4.75]	0.9135	
Region									
Non-OECD country	5	5	3.26 [0.81 , 13.07]	5	5	11.14 [3.52 , 35.32]	0.29 [0.04 , 1.93]	0.2010	0.7191
OECD country	10	10	5.48 [1.94 , 15.49]	5	5	6.53 [2.01 , 21.21]	0.84 [0.17 , 4.07]	0.8283	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

3: All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	4.93 [2.84 , 8.59]	9	9	19.87 [9.50 , 41.56]	0.25 [0.11 , 0.58]	0.0013	
Age									
< 18 years	10	10	4.24 [2.15 , 8.35]	1	1	22.73 [3.21 , 160.82]	0.19 [0.02 , 1.45]	0.1087	0.7776
>= 18 years	7	7	6.25 [2.62 , 14.93]	8	8	20.42 [9.39 , 44.39]	0.31 [0.11 , 0.87]	0.0270	
Disease severity									
high titer	5	5	12.13 [4.92 , 29.90]	6	6	33.97 [14.62 , 78.94]	0.36 [0.12 , 1.02]	0.0549	0.0293
low titer	12	12	3.47 [1.96 , 6.17]	3	3	9.39 [3.31 , 26.62]	0.37 [0.11 , 1.22]	0.1019	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

4: All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	3.16 [1.61 , 6.19]	10	10	9.41 [4.77 , 18.58]	0.34 [0.13 , 0.86]	0.0231	
Age									
< 18 years	6	6	3.06 [1.09 , 8.53]	5	5	11.30 [4.48 , 28.52]	0.27 [0.06 , 1.15]	0.0769	0.8367
>= 18 years	6	6	3.28 [1.20 , 8.98]	5	5	7.58 [2.88 , 19.92]	0.43 [0.11 , 1.66]	0.2230	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

5: All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	17	17	4.92 [2.83 , 8.57]	9	9	19.83 [9.48 , 41.47]	0.25 [0.11 , 0.58]	0.0013	
Age									
< 18 years	10	10	4.23 [2.15 , 8.34]	1	1	22.70 [3.21 , 160.65]	0.19 [0.02 , 1.45]	0.1088	0.7800
>= 18 years	7	7	6.23 [2.61 , 14.88]	8	8	20.37 [9.37 , 44.29]	0.31 [0.11 , 0.87]	0.0269	
Disease severity									
high titer	5	5	12.09 [4.91 , 29.81]	6	6	33.94 [14.61 , 78.84]	0.36 [0.12 , 1.02]	0.0544	0.0292
low titer	12	12	3.47 [1.95 , 6.16]	3	3	9.35 [3.30 , 26.46]	0.37 [0.11 , 1.22]	0.1027	

ABR: Annualized bleeding rate, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

6: All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	ABR [95% CI]	N	n	ABR [95% CI]	ABR ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	12	3.15 [1.60 , 6.19]	10	10	9.06 [4.56 , 18.00]	0.35 [0.13 , 0.90]	0.0289	
Age									
< 18 years	6	6	3.11 [1.11 , 8.70]	5	5	11.10 [4.41 , 27.95]	0.28 [0.07 , 1.19]	0.0849	0.7899
>= 18 years	6	6	3.20 [1.17 , 8.77]	5	5	7.00 [2.64 , 18.53]	0.46 [0.12 , 1.75]	0.2544	

ABR: Annualized bleeding rate, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with an observation, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). Bleeding endpoints are analysed using a negative binomial regression model with the logarithm of the length of the observation period included (in years) as offset with treatment and bleeding frequency prior to screening as factors. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment.

7: Zero treated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)	
	N	n	Odds [95% CI]	N	n	Odds [95% CI]	Odds ratio [95% CI]	p-value int.
Total								
All subjects	18	8	NA [NA , NA]	9	0	NA [NA , NA]	NA [NA , NA]	NA
Age								
< 18 years	11	4	NA [NA , NA]	1	0	NA [NA , NA]	NA [NA , NA]	NA
>= 18 years	7	4	NA [NA , NA]	8	0	NA [NA , NA]	NA [NA , NA]	
Disease severity								
high titer	5	2	NA [NA , NA]	6	0	NA [NA , NA]	NA [NA , NA]	NA
low titer	12	6	NA [NA , NA]	3	0	NA [NA , NA]	NA [NA , NA]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with zero bleeding episodes, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). The number of subjects with zero bleeding episodes is analysed using a logistic regression model with treatment and bleeding frequency prior to screening as fixed effects. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. In case there are no subjects having zero treated spontaneous or traumatic bleeding episodes in a group the analysis comparing the number of subjects with zero bleeding episodes is not performed (indicated by "NA" in the table).

8: Zero treated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen for subjects exposed to both regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Odds [95% CI]	N	n	Odds [95% CI]	Odds ratio [95% CI]	p-value	p-value int.
Total									
All subjects	15	9	1.69 [0.56 , 5.10]	10	1	0.11 [0.01 , 0.91]	15.13 [1.39 , 165.01]	0.0258	NA
Age									
< 18 years	7	5	NA [NA , NA]	5	1	NA [NA , NA]	NA [NA , NA]		NA
>= 18 years	8	4	NA [NA , NA]	5	0	NA [NA , NA]	NA [NA , NA]		
Region									
Non-OECD country	5	2	NA [NA , NA]	5	0	NA [NA , NA]	NA [NA , NA]		NA
OECD country	10	7	NA [NA , NA]	5	1	NA [NA , NA]	NA [NA , NA]		

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with zero bleeding episodes, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). The number of subjects with zero bleeding episodes is analysed using a logistic regression model with treatment and bleeding frequency prior to screening as fixed effects. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. In case there are no subjects having zero treated spontaneous or traumatic bleeding episodes in a group the analysis comparing the number of subjects with zero bleeding episodes is not performed (indicated by "NA" in the table).

9: Zero treated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)	
	N	n	Odds [95% CI]	N	n	Odds [95% CI]	Odds ratio [95% CI]	p-value int.
Total								
All subjects	17	8	NA [NA , NA]	9	0	NA [NA , NA]	NA [NA , NA]	NA
Age								
< 18 years	10	4	NA [NA , NA]	1	0	NA [NA , NA]	NA [NA , NA]	NA
>= 18 years	7	4	NA [NA , NA]	8	0	NA [NA , NA]	NA [NA , NA]	
Disease severity								
high titer	5	2	NA [NA , NA]	6	0	NA [NA , NA]	NA [NA , NA]	NA
low titer	12	6	NA [NA , NA]	3	0	NA [NA , NA]	NA [NA , NA]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with zero bleeding episodes, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). The number of subjects with zero bleeding episodes is analysed using a logistic regression model with treatment and bleeding frequency prior to screening as fixed effects. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. In case there are no subjects having zero treated spontaneous or traumatic bleeding episodes in a group the analysis comparing the number of subjects with zero bleeding episodes is not performed (indicated by "NA" in the table).

10: Zero treated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without ancillary therapy excl. data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Odds [95% CI]	N	n	Odds [95% CI]	Odds ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	9	3.62 [0.84 , 15.58]	10	1	0.11 [0.01 , 0.91]	33.21 [2.35 , 470.42]	0.0096	NA
Age									
< 18 years	6	5	NA [NA , NA]	5	1	NA [NA , NA]	NA [NA , NA]		NA
>= 18 years	6	4	NA [NA , NA]	5	0	NA [NA , NA]	NA [NA , NA]		

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with zero bleeding episodes, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). The number of subjects with zero bleeding episodes is analysed using a logistic regression model with treatment and bleeding frequency prior to screening as fixed effects. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. In case there are no subjects having zero treated spontaneous or traumatic bleeding episodes in a group the analysis comparing the number of subjects with zero bleeding episodes is not performed (indicated by "NA" in the table).

11: Zero treated spontaneous and traumatic bleeding episodes - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)	
	N	n	Odds [95% CI]	N	n	Odds [95% CI]	Odds ratio [95% CI]	p-value int.
Total								
All subjects	17	8	NA [NA , NA]	9	0	NA [NA , NA]	NA [NA , NA]	NA
Age								
< 18 years	10	4	NA [NA , NA]	1	0	NA [NA , NA]	NA [NA , NA]	NA
>= 18 years	7	4	NA [NA , NA]	8	0	NA [NA , NA]	NA [NA , NA]	
Disease severity								
high titer	5	2	NA [NA , NA]	6	0	NA [NA , NA]	NA [NA , NA]	NA
low titer	12	6	NA [NA , NA]	3	0	NA [NA , NA]	NA [NA , NA]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with zero bleeding episodes, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). The number of subjects with zero bleeding episodes is analysed using a logistic regression model with treatment and bleeding frequency prior to screening as fixed effects. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. In case there are no subjects having zero treated spontaneous or traumatic bleeding episodes in a group the analysis comparing the number of subjects with zero bleeding episodes is not performed (indicated by "NA" in the table).

12: Zero treated spontaneous and traumatic bleeding episodes - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizunab PPX (arm 2)			No PPX (arm 1)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Odds [95% CI]	N	n	Odds [95% CI]	Odds ratio [95% CI]	p-value	p-value int.
Total									
All subjects	12	9	3.62 [0.84 , 15.58]	10	1	0.11 [0.01 , 0.91]	33.21 [2.35 , 470.42]	0.0096	NA
Age									
< 18 years	6	5	NA [NA , NA]	5	1	NA [NA , NA]	NA [NA , NA]		NA
>= 18 years	6	4	NA [NA , NA]	5	0	NA [NA , NA]	NA [NA , NA]		

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects with zero bleeding episodes, SD: Standard deviation, SE: Standard error, CI: confidence interval, p-value: unadjusted two-sided p-value for test of no difference from arm 1 (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test). The number of subjects with zero bleeding episodes is analysed using a logistic regression model with treatment and bleeding frequency prior to screening as fixed effects. For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. In case there are no subjects having zero treated spontaneous or traumatic bleeding episodes in a group the analysis comparing the number of subjects with zero bleeding episodes is not performed (indicated by "NA" in the table).

Table of contents

Page

1: PGI-C on physical functioning responders a week 24 - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)				
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value	p-value int.
All subjects (total)	17	13 (76.5)	9	0 (0.0)	57.00 (2.73, 1188.44)	15.00 (0.99, 226.51)	76.47 (56.31, 96.63)	0.0002*	
Region									NA
Non-OECD country	14	10 (71.4)	4	0 (0.0)	21.00 (0.92, 477.23)	7.00 (0.49, 99.11)	71.43 (47.76, 95.09)	0.0146*	
OECD country	3	3 (100.0)	5	0 (0.0)	77.00 (1.22, 4848.82)	10.50 (0.72, 153.07)	100.00 (100.00, 100.00)	0.0078*	
Disease severity									NA
high titer	5	2 (40.0)	6	0 (0.0)	9.29 (0.34, 252.45)	5.83 (0.34, 99.23)	40.00 (-2.94, 82.94)	0.1143*	
low titer	12	11 (91.7)	3	0 (0.0)	53.67 (1.76, 1635.55)	7.08 (0.53, 95.30)	91.67 (76.03, 107.30)	0.0025*	

PGI-C: Patient Global Impression of Change, responder: Subjects with VERY MUCH BETTER or MODERATELY BETTER at week 24, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with an observed response at week 24, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). Missing values are counted as 'non responder'. P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

2: PGI-C on physical functioning responders a week 24 - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	7 (58.3)	10	1 (10.0)	12.60 (1.19, 133.89)	5.83 (0.86, 39.78)	48.33 (14.81, 81.86)	0.0208*

PGI-C: Patient Global Impression of Change, responder: Subjects with VERY MUCH BETTER or MODERATELY BETTER at week 24, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with an observed response at week 24, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). Missing values are counted as 'non responder'. P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

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3: PGI-S on physical functioning responders a week 24 - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	17	8 (47.1)	9	1 (11.1)	7.11 (0.72, 69.99)	4.24 (0.62, 28.76)	35.95 (4.57, 67.32)	0.0800*

PGI-S: Patient Global Impression of Severity, responder: Subjects who improve at least one level from baseline to week 24, HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with an observed response at week 24, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). Missing values are counted as "non responder". P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

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23JAN2025:14:43:27 - t-safety-baker.R/PGI_S_HAwI_saf_4311.txt

4: PGI-S on physical functioning responders a week 24 - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	4 (33.3)	10	0 (0.0)	11.12 (0.52, 236.75)	7.62 (0.46, 126.40)	33.33 (6.66, 60.01)	0.0546*

PGI-S: Patient Global Impression of Severity, responder: Subjects who improve at least one level from baseline to week 24, HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with an observed response at week 24, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). Missing values are counted as "non responder". P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

5: Change from baseline to week 24 in Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	33.33 (11.79)	17	9	37.04 (19.59)				
Week 24	6	3	13.89 (4.81)	17	7	35.71 (20.81)				
Change from baseline to week 24	6	3	-13.89 (4.81) -16.31 (12.97)	17	7	-2.38 (25.33)	2.82 (7.77)	19.14 [-13.58; 51.85]	0.2285	0.76 [-0.58; 2.10]
Age										
< 18 years										
Baseline				10	2	54.17 (29.46)				
Week 24				10	1	66.67 (NA)				
Change from baseline to week 24				10	1	-8.33 (NA)	53.50 (28.07)	NE [NE; NE]	NE	NE [NE; NE] 0.4221
>= 18 years										
Baseline	8	5	33.33 (11.79)	7	7	32.14 (15.54)				
Week 24	5	3	13.89 (4.81)	7	6	30.56 (17.21)				
Change from baseline to week 24	5	3	-13.89 (4.81) -19.89 (13.10)	7	6	-1.39 (27.60)	-4.07 (8.58)	15.82 [-18.65; 50.29]	0.3264	0.63 [-0.75; 2.01]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	4	37.50 (8.33)		5	3	38.89 (9.62)					
Week 24	4	2	16.67 (0.00)		5	2	29.17 (5.89)					
Change from baseline to week 24	4	2	-16.67 (0.00)	-10.63 (17.49)	5	2	-12.50 (17.68)	-11.67 (16.87)	-1.04 [-62.85; 60.78]	0.9695	-0.03 [-1.82; 1.76]	0.8753
low titer												
Baseline	3	1	16.67 (NA)		12	6	36.11 (23.96)					
Week 24	2	1	8.33 (NA)		12	5	38.33 (24.72)					
Change from baseline to week 24	2	1	-8.33 (NA)	-20.73 (23.99)	12	5	1.67 (28.50)	8.67 (10.65)	29.40 [-32.18; 90.98]	0.2961	0.95 [-1.23; 3.12]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

6: Change from baseline to week 24 in Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	38.89 (29.27)		12	5	21.67 (13.94)				
Week 24	8	1	33.33 (NA)		11	3	16.67 (16.67)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	2.78 (12.73)	1.19 (12.56)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	41.67 (NA)		6	1	33.33 (NA)				
Week 24	5	1	33.33 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	37.50 (41.25)		6	4	18.75 (14.23)				
Week 24					5	3	16.67 (16.67)				
Change from baseline to week 24					5	3	2.78 (12.73)	1.63 (10.85)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

7: Change from baseline to week 24 in Haem-A-QoL feeling domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	58.75 (28.50)	17	9	31.94 (24.30)				
Week 24	6	3	72.92 (28.18)	17	7	25.00 (30.41)				
Change from baseline to week 24	6	3	8.33 (7.22) 7.90 (10.19)	17	7	-11.61 (10.48)	-10.89 (5.96)	-18.79 [-44.94; 7.35]	0.1445	-0.97 [-2.34; 0.39]
Age										
< 18 years										
Baseline				10	2	28.12 (22.10)				
Week 24				10	1	25.00 (NA)				
Change from baseline to week 24				10	1	-18.75 (NA)	-18.34 (18.56)	NE [NE; NE]	NE	NE [NE; NE] 0.2613
>= 18 years										
Baseline	8	5	58.75 (28.50)	7	7	33.04 (26.45)				
Week 24	5	3	72.92 (28.18)	7	6	25.00 (33.31)				
Change from baseline to week 24	5	3	8.33 (7.22) 7.70 (10.68)	7	6	-10.42 (10.94)	-8.80 (6.69)	-16.49 [-46.44; 13.45]	0.2442	-0.83 [-2.23; 0.57]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL feeling domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity										
high titer										
Baseline	6	4	65.62 (27.72)	5	3	47.92 (37.67)				
Week 24	4	2	87.50 (17.68)	5	2	62.50 (35.36)				
Change from baseline to week 24	4	2	6.25 (8.84) 10.34 (20.07)	5	2	-3.12 (4.42) -0.95 (15.43)	-11.29 [-56.19; 33.60]	0.5707	-0.30 [-2.10; 1.50]	0.8551
low titer										
Baseline	3	1	31.25 (NA)	12	6	23.96 (12.13)				
Week 24	2	1	43.75 (NA)	12	5	10.00 (9.48)				
Change from baseline to week 24	2	1	12.50 (NA) 11.30 (17.49)	12	5	-15.00 (10.46) -16.58 (10.38)	-27.88 [-73.28; 17.52]	0.1898	-0.92 [-3.10; 1.25]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

8: Change from baseline to week 24 in Haem-A-QoL feeling domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	52.08 (23.66)		12	5	57.50 (33.19)				
Week 24	8	1	0.00 (NA)		11	3	29.17 (26.02)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-29.17 (50.90)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	68.75 (NA)		6	1	18.75 (NA)				
Week 24	5	1	0.00 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	43.75 (26.52)		6	4	67.19 (29.04)				
Week 24					5	3	29.17 (26.02)				
Change from baseline to week 24					5	3	-29.17 (50.90)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

9: Change from baseline to week 24 in Haem-A-QoL future domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N n	Mean (SD)	CSE (SE)	N n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9 5	54.00 (14.75)		17 9	41.67 (21.21)					
Week 24	6 3	61.67 (20.21)		17 7	40.71 (19.67)					
Change from baseline to week 24	6 3	13.33 (2.89)	13.23 (10.06)	17 7	-7.14 (15.51)	-7.76 (6.32)	-20.99 [-46.43; 4.45]	0.0980	-1.04 [-2.41; 0.33]	
Age										
< 18 years										
Baseline				10 2	17.50 (3.54)					
Week 24				10 1	35.00 (NA)					
Change from baseline to week 24				10 1	20.00 (NA)	15.79 (21.03)	NE [NE; NE]	NE	NE [NE; NE]	0.6310
>= 18 years										
Baseline	8 5	54.00 (14.75)		7 7	48.57 (18.64)					
Week 24	5 3	61.67 (20.21)		7 6	41.67 (21.37)					
Change from baseline to week 24	5 3	13.33 (2.89)	13.36 (9.77)	7 6	-11.67 (10.80)	-11.70 (7.19)	-25.06 [-52.20; 2.08]	0.0663	-1.22 [-2.68; 0.23]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL future domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	4	60.00 (7.07)		5	3	40.00 (22.91)					
Week 24	4	2	72.50 (10.61)		5	2	50.00 (28.28)					
Change from baseline to week 24	4	2	15.00 (0.00)	14.55 (16.02)	5	2	0.00 (7.07)	-2.83 (13.19)	-17.38 [-69.24; 34.47]	0.4540	-0.55 [-2.38; 1.27]	0.9135
low titer												
Baseline	3	1	30.00 (NA)		12	6	42.50 (22.53)					
Week 24	2	1	40.00 (NA)		12	5	37.00 (17.89)					
Change from baseline to week 24	2	1	10.00 (NA)	9.35 (21.51)	12	5	-10.00 (17.68)	-11.03 (8.76)	-20.38 [-77.27; 36.51]	0.4249	-0.80 [-2.96; 1.36]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

10: Change from baseline to week 24 in Haem-A-QoL future domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	58.33 (23.63)		12	5	64.00 (32.09)				
Week 24	8	1	30.00 (NA)		11	3	60.00 (35.00)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-16.67 (46.46)	14.58 (28.99)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	50.00 (NA)		6	1	10.00 (NA)				
Week 24	5	1	30.00 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	62.50 (31.82)		6	4	77.50 (12.58)				
Week 24					5	3	60.00 (35.00)				
Change from baseline to week 24					5	3	-16.67 (46.46)	-10.53 (20.87)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

11: Change from baseline to week 24 in Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	36.67 (22.52)	17	9	16.67 (10.21)				
Week 24	6	3	25.00 (16.67)	17	7	17.86 (25.65)				
Change from baseline to week 24	6	3	0.00 (8.33) / -1.65 (9.70)	17	7	1.19 (19.50) / 2.96 (7.13)	4.61 [-21.86; 31.08]	0.7128	0.21 [-1.10; 1.52]	
Age										
< 18 years										
Baseline				10	2	20.83 (5.89)				
Week 24				10	1	50.00 (NA)				
Change from baseline to week 24				10	1	25.00 (NA) / 30.94 (16.92)	NE [NE; NE]	NE	NE [NE; NE]	0.1586
>= 18 years										
Baseline	8	5	36.67 (22.52)	7	7	15.48 (11.21)				
Week 24	5	3	25.00 (16.67)	7	6	12.50 (23.42)				
Change from baseline to week 24	5	3	0.00 (8.33) / 0.51 (9.43)	7	6	-2.78 (18.00) / -2.94 (8.15)	-3.44 [-32.95; 26.06]	0.7978	-0.15 [-1.51; 1.20]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	4	39.58 (24.88)		5	3	25.00 (8.33)					
Week 24	4	2	25.00 (23.57)		5	2	29.17 (41.25)					
Change from baseline to week 24	4	2	0.00 (11.79)	-2.68 (13.23)	5	2	0.00 (35.36)	-16.26 (11.98)	-13.58 [-56.99; 29.83]	0.4836	-0.49 [-2.31; 1.32]	0.1389
low titer												
Baseline	3	1	25.00 (NA)		12	6	12.50 (8.74)					
Week 24	2	1	25.00 (NA)		12	5	13.33 (21.73)					
Change from baseline to week 24	2	1	0.00 (NA)	-1.16 (18.13)	12	5	1.67 (16.03)	17.54 (11.55)	18.70 [-33.62; 71.03]	0.4260	0.56 [-1.58; 2.69]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

12: Change from baseline to week 24 in Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	25.00 (22.05)		12	5	45.00 (38.91)				
Week 24	8	1	0.00 (NA)		11	3	33.33 (38.19)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-22.22 (45.90)	-13.32 (27.87)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	41.67 (NA)		6	1	25.00 (NA)				
Week 24	5	1	0.00 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	16.67 (23.57)		6	4	50.00 (43.03)				
Week 24					5	3	33.33 (38.19)				
Change from baseline to week 24					5	3	-22.22 (45.90)	-14.91 (27.39)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

13: Change from baseline to week 24 in Haem-A-QoL physical health domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	72.00 (9.75)	17	9	47.22 (28.95)				
Week 24	6	3	63.33 (12.58)	17	7	32.14 (34.26)				
Change from baseline to week 24	6	3	-6.67 (10.41) / -7.64 (12.13)	17	7	-15.00 (22.55) / -16.52 (7.14)	-8.88 [-40.74; 22.98]	0.5575	-0.38 [-1.70; 0.93]	
Age										
< 18 years										
Baseline				10	2	22.50 (3.54)				
Week 24				10	1	35.00 (NA)				
Change from baseline to week 24				10	1	10.00 (NA) / 14.45 (20.25)	NE [NE; NE]	NE	NE [NE; NE]	0.5114
>= 18 years										
Baseline	8	5	72.00 (9.75)	7	7	54.29 (29.22)				
Week 24	5	3	63.33 (12.58)	7	6	31.67 (37.51)				
Change from baseline to week 24	5	3	-6.67 (10.41) / -7.17 (12.79)	7	6	-19.17 (21.54) / -20.95 (8.04)	-13.77 [-49.31; 21.76]	0.4033	-0.58 [-1.95; 0.80]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL physical health domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	4	73.75 (10.31)		5	3	48.33 (40.72)					
Week 24	4	2	70.00 (7.07)		5	2	45.00 (28.28)					
Change from baseline to week 24	4	2	-2.50 (10.61)	-10.56 (14.08)	5	2	-17.50 (17.68)	-12.61 (11.53)	-2.05 [-47.26; 43.15]	0.9174	-0.07 [-1.86; 1.71]	0.2427
low titer												
Baseline	3	1	65.00 (NA)		12	6	46.67 (26.01)					
Week 24	2	1	50.00 (NA)		12	5	27.00 (38.01)					
Change from baseline to week 24	2	1	-15.00 (NA)	-10.57 (16.90)	12	5	-14.00 (26.08)	-18.04 (7.77)	-7.47 [-52.33; 37.38]	0.7053	-0.33 [-2.45; 1.79]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

14: Change from baseline to week 24 in Haem-A-QoL physical health domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	46.67 (42.52)		12	5	67.00 (16.81)				
Week 24	8	1	40.00 (NA)		11	3	30.00 (30.00)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-36.67 (35.47)	-19.55 (17.02)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	45.00 (NA)		6	1	45.00 (NA)				
Week 24	5	1	40.00 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	47.50 (60.10)		6	4	72.50 (13.23)				
Week 24					5	3	30.00 (30.00)				
Change from baseline to week 24					5	3	-36.67 (35.47)	-35.41 (13.52)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

15: Change from baseline to week 24 in Haem-A-QoL sport and leisure domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	79.75 (18.12)	17	8	67.03 (17.58)				
Week 24	6	3	87.92 (15.83)	17	5	45.25 (22.02)				
Change from baseline to week 24	6	3	12.92 (22.37) 18.10 (8.18)	17	5	-15.50 (21.81) -20.19 (6.91)	-38.29 [-64.98; -11.60]	0.0127	-1.99 [-3.61; -0.38]	
Age										
< 18 years										
Baseline				10	2	55.00 (35.36)				
Week 24				10	1	35.00 (NA)				
Change from baseline to week 24				10	1	5.00 (NA) 8.39 (23.90)	NE [NE; NE]	NE	NE [NE; NE]	0.6827
>= 18 years										
Baseline	8	5	79.75 (18.12)	7	6	71.04 (10.26)				
Week 24	5	3	87.92 (15.83)	7	4	47.81 (24.55)				
Change from baseline to week 24	5	3	12.92 (22.37) 17.52 (8.83)	7	4	-20.62 (21.42) -21.87 (7.55)	-39.40 [-90.07; 11.27]	0.0789	-2.09 [-3.85; -0.33]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL sport and leisure domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	4	85.94 (13.52)		5	3	73.33 (7.64)					
Week 24	4	2	85.00 (21.21)		5	2	65.62 (22.10)					
Change from baseline to week 24	4	2	0.00 (0.00)	14.43 (11.88)	5	2	-4.38 (15.03)	-8.58 (9.39)	-23.02 [NE; NE]	NE	-1.02 [-2.92; 0.88]	NE
low titer												
Baseline	3	1	55.00 (NA)		12	5	63.25 (21.53)					
Week 24	2	1	93.75 (NA)		12	3	31.67 (5.77)					
Change from baseline to week 24	2	1	38.75 (NA)	20.31 (15.61)	12	3	-22.92 (25.14)	-32.35 (9.14)	-52.66 [NE; NE]	NE	-2.09 [-4.64; 0.45]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

16: Change from baseline to week 24 in Haem-A-QoL sport and leisure domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)										
total										
Baseline	10	3	56.67 (32.53)	12	3	81.67 (23.63)				
Week 24				11	2	50.00 (70.71)				
Change from baseline to week 24				11	1	10.00 (NA)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]
Age										
< 18 years										
Baseline	5	1	55.00 (NA)	6	1	55.00 (NA)				
>= 18 years										
Baseline	5	2	57.50 (45.96)	6	2	95.00 (7.07)				
Week 24				5	2	50.00 (70.71)				
Change from baseline to week 24				5	1	10.00 (NA)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

17: Change from baseline to week 24 in Haem-A-QoL total score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	55.52 (13.90)	17	9	40.32 (12.82)				
Week 24	6	3	59.30 (14.90)	17	7	31.85 (18.26)				
Change from baseline to week 24	6	3	7.88 (0.39) / 6.42 (5.85)	17	7	-10.00 (10.48)	-9.89 (3.67)	-16.31 [-31.62; -1.00]	0.0386	-1.39 [-2.81; 0.03]
Age										
< 18 years										
Baseline				10	2	30.71 (1.92)				
Week 24				10	1	38.89 (NA)				
Change from baseline to week 24				10	1	6.82 (NA)	10.72 (9.98)	NE [NE; NE]	NE	NE [NE; NE]	0.0738
>= 18 years										
Baseline	8	5	55.52 (13.90)	7	7	43.07 (13.37)				
Week 24	5	3	59.30 (14.90)	7	6	30.68 (19.72)				
Change from baseline to week 24	5	3	7.88 (0.39) / 7.15 (5.17)	7	6	-12.81 (8.11)	-12.50 (3.49)	-19.65 [-34.27; -5.04]	0.0140	-1.93 [-3.53; -0.34]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL total score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity										
high titer										
Baseline	6	4	59.74 (11.78)	5	3	44.57 (21.40)				
Week 24	4	2	65.78 (13.86)	5	2	47.16 (22.12)				
Change from baseline to week 24	4	2	7.96 (0.50) / 3.05 (9.36)	5	2	-5.02 (1.72) / -3.98 (7.17)	-7.03 [-34.47; 20.42]	0.5640	-0.40 [-2.21; 1.40]	0.7000
low titer										
Baseline	3	1	38.64 (NA)	12	6	38.19 (7.96)				
Week 24	2	1	46.34 (NA)	12	5	25.72 (14.63)				
Change from baseline to week 24	2	1	7.71 (NA) / 11.13 (10.73)	12	5	-11.99 (12.11) / -12.60 (5.03)	-23.73 [-50.57; 3.11]	0.0749	-1.62 [-3.90; 0.66]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

18: Change from baseline to week 24 in Haem-A-QoL total score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	47.84 (17.62)		12	5	55.93 (21.01)				
Week 24	8	1	27.03 (NA)		11	3	38.30 (23.68)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-17.59 (32.03)	-13.92 (18.94)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	52.33 (NA)		6	1	29.35 (NA)				
Week 24	5	1	27.03 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	45.59 (24.30)		6	4	62.57 (17.15)				
Week 24					5	3	38.30 (23.68)				
Change from baseline to week 24					5	3	-17.59 (32.03)	-21.36 (18.96)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

19: Change from baseline to week 24 in Haem-A-QoL treatment domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	53.75 (14.89)	17	9	38.54 (21.88)				
Week 24	6	3	64.58 (23.45)	17	7	26.79 (19.42)				
Change from baseline to week 24	6	3	15.62 (11.27) 16.20 (9.88)	17	7	-10.27 (17.74) -13.21 (6.50)	-29.41 [-55.53; -3.29]	0.0302	-1.43 [-2.85; 0.00]	
Age										
< 18 years										
Baseline				10	2	25.00 (0.00)				
Week 24				10	1	31.25 (NA)				
Change from baseline to week 24				10	1	6.25 (NA) 0.64 (19.78)	NE [NE; NE]	NE	NE [NE; NE]	0.5220
>= 18 years										
Baseline	8	5	53.75 (14.89)	7	7	42.41 (23.65)				
Week 24	5	3	64.58 (23.45)	7	6	26.04 (21.16)				
Change from baseline to week 24	5	3	15.62 (11.27) 16.72 (10.05)	7	6	-13.02 (17.72) -14.15 (7.10)	-30.87 [-59.78; -1.97]	0.0389	-1.51 [-3.02; -0.01]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL treatment domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity										
high titer										
Baseline	6	4	57.81 (13.62)	5	3	39.58 (30.83)				
Week 24	4	2	76.56 (15.47)	5	2	46.88 (17.68)				
Change from baseline to week 24	4	2	21.88 (4.42) / 26.59 (14.33)	5	2	0.00 (22.10) / 1.87 (12.42)	-24.73 [-71.69; 22.23]	0.2532	-0.85 [-2.72; 1.01]	0.5920
low titer										
Baseline	3	1	37.50 (NA)	12	6	38.02 (19.61)				
Week 24	2	1	40.62 (NA)	12	5	18.75 (14.32)				
Change from baseline to week 24	2	1	3.12 (NA) / 0.22 (17.99)	12	5	-14.38 (16.62) / -22.60 (8.39)	-22.82 [-69.21; 23.57]	0.2829	-0.93 [-3.11; 1.24]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

20: Change from baseline to week 24 in Haem-A-QoL treatment domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	46.88 (16.54)		12	5	46.88 (29.89)				
Week 24	8	1	37.50 (NA)		11	3	27.08 (19.09)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-8.33 (17.77)	61.85 (53.02)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	59.38 (NA)		6	1	28.12 (NA)				
Week 24	5	1	37.50 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	40.62 (17.68)		6	4	51.56 (32.33)				
Week 24					5	3	27.08 (19.09)				
Change from baseline to week 24					5	3	-8.33 (17.77)	70.72 (59.59)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

21: Change from baseline to week 24 in Haem-A-QoL view of yourself domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	68.00 (18.57)	17	9	43.89 (8.94)				
Week 24	6	3	81.67 (17.56)	17	7	38.57 (19.73)				
Change from baseline to week 24	6	3	13.33 (7.64) 18.23 (12.42)	17	7	-6.43 (19.30)	-9.17 (7.13) -27.40 [-61.26; 6.45]	0.1039	-1.18 [-2.57; 0.21]	
Age										
< 18 years										
Baseline				10	2	37.50 (3.54)				
Week 24				10	1	50.00 (NA)				
Change from baseline to week 24				10	1	15.00 (NA)	13.39 (21.47) NE [NE; NE]	NE	NE [NE; NE]	0.7731
>= 18 years										
Baseline	8	5	68.00 (18.57)	7	7	45.71 (9.32)				
Week 24	5	3	81.67 (17.56)	7	6	36.67 (20.90)				
Change from baseline to week 24	5	3	13.33 (7.64) 18.79 (12.90)	7	6	-10.00 (18.44)	-11.85 (7.83) -30.64 [-68.00; 6.72]	0.0966	-1.31 [-2.78; 0.16]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL view of yourself domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	4	73.75 (15.48)		5	3	43.33 (10.41)					
Week 24	4	2	90.00 (14.14)		5	2	55.00 (21.21)					
Change from baseline to week 24	4	2	10.00 (7.07)	-7.53 (35.26)	5	2	10.00 (7.07)	16.29 (17.73)	23.82 [-91.22; 138.86]	0.6394	0.45 [-1.36; 2.26]	0.7454
low titer												
Baseline	3	1	45.00 (NA)		12	6	44.17 (9.17)					
Week 24	2	1	65.00 (NA)		12	5	32.00 (16.81)					
Change from baseline to week 24	2	1	20.00 (NA)	28.08 (21.87)	12	5	-13.00 (18.91)	-13.87 (9.33)	-41.95 [-94.00; 10.10]	0.0984	-1.55 [-3.81; 0.72]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

22: Change from baseline to week 24 in Haem-A-QoL view of yourself domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	53.33 (15.28)		12	5	59.00 (18.84)				
Week 24	8	1	25.00 (NA)		11	3	45.00 (22.91)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	3	-16.67 (29.30)	-4.08 (11.14)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	50.00 (NA)		6	1	30.00 (NA)				
Week 24	5	1	25.00 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	55.00 (21.21)		6	4	66.25 (11.09)				
Week 24					5	3	45.00 (22.91)				
Change from baseline to week 24					5	3	-16.67 (29.30)	-21.67 (9.81)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

23: Change from baseline to week 24 in Haem-A-QoL work and studies domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	42.50 (19.47)	17	8	41.41 (11.54)				
Week 24	6	3	49.31 (16.97)	17	6	30.21 (15.52)				
Change from baseline to week 24	6	3	18.06 (12.03) 6.81 (9.92)	17	6	-11.46 (17.42) -11.06 (5.64)	-17.87 [-43.14; 7.40]	0.1461	-1.01 [-2.40; 0.39]	
Age										
< 18 years										
Baseline				10	2	43.75 (8.84)				
Week 24				10	1	43.75 (NA)				
Change from baseline to week 24				10	1	-6.25 (NA) -32.57 (20.55)	NE [NE; NE]	NE	NE [NE; NE]	0.7007
>= 18 years										
Baseline	8	5	42.50 (19.47)	7	6	40.62 (12.96)				
Week 24	5	3	49.31 (16.97)	7	5	27.50 (15.69)				
Change from baseline to week 24	5	3	18.06 (12.03) 3.54 (11.31)	7	5	-12.50 (19.26) -7.29 (7.28)	-10.83 [-45.86; 24.20]	0.4782	-0.52 [-1.93; 0.88]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Change from baseline to week 24 in Haem-A-QoL work and studies domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity										
high titer										
Baseline	6	4	43.75 (22.24)	5	3	47.92 (13.01)				
Week 24	4	2	53.12 (22.10)	5	2	34.38 (4.42)				
Change from baseline to week 24	4	2	25.00 (0.00) 3.57 (23.65)	5	2	-18.75 (8.84) -5.27 (17.53)	-8.84 [-113.34; 95.66]	0.8259	-0.20 [-2.00; 1.59]	0.9776
low titer										
Baseline	3	1	37.50 (NA)	12	5	37.50 (9.88)				
Week 24	2	1	41.67 (NA)	12	4	28.12 (19.43)				
Change from baseline to week 24	2	1	4.17 (NA) 3.36 (16.46)	12	4	-7.81 (20.65) -14.44 (11.02)	-17.80 [-72.38; 36.79]	0.4166	-0.58 [-2.75; 1.59]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

24: Change from baseline to week 24 in Haem-A-QoL family planning domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)
All subjects (Total)								
total								
Baseline	9	4	25.00 (33.85)		17	4	12.50 (15.31)	
Week 24	6	1	0.00 (NA)		17	3	17.36 (16.71)	
Change from baseline to week 24	6	1	0.00 (NA)	NE (NE)	17	2	1.04 (19.15)	NE (NE)
Age								
< 18 years								
Baseline					10	2	9.38 (13.26)	
Week 24					10	1	33.33 (NA)	
Change from baseline to week 24					10	1	14.58 (NA)	NE (NE)
>= 18 years								
Baseline	8	4	25.00 (33.85)		7	2	15.62 (22.10)	
Week 24	5	1	0.00 (NA)		7	2	9.38 (13.26)	
Change from baseline to week 24	5	1	0.00 (NA)	NE (NE)	7	1	-12.50 (NA)	NE (NE)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics. Analytical statistics have not been done for this output as models failed due to too few subjects.

Change from baseline to week 24 in Haem-A-QoL family planning domain score for subjects older than 16 years - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)
Disease severity								
high titer								
Baseline	6	3	29.17 (40.18)		5	2	15.62 (22.10)	
Week 24	4	1	0.00 (NA)		5	1	18.75 (NA)	
Change from baseline to week 24	4	1	0.00 (NA)	NE (NE)	5	1	-12.50 (NA)	NE (NE)
low titer								
Baseline	3	1	12.50 (NA)		12	2	9.38 (13.26)	
Week 24					12	2	16.67 (23.57)	
Change from baseline to week 24					12	1	14.58 (NA)	NE (NE)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics. Analytical statistics have not been done for this output as models failed due to too few subjects.

25: Change from baseline to week 24 in Haem-A-QoL family planning domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			
	N	n	Mean (SD)	N	n	Mean (SD)	CSE (SE)
All subjects (Total)							
total							
Baseline	10	2	42.71 (33.88)	12	3	45.14 (39.11)	
Week 24				11	1	33.33 (NA)	
Change from baseline to week 24				11	1	-33.33 (NA)	NE (NE)
Age							
< 18 years							
Baseline				6	1	0.00 (NA)	
>= 18 years							
Baseline	5	2	42.71 (33.88)	6	2	67.71 (1.47)	
Week 24				5	1	33.33 (NA)	
Change from baseline to week 24				5	1	-33.33 (NA)	NE (NE)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics. Analytical statistics have not been done for this output as models failed due to too few subjects.

26: Change from baseline to week 24 in Haem-A-QoL work and studies domain score for subjects older than 16 years - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]
All subjects (Total)											
total											
Baseline	10	3	43.06 (6.36)		12	3	72.92 (28.18)				
Week 24	8	1	31.25 (NA)		11	1	87.50 (NA)				
Change from baseline to week 24	8	0	NA (NA)	NE (NE)	11	0	NA (NA)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]
Age											
< 18 years											
Baseline	5	1	50.00 (NA)		6	1	43.75 (NA)				
Week 24	5	1	31.25 (NA)								
Change from baseline to week 24	5	0	NA (NA)	NE (NE)							
>= 18 years											
Baseline	5	2	39.58 (2.95)		6	2	87.50 (17.68)				
Week 24					5	1	87.50 (NA)				
Change from baseline to week 24					5	0	NA (NA)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

27: Change from baseline to week 24 in Hemo-TEM Total Score - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	35.38 (11.25)		17	16	25.46 (20.48)					
Week 24	6	5	35.17 (20.34)		17	14	11.20 (11.55)					
Change from baseline to week 24	6	4	1.46 (24.53)	9.59 (7.81)	17	13	-16.99 (21.20)	-15.46 (4.10)	-25.05 [-44.16; -5.93]	0.0142	-1.59 [-2.83; -0.35]	
Age												
< 18 years												
Baseline	1	1	46.85 (NA)		10	9	24.83 (18.57)					
Week 24	1	1	62.74 (NA)		10	9	15.91 (12.08)					
Change from baseline to week 24	1	1	15.89 (NA)	31.85 (11.57)	10	8	-9.55 (15.23)	-9.32 (3.96)	-41.17 [-68.23; -14.10]	0.0065	-3.27 [-5.84; -0.70]	0.0191
>= 18 years												
Baseline	8	4	32.51 (10.67)		7	7	26.28 (24.23)					
Week 24	5	4	28.27 (15.32)		7	5	2.73 (1.46)					
Change from baseline to week 24	5	3	-3.35 (27.64)	2.04 (6.65)	7	5	-28.90 (25.57)	-25.11 (5.01)	-27.15 [-45.34; -8.97]	0.0073	-2.09 [-3.85; -0.33]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in Hemo-TEM Total Score - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	36.88 (13.57)		5	5	33.36 (24.85)					
Week 24	4	4	35.65 (23.45)		5	3	17.06 (13.40)					
Change from baseline to week 24	4	3	4.50 (29.10)	11.80 (9.65)	5	3	-29.42 (36.11)	-13.50 (10.50)	-25.29 [-54.00; 3.41]	0.0785	-1.16 [-2.89; 0.57]	0.8675
low titer												
Baseline	3	2	33.12 (10.99)		12	11	21.87 (18.35)					
Week 24	2	1	33.21 (NA)		12	11	9.60 (11.15)					
Change from baseline to week 24	2	1	-7.68 (NA)	3.22 (16.24)	12	10	-13.26 (15.57)	-16.52 (5.26)	-19.74 [-58.17; 18.70]	0.2824	-1.09 [-3.19; 1.02]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

28: Change from baseline to week 24 in Hemo-TEM Total Score - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	4	24.52 (6.07)		12	7	26.65 (13.63)					
Week 24	8	6	27.57 (18.46)		11	9	9.28 (10.26)					
Change from baseline to week 24	8	2	0.06 (4.80)	-5.38 (10.75)	11	6	-14.87 (17.20)	-14.72 (6.02)	-9.34 [-44.97; 26.29]	0.5070	-0.55 [-2.17; 1.07]	
Age												
< 18 years												
Baseline	5	2	23.57 (9.51)		6	4	21.29 (16.48)					
Week 24	5	4	26.96 (18.49)		6	5	4.45 (6.91)					
Change from baseline to week 24	5	2	0.06 (4.80)	-2.08 (10.10)	6	4	-16.15 (19.77)	-26.84 (10.78)	-24.76 [-77.61; 28.09]	0.2328	-0.99 [-2.78; 0.80]	0.2791
>= 18 years												
Baseline	5	2	25.48 (4.04)		6	3	33.79 (4.00)					
Week 24	3	2	28.78 (25.97)		5	4	15.31 (11.38)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	-12.32 (16.92)	-1.86 (11.30)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

29: Change from baseline to week 24 in Hemo-TEM ease of use - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	53.33 (20.92)		17	16	29.69 (33.74)					
Week 24	6	5	36.67 (25.41)		17	14	10.71 (11.98)					
Change from baseline to week 24	6	4	-2.08 (7.98)	9.99 (7.15)	17	13	-23.08 (36.82)	-21.90 (3.83)	-31.89 [-49.54; -14.23]	0.0018	-2.18 [-3.51; -0.84]	
Age												
< 18 years												
Baseline	1	1	75.00 (NA)		10	9	30.56 (36.32)					
Week 24	1	1	66.67 (NA)		10	9	16.67 (11.02)					
Change from baseline to week 24	1	1	-8.33 (NA)	30.25 (8.91)	10	8	-14.58 (36.93)	-14.36 (3.01)	-44.61 [-65.37; -23.86]	0.0006	-4.66 [-7.65; -1.67]	0.0019
>= 18 years												
Baseline	8	4	47.92 (19.69)		7	7	28.57 (32.93)					
Week 24	5	4	29.17 (22.05)		7	5	0.00 (0.00)					
Change from baseline to week 24	5	3	0.00 (8.33)	3.47 (4.98)	7	5	-36.67 (36.13)	-33.64 (3.78)	-37.10 [-50.89; -23.32]	0.0001	-3.79 [-6.13; -1.44]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in Hemo-TEM ease of use - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	52.78 (20.97)		5	5	40.00 (32.49)					
Week 24	4	4	35.42 (29.17)		5	3	16.67 (16.67)					
Change from baseline to week 24	4	3	-5.56 (4.81)	9.95 (8.98)	5	3	-41.67 (44.10)	-20.87 (9.16)	-30.81 [-57.42; -4.20]	0.0271	-1.57 [-3.40; 0.26]	0.9211
low titer												
Baseline	3	2	54.17 (29.46)		12	11	25.00 (34.76)					
Week 24	2	1	41.67 (NA)		12	11	9.09 (10.84)					
Change from baseline to week 24	2	1	8.33 (NA)	5.30 (14.92)	12	10	-17.50 (35.02)	-24.30 (4.89)	-29.60 [-64.39; 5.20]	0.0880	-1.75 [-3.93; 0.43]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

30: Change from baseline to week 24 in Hemo-TEM ease of use - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	4	41.67 (15.21)		12	7	33.33 (23.57)					
Week 24	8	6	29.17 (35.65)		11	9	11.11 (13.82)					
Change from baseline to week 24	8	2	8.33 (35.36)	10.14 (22.65)	11	6	-23.61 (28.59)	-24.25 (12.86)	-34.40 [-110.17; 41.38]	0.2761	-0.95 [-2.61; 0.72]	
Age												
< 18 years												
Baseline	5	2	45.83 (17.68)		6	4	29.17 (30.81)					
Week 24	5	4	39.58 (40.47)		6	5	1.67 (3.73)					
Change from baseline to week 24	5	2	8.33 (35.36)	16.14 (25.11)	6	4	-27.08 (33.59)	-37.15 (22.98)	-53.29 [-177.62; 71.03]	0.2658	-0.98 [-2.76; 0.81]	0.5213
>= 18 years												
Baseline	5	2	37.50 (17.68)		6	3	38.89 (12.73)					
Week 24	3	2	8.33 (11.79)		5	4	22.92 (12.50)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	-16.67 (23.57)	-8.86 (25.11)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

31: Change from baseline to week 24 in Hemo-TEM emotional impact - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	30.83 (16.03)		17	16	27.86 (26.30)					
Week 24	6	5	37.50 (24.30)		17	14	13.69 (14.93)					
Change from baseline to week 24	6	4	4.17 (32.27)	6.27 (9.20)	17	13	-16.35 (22.40)	-14.04 (4.92)	-20.31 [-42.98; 2.36]	0.0750	-1.08 [-2.26; 0.10]	
Age												
< 18 years												
Baseline	1	1	50.00 (NA)		10	9	29.63 (27.67)					
Week 24	1	1	66.67 (NA)		10	9	18.98 (16.29)					
Change from baseline to week 24	1	1	16.67 (NA)	31.16 (15.67)	10	8	-11.98 (20.22)	-7.57 (5.39)	-38.73 [-75.03; -2.43]	0.0386	-2.26 [-4.58; 0.07]	0.0710
>= 18 years												
Baseline	8	4	26.04 (13.77)		7	7	25.60 (26.40)					
Week 24	5	4	30.21 (20.80)		7	5	4.17 (4.17)					
Change from baseline to week 24	5	3	0.00 (38.19)	-1.25 (8.89)	7	5	-23.33 (26.29)	-23.84 (6.73)	-22.58 [-47.21; 2.04]	0.0685	-1.30 [-2.86; 0.27]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in Hemo-TEM emotional impact - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	37.50 (18.16)		5	5	40.00 (26.29)					
Week 24	4	4	42.71 (24.62)		5	3	22.22 (12.73)					
Change from baseline to week 24	4	3	8.33 (38.19)	11.98 (11.14)	5	3	-31.94 (26.79)	-17.28 (12.94)	-29.27 [-62.59; 4.06]	0.0794	-1.12 [-2.84; 0.60]	0.4828
low titer												
Baseline	3	2	20.83 (5.89)		12	11	22.35 (25.57)					
Week 24	2	1	16.67 (NA)		12	11	11.36 (15.15)					
Change from baseline to week 24	2	1	-8.33 (NA)	-12.94 (18.05)	12	10	-11.67 (20.11)	-13.28 (6.09)	-0.34 [-42.74; 42.06]	0.9862	-0.02 [-2.07; 2.04]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

32: Change from baseline to week 24 in Hemo-TEM emotional impact - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	4	21.88 (13.77)		12	7	22.62 (14.60)					
Week 24	8	6	31.25 (16.82)		11	9	5.09 (11.37)					
Change from baseline to week 24	8	2	20.83 (17.68)	8.05 (13.67)	11	6	-12.50 (16.24)	-14.56 (7.14)	-22.61 [-64.23; 19.02]	0.2061	-1.10 [-2.79; 0.59]	
Age												
< 18 years												
Baseline	5	2	10.42 (2.95)		6	4	18.75 (17.51)					
Week 24	5	4	33.33 (14.83)		6	5	2.50 (5.59)					
Change from baseline to week 24	5	2	20.83 (17.68)	11.31 (14.31)	6	4	-15.62 (18.12)	-20.30 (12.87)	-31.61 [-97.25; 34.03]	0.2229	-1.03 [-2.83; 0.76]	0.5365
>= 18 years												
Baseline	5	2	33.33 (5.89)		6	3	27.78 (10.49)					
Week 24	3	2	27.08 (26.52)		5	4	8.33 (16.67)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	-6.25 (14.73)	-5.43 (13.31)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

33: Change from baseline to week 24 in Hemo-TEM interference - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	33.33 (23.98)		17	16	28.12 (24.26)					
Week 24	6	5	37.50 (34.23)		17	14	8.93 (11.16)					
Change from baseline to week 24	6	4	6.25 (43.60)	14.05 (10.75)	17	13	-23.56 (26.16)	-19.55 (5.76)	-33.59 [-59.92; -7.27]	0.0163	-1.53 [-2.76; -0.29]	
Age												
< 18 years												
Baseline	1	1	43.75 (NA)		10	9	26.39 (20.91)					
Week 24	1	1	87.50 (NA)		10	9	13.19 (11.88)					
Change from baseline to week 24	1	1	43.75 (NA)	57.38 (14.79)	10	8	-14.84 (19.46)	-14.14 (5.15)	-71.52 [-106.18; -36.87]	0.0008	-4.37 [-7.26; -1.47]	0.0088
>= 18 years												
Baseline	8	4	30.73 (26.86)		7	7	30.36 (29.63)					
Week 24	5	4	25.00 (22.82)		7	5	1.25 (2.80)					
Change from baseline to week 24	5	3	-6.25 (43.75)	-0.71 (8.62)	7	5	-37.50 (31.56)	-28.14 (6.63)	-27.43 [-51.03; -3.83]	0.0266	-1.60 [-3.24; 0.03]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in Hemo-TEM interference - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	31.25 (27.24)		5	5	27.50 (32.36)					
Week 24	4	4	34.38 (38.70)		5	3	12.50 (12.50)					
Change from baseline to week 24	4	3	10.42 (52.42)	12.22 (13.12)	5	3	-27.08 (50.52)	-16.88 (13.47)	-29.10 [-69.01; 10.81]	0.1368	-1.01 [-2.71; 0.69]	0.9264
low titer												
Baseline	3	2	36.46 (27.99)		12	11	28.41 (21.54)					
Week 24	2	1	50.00 (NA)		12	11	7.95 (11.21)					
Change from baseline to week 24	2	1	-6.25 (NA)	20.75 (23.47)	12	10	-22.50 (18.45)	-20.55 (7.17)	-41.30 [-95.71; 13.11]	0.1230	-1.66 [-3.83; 0.51]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

34: Change from baseline to week 24 in Hemo-TEM interference - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	4	15.62 (8.07)		12	7	25.00 (17.31)					
Week 24	8	6	30.90 (26.53)		11	9	13.66 (15.06)					
Change from baseline to week 24	8	2	0.00 (17.68)	-7.83 (13.84)	11	6	-8.68 (21.26)	-6.74 (7.73)	1.09 [-45.06; 47.25]	0.9508	0.05 [-1.55; 1.65]	
Age												
< 18 years												
Baseline	5	2	12.50 (8.84)		6	4	23.44 (24.14)					
Week 24	5	4	18.75 (22.24)		6	5	10.83 (18.07)					
Change from baseline to week 24	5	2	0.00 (17.68)	-5.38 (14.33)	6	4	-9.90 (26.86)	-19.56 (15.10)	-14.18 [-88.29; 59.93]	0.5856	-0.40 [-2.12; 1.31]	0.4126
>= 18 years												
Baseline	5	2	18.75 (8.84)		6	3	27.08 (3.61)					
Week 24	3	2	55.21 (16.20)		5	4	17.19 (11.83)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	-6.25 (8.84)	6.10 (16.32)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

35: Change from baseline to week 24 in Hemo-TEM physical impact - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	35.83 (20.54)		17	16	21.09 (15.10)					
Week 24	6	5	34.17 (12.98)		17	14	10.42 (13.35)					
Change from baseline to week 24	6	4	-7.29 (25.54)	7.56 (8.36)	17	13	-11.54 (19.11)	-13.32 (3.87)	-20.89 [-41.65; -0.12]	0.0488	-1.36 [-2.57; -0.15]	
Age												
< 18 years												
Baseline	1	1	33.33 (NA)		10	9	21.30 (12.92)					
Week 24	1	1	50.00 (NA)		10	9	14.81 (14.89)					
Change from baseline to week 24	1	1	16.67 (NA)	21.27 (12.12)	10	8	-6.77 (18.22)	-7.82 (4.27)	-29.09 [-57.68; -0.49]	0.0468	-2.14 [-4.44; 0.16]	0.0863
>= 18 years												
Baseline	8	4	36.46 (23.66)		7	7	20.83 (18.63)					
Week 24	5	4	30.21 (10.96)		7	5	2.50 (3.73)					
Change from baseline to week 24	5	3	-15.28 (24.41)	1.38 (8.45)	7	5	-19.17 (19.90)	-21.62 (5.35)	-23.00 [-45.73; -0.27]	0.0478	-1.55 [-3.17; 0.07]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in Hemo-TEM physical impact - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	40.28 (12.03)		5	5	30.00 (15.42)					
Week 24	4	4	35.42 (14.63)		5	3	20.83 (19.09)					
Change from baseline to week 24	4	3	-1.39 (27.74)	13.19 (9.84)	5	3	-16.67 (30.05)	-5.01 (9.43)	-18.20 [-43.41; 7.01]	0.1403	-0.87 [-2.55; 0.80]	0.5230
low titer												
Baseline	3	2	29.17 (35.36)		12	11	17.05 (13.75)					
Week 24	2	1	29.17 (NA)		12	11	7.58 (10.84)					
Change from baseline to week 24	2	1	-25.00 (NA)	4.19 (16.95)	12	10	-10.00 (16.57)	-16.37 (5.19)	-20.56 [-62.61; 21.49]	0.3049	-1.15 [-3.26; 0.96]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

36: Change from baseline to week 24 in Hemo-TEM physical impact - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	4	22.92 (11.02)		12	7	33.93 (17.25)					
Week 24	8	6	25.69 (20.65)		11	9	12.96 (16.06)					
Change from baseline to week 24	8	2	-14.58 (8.84)	-22.09 (14.19)	11	6	-15.28 (22.15)	-12.21 (8.16)	9.89 [-37.96; 57.73]	0.5969	0.43 [-1.18; 2.04]	
Age												
< 18 years												
Baseline	5	2	31.25 (8.84)		6	4	27.08 (19.39)					
Week 24	5	4	27.08 (18.79)		6	5	5.83 (9.13)					
Change from baseline to week 24	5	2	-14.58 (8.84)	-16.56 (15.10)	6	4	-21.88 (23.91)	-33.81 (22.06)	-17.25 [-116.75; 82.25]	0.6197	-0.35 [-2.06; 1.36]	0.3764
>= 18 years												
Baseline	5	2	14.58 (2.95)		6	3	43.06 (10.49)					
Week 24	3	2	22.92 (32.41)		5	4	21.88 (19.65)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	-2.08 (14.73)	2.32 (17.10)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

37: Change from baseline to week 24 in Hemo-TEM treatment burden - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	23.57 (12.27)		17	16	20.54 (19.19)					
Week 24	6	5	30.00 (14.85)		17	14	12.24 (14.94)					
Change from baseline to week 24	6	4	6.25 (24.98)	11.05 (8.47)	17	13	-10.44 (23.58)	-8.28 (4.65)	-19.32 [-40.35; 1.70]	0.0686	-1.09 [-2.27; 0.09]	
Age												
< 18 years												
Baseline	1	1	32.14 (NA)		10	9	16.27 (10.28)					
Week 24	1	1	42.86 (NA)		10	9	15.87 (17.69)					
Change from baseline to week 24	1	1	10.71 (NA)	20.26 (16.23)	10	8	0.45 (14.21)	-2.95 (5.74)	-23.21 [-61.47; 15.06]	0.2089	-1.27 [-3.43; 0.89]	0.2888
>= 18 years												
Baseline	8	4	21.43 (13.04)		7	7	26.02 (26.78)					
Week 24	5	4	26.79 (15.01)		7	5	5.71 (4.07)					
Change from baseline to week 24	5	3	4.76 (30.37)	7.38 (9.42)	7	5	-27.86 (26.41)	-17.67 (7.80)	-25.05 [-52.00; 1.89]	0.0654	-1.28 [-2.84; 0.29]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in Hemo-TEM treatment burden - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	22.62 (13.52)		5	5	29.29 (27.13)					
Week 24	4	4	30.36 (17.13)		5	3	13.10 (13.52)					
Change from baseline to week 24	4	3	10.71 (28.57)	12.36 (10.55)	5	3	-29.76 (34.69)	-9.17 (12.13)	-21.53 [-56.14; 13.07]	0.1981	-0.87 [-2.55; 0.80]	0.9634
low titer												
Baseline	3	2	25.00 (15.15)		12	11	16.56 (14.22)					
Week 24	2	1	28.57 (NA)		12	11	12.01 (15.91)					
Change from baseline to week 24	2	1	-7.14 (NA)	6.76 (18.39)	12	10	-4.64 (17.66)	-8.04 (5.85)	-14.80 [-57.97; 28.36]	0.4662	-0.73 [-2.81; 1.35]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

38: Change from baseline to week 24 in Hemo-TEM treatment burden - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	4	20.54 (9.39)		12	7	18.37 (20.04)					
Week 24	8	6	20.83 (27.14)		11	9	3.57 (5.05)					
Change from baseline to week 24	8	2	-14.29 (20.20)	-16.55 (4.09)	11	6	-14.29 (17.35)	-14.42 (2.29)	2.14 [-11.58; 15.85]	0.6876	0.33 [-1.28; 1.94]	
Age												
< 18 years												
Baseline	5	2	17.86 (15.15)		6	4	8.04 (7.36)					
Week 24	5	4	16.07 (22.87)		6	5	1.43 (3.19)					
Change from baseline to week 24	5	2	-14.29 (20.20)	-14.72 (4.17)	6	4	-6.25 (8.44)	-17.66 (4.57)	-2.94 [-25.46; 19.59]	0.7060	-0.28 [-1.98; 1.43]	0.3906
>= 18 years												
Baseline	5	2	23.21 (2.53)		6	3	32.14 (25.00)					
Week 24	3	2	30.36 (42.93)		5	4	6.25 (6.10)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	-30.36 (22.73)	-8.40 (5.83)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

39: Change from baseline to week 24 in PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	4.40 (2.70)		17	16	4.69 (2.91)					
Week 24	6	6	4.00 (2.00)		17	14	1.86 (2.98)					
Change from baseline to week 24	6	4	-0.25 (1.71)	-0.36 (1.15)	17	13	-2.38 (2.10)	-2.40 (0.62)	-2.04 [-4.74; 0.65]	0.1321	-0.78 [-1.82; 0.25]	
Age												
< 18 years												
Baseline	1	1	6.00 (NA)		10	9	4.67 (2.55)					
Week 24	1	1	5.00 (NA)		10	9	1.44 (2.60)					
Change from baseline to week 24	1	1	-1.00 (NA)	-0.63 (2.24)	10	8	-3.12 (2.30)	-3.06 (0.78)	-2.43 [-7.34; 2.48]	0.3166	-0.94 [-3.05; 1.17]	0.1643
>= 18 years												
Baseline	8	4	4.00 (2.94)		7	7	4.71 (3.55)					
Week 24	5	5	3.80 (2.17)		7	5	2.60 (3.78)					
Change from baseline to week 24	5	3	0.00 (2.00)	-0.29 (1.28)	7	5	-1.20 (1.10)	-1.47 (0.95)	-1.18 [-4.47; 2.11]	0.4646	-0.43 [-1.67; 0.82]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	3.67 (3.21)		5	5	4.60 (0.89)					
Week 24	4	4	4.50 (1.73)		5	3	1.67 (1.53)					
Change from baseline to week 24	4	3	0.33 (1.53)	0.00 (1.24)	5	3	-3.33 (2.31)	-2.98 (1.11)	-2.98 [-6.34; 0.37]	0.0784	-1.09 [-2.62; 0.44]	0.0035
low titer												
Baseline	3	2	5.50 (2.12)		12	11	4.73 (3.52)					
Week 24	2	2	3.00 (2.83)		12	11	1.91 (3.33)					
Change from baseline to week 24	2	1	-2.00 (NA)	-1.47 (1.95)	12	10	-2.10 (2.08)	-2.20 (0.65)	-0.74 [-4.99; 3.52]	0.7243	-0.31 [-1.82; 1.20]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

40: Change from baseline to week 24 in PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	4.80 (2.86)	12	7	2.43 (1.81)				
Week 24	8	6	4.50 (2.74)	11	9	1.78 (2.49)				
Change from baseline to week 24	8	3	-2.00 (1.00) / -2.13 (1.03)	11	6	-0.17 (1.72) / 0.03 (0.85)	2.16 [-1.64; 5.96]	0.2035	0.94 [-0.39; 2.27]	
Age										
< 18 years										
Baseline	5	3	5.33 (2.52)	6	4	1.50 (1.73)				
Week 24	5	4	4.25 (3.10)	6	5	0.80 (1.79)				
Change from baseline to week 24	5	3	-2.00 (1.00) / -2.21 (1.22)	6	4	-0.50 (0.58) / -0.64 (1.29)	1.57 [NE; NE]	NE	0.55 [-0.98; 2.07]	NE
>= 18 years										
Baseline	5	2	4.00 (4.24)	6	3	3.67 (1.15)				
Week 24	3	2	5.00 (2.83)	5	4	3.00 (2.94)				
Change from baseline to week 24	3	0	NA (NA) / NE (NE)	5	2	0.50 (3.54) / 0.94 (1.36)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

41: Change from baseline to week 24 in PROMIS Short Form v2.0 Upper Extremity 7a - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI] / p-value interact.
All subjects (Total)									
total									
Baseline	9	7	38.88 (11.04)	17	17	39.31 (8.69)			
Week 24	6	6	38.82 (10.84)	17	14	41.38 (8.82)			
Change from baseline to week 24	6	5	-2.94 (7.57) -2.11 (3.20)	17	14	3.91 (7.85) 2.32 (1.92)	4.43 [-3.25; 12.11]	0.2500	0.55 [-0.40; 1.50]
Age									
< 18 years									
Baseline	1	1	36.17 (NA)	10	10	40.15 (10.22)			
Week 24	1	1	36.17 (NA)	10	9	42.93 (9.44)			
Change from baseline to week 24	1	1	0.00 (NA) -0.09 (7.46)	10	9	4.78 (9.39) 3.90 (2.53)	3.98 [-12.21; 20.18]	0.6182	0.47 [-1.60; 2.55] / 0.9392
>= 18 years									
Baseline	8	6	39.33 (12.02)	7	7	38.12 (6.48)			
Week 24	5	5	39.35 (12.03)	7	5	38.60 (7.71)			
Change from baseline to week 24	5	4	-3.68 (8.53) -2.56 (3.66)	7	5	2.34 (4.37) 0.20 (3.08)	2.76 [-7.23; 12.75]	0.5761	0.31 [-0.84; 1.47]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in PROMIS Short Form v2.0 Upper Extremity 7a - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	5	40.62 (11.89)		5	5	45.88 (9.67)					
Week 24	4	4	38.42 (13.55)		5	3	38.08 (7.83)					
Change from baseline to week 24	4	4	-4.10 (8.21)	-3.15 (3.83)	5	3	-1.96 (4.20)	-1.56 (4.30)	1.59 [-9.82; 12.99]	0.7780	0.17 [-1.22; 1.56]	0.8034
low titer												
Baseline	3	2	34.54 (10.65)		12	12	36.58 (6.94)					
Week 24	2	2	39.61 (5.86)		12	11	42.28 (9.21)					
Change from baseline to week 24	2	1	1.70 (NA)	0.76 (6.82)	12	11	5.51 (7.96)	3.87 (2.40)	3.11 [-11.85; 18.08]	0.6735	0.34 [-1.16; 1.85]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

42: Change from baseline to week 24 in PROMIS Short Form v2.0 Upper Extremity 7a - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)		
	N n	Mean (SD)	CSE (SE)	N n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI] p-value interact.
All subjects (Total)									
total									
Baseline	10 4	41.08 (11.43)		12 7	41.31 (10.46)				
Week 24	8 6	36.30 (7.50)		11 8	45.60 (11.39)				
Change from baseline to week 24	8 3	-4.62 (3.16)	-4.42 (3.36)	11 6	0.95 (4.91)	1.70 (2.78)	6.12 [-5.40; 17.64]	0.2141	0.83 [-0.61; 2.27]
Age									
< 18 years									
Baseline	5 3	42.66 (13.45)		6 4	43.78 (10.96)				
Week 24	5 4	37.19 (8.74)		6 5	46.19 (12.52)				
Change from baseline to week 24	5 3	-4.62 (3.16)	-4.65 (3.57)	6 4	-0.59 (2.10)	-0.89 (4.67)	3.76 [NE; NE]	NE	0.39 [-1.13; 1.90] NE
>= 18 years									
Baseline	5 1	36.34 (NA)		6 3	38.01 (10.94)				
Week 24	3 2	34.53 (6.55)		5 3	44.62 (11.75)				
Change from baseline to week 24	3 0	NA (NA)	NE (NE)	5 2	4.03 (8.89)	4.15 (4.76)	NE [NE; NE]	NE	NE [NE; NE]

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

43: Change from baseline to week 24 in SF-36v2 general health - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	30.36 (4.25)		17	17	43.12 (8.52)					
Week 24	6	6	30.20 (4.77)		17	15	48.75 (9.10)					
Change from baseline to week 24	6	4	-2.38 (7.00)	-5.17 (4.11)	17	15	6.66 (6.76)	7.50 (1.90)	12.67 [2.99; 22.36]	0.0118	1.50 [0.41; 2.59]	
Age												
< 18 years												
Baseline	1	1	23.71 (NA)		10	10	45.53 (6.79)					
Week 24	1	1	30.84 (NA)		10	9	50.39 (8.54)					
Change from baseline to week 24	1	1	7.13 (NA)	3.51 (8.46)	10	9	5.18 (5.61)	6.92 (2.69)	3.40 [-15.92; 22.72]	0.7208	0.37 [-1.70; 2.43]	0.5709
>= 18 years												
Baseline	8	4	32.03 (2.38)		7	7	39.67 (10.04)					
Week 24	5	5	30.08 (5.32)		7	6	46.29 (10.15)					
Change from baseline to week 24	5	3	-5.55 (3.63)	-6.84 (4.47)	7	6	8.88 (8.24)	7.93 (2.94)	14.78 [4.09; 25.46]	0.0085	1.65 [0.24; 3.06]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 general health - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	30.05 (5.98)		5	5	43.96 (12.93)					
Week 24	4	4	29.06 (2.28)		5	3	52.39 (12.20)					
Change from baseline to week 24	4	3	-1.59 (8.35)	-4.19 (4.81)	5	3	13.00 (4.15)	13.64 (3.89)	17.83 [5.01; 30.66]	0.0082	1.81 [0.13; 3.49]	0.5533
low titer												
Baseline	3	2	30.84 (0.00)		12	12	42.77 (6.66)					
Week 24	2	2	32.50 (9.08)		12	12	47.84 (8.58)					
Change from baseline to week 24	2	1	-4.76 (NA)	-8.05 (6.71)	12	12	5.07 (6.43)	5.54 (2.22)	13.59 [-1.18; 28.35]	0.0697	1.62 [0.01; 3.23]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

44: Change from baseline to week 24 in SF-36v2 general health - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) CSE (SE)	N	n	Mean (SD) CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	40.06 (8.43)	12	7	41.23 (9.14)				
Week 24	8	6	38.68 (9.77)	11	9	51.39 (9.15)				
Change from baseline to week 24	8	3	-0.48 (6.86) 1.82 (3.78)	11	6	7.13 (8.99) 7.72 (2.79)	5.90 [-5.49; 17.29]	0.2520	0.75 [-0.56; 2.06]	
Age										
< 18 years										
Baseline	5	3	42.73 (10.36)	6	4	45.22 (9.30)				
Week 24	5	4	38.80 (7.55)	6	5	56.14 (5.16)				
Change from baseline to week 24	5	3	-0.48 (6.86) 0.87 (3.74)	6	4	9.87 (8.79) 13.91 (4.02)	13.04 [NE; NE]	NE	1.47 [-0.21; 3.16]	NE
>= 18 years										
Baseline	5	2	36.07 (4.03)	6	3	35.91 (6.83)				
Week 24	3	2	38.44 (17.49)	5	4	45.46 (10.16)				
Change from baseline to week 24	3	0	NA (NA) NE (NE)	5	2	1.66 (9.08) -1.82 (5.05)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

45: Change from baseline to week 24 in SF-36v2 mental health - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	41.97 (8.60)		17	17	44.56 (10.87)					
Week 24	6	6	43.02 (9.79)		17	15	50.00 (8.60)					
Change from baseline to week 24	6	4	-3.92 (11.41)	-4.40 (3.75)	17	15	4.19 (9.32)	5.69 (1.93)	10.09 [1.46; 18.73]	0.0233	1.21 [0.15; 2.26]	
Age												
< 18 years												
Baseline	1	1	40.40 (NA)		10	10	44.33 (10.91)					
Week 24	1	1	50.87 (NA)		10	9	50.87 (8.58)					
Change from baseline to week 24	1	1	10.47 (NA)	8.72 (7.00)	10	9	6.10 (10.05)	7.38 (2.32)	-1.34 [-16.60; 13.93]	0.8588	-0.17 [-2.22; 1.89]	0.1255
>= 18 years												
Baseline	8	4	42.37 (9.88)		7	7	44.89 (11.67)					
Week 24	5	5	41.45 (10.06)		7	6	48.69 (9.27)					
Change from baseline to week 24	5	3	-8.72 (7.55)	-8.53 (3.98)	7	6	1.31 (8.06)	3.17 (2.83)	11.70 [1.77; 21.63]	0.0227	1.40 [0.04; 2.76]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 mental health - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	41.28 (9.19)		5	5	43.54 (13.52)					
Week 24	4	4	40.41 (7.70)		5	3	53.49 (9.06)					
Change from baseline to week 24	4	3	-0.87 (11.80)	-1.71 (4.52)	5	3	4.36 (6.58)	8.56 (4.31)	10.28 [-2.26; 22.82]	0.1042	0.99 [-0.52; 2.50]	0.7888
low titer												
Baseline	3	2	43.02 (11.10)		12	12	44.98 (10.23)					
Week 24	2	2	48.25 (14.80)		12	12	49.12 (8.66)					
Change from baseline to week 24	2	1	-13.08 (NA)	-8.72 (7.31)	12	12	4.14 (10.13)	4.39 (2.24)	13.11 [-2.61; 28.84]	0.0986	1.53 [-0.07; 3.13]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

46: Change from baseline to week 24 in SF-36v2 mental health - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	5	44.06 (6.02)		12	7	50.12 (4.71)					
Week 24	8	6	41.71 (10.30)		11	9	49.42 (8.39)					
Change from baseline to week 24	8	3	-8.72 (12.90)	-5.46 (5.38)	11	6	0.00 (10.06)	8.61 (6.17)	14.08 [-2.47; 30.62]	0.0826	0.93 [-0.40; 2.26]	
Age												
< 18 years												
Baseline	5	3	48.25 (0.00)		6	4	52.83 (3.29)					
Week 24	5	4	43.02 (12.63)		6	5	52.44 (8.40)					
Change from baseline to week 24	5	3	-8.72 (12.90)	-5.71 (6.02)	6	4	-1.30 (11.00)	11.98 (10.64)	17.69 [NE; NE]	NE	0.84 [-0.72; 2.40]	NE
>= 18 years												
Baseline	5	2	37.78 (3.70)		6	3	46.51 (4.00)					
Week 24	3	2	39.09 (5.55)		5	4	45.64 (7.70)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	2.62 (11.09)	5.80 (7.80)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

47: Change from baseline to week 24 in SF-36v2 role emotional - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	36.67 (5.83)		17	17	42.04 (10.48)					
Week 24	6	6	40.50 (11.18)		17	15	47.12 (9.74)					
Change from baseline to week 24	6	4	-2.61 (3.34)	-2.75 (4.11)	17	15	5.34 (8.72)	5.11 (2.06)	7.86 [-1.62; 17.33]	0.1011	0.88 [-0.15; 1.91]	
Age												
< 18 years												
Baseline	1	1	42.24 (NA)		10	10	43.63 (11.74)					
Week 24	1	1	42.24 (NA)		10	9	48.04 (10.45)					
Change from baseline to week 24	1	1	0.00 (NA)	2.35 (8.14)	10	9	4.64 (10.15)	4.81 (2.78)	2.46 [-15.28; 20.20]	0.7782	0.26 [-1.80; 2.31]	0.6454
>= 18 years												
Baseline	8	4	35.28 (5.69)		7	7	39.75 (8.70)					
Week 24	5	5	40.15 (12.46)		7	6	45.72 (9.34)					
Change from baseline to week 24	5	3	-3.48 (3.49)	-4.39 (4.83)	7	6	6.38 (6.76)	5.50 (3.28)	9.89 [-1.94; 21.71]	0.0976	1.00 [-0.30; 2.30]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 role emotional - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	37.60 (8.04)		5	5	44.33 (10.33)					
Week 24	4	4	39.63 (8.70)		5	3	45.72 (9.21)					
Change from baseline to week 24	4	3	-1.16 (2.01)	-1.02 (4.84)	5	3	1.16 (5.32)	3.11 (4.75)	4.12 [-9.53; 17.78]	0.5408	0.36 [-1.08; 1.80]	0.6158
low titer												
Baseline	3	2	35.28 (0.00)		12	12	41.08 (10.84)					
Week 24	2	2	42.24 (19.70)		12	12	47.46 (10.23)					
Change from baseline to week 24	2	1	-6.97 (NA)	-9.05 (8.07)	12	12	6.38 (9.25)	5.82 (2.40)	14.87 [-2.53; 32.28]	0.0909	1.62 [0.01; 3.23]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

48: Change from baseline to week 24 in SF-36v2 role emotional - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) CSE (SE)	N	n	Mean (SD) CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	38.06 (10.56)	12	7	43.23 (12.01)				
Week 24	8	6	42.24 (7.63)	11	9	49.21 (9.05)				
Change from baseline to week 24	8	3	0.00 (12.56) 0.31 (3.10)	11	6	4.07 (5.13) 3.84 (3.02)	3.53 [-7.06; 14.11]	0.4461	0.46 [-0.82; 1.74]	
Age										
< 18 years										
Baseline	5	3	39.92 (14.50)	6	4	44.85 (11.85)				
Week 24	5	4	43.11 (8.70)	6	5	51.30 (9.08)				
Change from baseline to week 24	5	3	0.00 (12.56) 0.39 (3.59)	6	4	6.10 (4.38) 1.60 (4.83)	1.22 [NE; NE]	NE	0.12 [-1.38; 1.62]	NE
>= 18 years										
Baseline	5	2	35.28 (0.00)	6	3	41.08 (14.50)				
Week 24	3	2	40.50 (7.38)	5	4	46.59 (9.59)				
Change from baseline to week 24	3	0	NA (NA) NE (NE)	5	2	0.00 (4.92) 5.44 (4.87)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

49: Change from baseline to week 24 in SF-36v2 role physical - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	36.50 (8.31)		17	17	40.65 (6.87)					
Week 24	6	6	38.44 (8.36)		17	15	46.98 (9.02)					
Change from baseline to week 24	6	4	1.69 (4.63)	-1.01 (4.06)	17	15	6.59 (9.55)	6.63 (1.93)	7.65 [-1.63; 16.92]	0.1032	0.90 [-0.14; 1.93]	
Age												
< 18 years												
Baseline	1	1	34.70 (NA)		10	10	40.77 (6.95)					
Week 24	1	1	36.95 (NA)		10	9	47.43 (9.26)					
Change from baseline to week 24	1	1	2.25 (NA)	-0.20 (7.95)	10	9	6.74 (9.26)	7.39 (2.59)	7.58 [-9.72; 24.88]	0.3765	0.85 [-1.24; 2.93]	0.3678
>= 18 years												
Baseline	8	4	36.95 (9.53)		7	7	40.47 (7.32)					
Week 24	5	5	38.74 (9.31)		7	6	46.30 (9.47)					
Change from baseline to week 24	5	3	1.50 (5.65)	-0.94 (4.68)	7	6	6.36 (10.86)	5.46 (3.11)	6.41 [-5.18; 17.99]	0.2667	0.68 [-0.58; 1.94]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 role physical - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	32.45 (3.89)		5	5	36.95 (7.28)					
Week 24	4	4	34.14 (4.63)		5	3	46.68 (7.22)					
Change from baseline to week 24	4	3	0.00 (3.89)	-2.85 (5.03)	5	3	13.47 (0.01)	9.65 (4.39)	12.50 [-0.03; 25.03]	0.0506	1.15 [-0.39; 2.69]	0.0922
low titer												
Baseline	3	2	42.56 (11.12)		12	12	42.19 (6.37)					
Week 24	2	2	47.05 (7.93)		12	12	47.05 (9.69)					
Change from baseline to week 24	2	1	6.74 (NA)	8.99 (7.19)	12	12	4.87 (9.99)	5.77 (2.39)	-3.22 [-18.95; 12.52]	0.6783	-0.36 [-1.86; 1.15]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

50: Change from baseline to week 24 in SF-36v2 role physical - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	39.19 (4.76)	12	7	41.44 (10.21)				
Week 24	8	6	37.32 (7.02)	11	9	48.92 (7.10)				
Change from baseline to week 24	8	3	4.49 (7.78) 3.45 (3.12)	11	6	2.99 (1.83) 3.60 (2.61)	0.15 [-10.39; 10.69]	0.9734	0.02 [-1.24; 1.29]	
Age										
< 18 years										
Baseline	5	3	36.95 (3.89)	6	4	47.05 (8.30)				
Week 24	5	4	38.63 (7.86)	6	5	51.32 (7.21)				
Change from baseline to week 24	5	3	4.49 (7.78) 5.20 (2.77)	6	4	2.81 (2.15) -1.88 (5.71)	-7.09 [NE; NE]	NE	-0.64 [-2.17; 0.90]	NE
>= 18 years										
Baseline	5	2	42.56 (4.77)	6	3	33.95 (7.89)				
Week 24	3	2	34.70 (6.35)	5	4	45.93 (6.61)				
Change from baseline to week 24	3	0	NA (NA) NE (NE)	5	2	3.37 (1.58) 6.32 (3.97)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

51: Change from baseline to week 24 in SF-36v2 social function - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	36.28 (4.20)		17	17	42.59 (8.02)					
Week 24	6	6	38.96 (13.70)		17	15	45.64 (9.02)					
Change from baseline to week 24	6	4	-1.26 (13.18)	-3.71 (4.42)	17	15	3.01 (8.22)	3.35 (2.17)	7.06 [-3.23; 17.36]	0.1725	0.74 [-0.28; 1.76]	
Age												
< 18 years												
Baseline	1	1	32.27 (NA)		10	10	44.31 (7.91)					
Week 24	1	1	42.30 (NA)		10	9	46.20 (7.84)					
Change from baseline to week 24	1	1	10.03 (NA)	7.36 (8.36)	10	9	2.78 (9.74)	3.41 (2.73)	-3.95 [-22.39; 14.49]	0.6637	-0.42 [-2.48; 1.65]	0.1036
>= 18 years												
Baseline	8	4	37.29 (4.09)		7	7	40.15 (8.11)					
Week 24	5	5	38.29 (15.21)		7	6	44.81 (11.32)					
Change from baseline to week 24	5	3	-5.02 (13.26)	-7.02 (4.69)	7	6	3.34 (6.07)	2.89 (3.20)	9.91 [-1.74; 21.56]	0.0923	1.03 [-0.27; 2.33]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 social function - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	33.94 (2.90)		5	5	37.29 (10.03)					
Week 24	4	4	33.53 (13.81)		5	3	40.63 (7.66)					
Change from baseline to week 24	4	3	-5.01 (13.27)	-7.71 (5.46)	5	3	6.68 (2.90)	4.57 (5.08)	12.28 [-1.45; 26.00]	0.0774	0.99 [-0.52; 2.50]	0.6242
low titer												
Baseline	3	2	39.80 (3.54)		12	12	44.81 (6.23)					
Week 24	2	2	49.82 (3.55)		12	12	46.89 (9.19)					
Change from baseline to week 24	2	1	10.02 (NA)	7.24 (8.07)	12	12	2.09 (8.93)	3.44 (2.73)	-3.80 [-21.63; 14.03]	0.6651	-0.37 [-1.87; 1.13]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

52: Change from baseline to week 24 in SF-36v2 social function - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	5	38.29 (8.97)		12	7	46.60 (9.79)					
Week 24	8	6	43.14 (9.73)		11	9	48.43 (9.64)					
Change from baseline to week 24	8	3	10.03 (8.68)	11.46 (6.22)	11	6	0.00 (8.39)	0.87 (5.03)	-10.59 [-32.61; 11.42]	0.2836	-0.77 [-2.08; 0.54]	
Age												
< 18 years												
Baseline	5	3	33.95 (5.79)		6	4	51.07 (7.52)					
Week 24	5	4	41.05 (8.56)		6	5	48.31 (10.28)					
Change from baseline to week 24	5	3	10.03 (8.68)	7.64 (8.04)	6	4	-2.51 (9.60)	3.44 (8.79)	-4.20 [NE; NE]	NE	-0.22 [-1.72; 1.28]	NE
>= 18 years												
Baseline	5	2	44.81 (10.63)		6	3	40.63 (10.44)					
Week 24	3	2	47.31 (14.18)		5	4	48.57 (10.33)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	5.01 (0.00)	2.30 (8.59)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

53: Change from baseline to week 24 in SF-36v2 vitality - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	43.09 (6.44)		17	17	48.23 (8.79)					
Week 24	6	6	44.18 (8.49)		17	15	52.00 (8.86)					
Change from baseline to week 24	6	4	-2.97 (4.20)	-4.18 (3.93)	17	15	3.56 (9.86)	4.77 (2.00)	8.95 [-0.09; 18.00]	0.0523	1.03 [-0.01; 2.07]	
Age												
< 18 years												
Baseline	1	1	46.66 (NA)		10	10	51.71 (8.97)					
Week 24	1	1	46.66 (NA)		10	9	53.92 (7.14)					
Change from baseline to week 24	1	1	0.00 (NA)	-0.09 (8.18)	10	9	1.32 (11.42)	5.70 (2.98)	5.79 [-12.07; 23.66]	0.5112	0.56 [-1.51; 2.63]	0.7348
>= 18 years												
Baseline	8	4	42.20 (7.08)		7	7	43.26 (6.05)					
Week 24	5	5	43.69 (9.40)		7	6	49.13 (11.02)					
Change from baseline to week 24	5	3	-3.96 (4.54)	-5.85 (4.67)	7	6	6.93 (6.42)	3.63 (3.44)	9.48 [-2.09; 21.05]	0.1044	0.94 [-0.35; 2.23]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 vitality - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	43.69 (7.86)		5	5	48.44 (9.99)					
Week 24	4	4	42.20 (5.69)		5	3	52.60 (12.95)					
Change from baseline to week 24	4	3	-0.99 (1.71)	-2.88 (4.84)	5	3	2.97 (2.97)	5.20 (4.67)	8.08 [-5.42; 21.58]	0.2301	0.72 [-0.76; 2.19]	0.8672
low titer												
Baseline	3	2	42.20 (6.31)		12	12	48.14 (8.73)					
Week 24	2	2	48.14 (14.71)		12	12	51.86 (8.32)					
Change from baseline to week 24	2	1	-8.92 (NA)	-9.20 (7.77)	12	12	3.71 (11.05)	4.30 (2.41)	13.50 [-3.27; 30.27]	0.1102	1.47 [-0.12; 3.06]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

54: Change from baseline to week 24 in SF-36v2 vitality - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	50.82 (7.74)	12	7	47.51 (8.35)				
Week 24	8	6	45.17 (10.08)	11	9	51.61 (8.00)				
Change from baseline to week 24	8	3	-6.93 (9.07) / -5.55 (4.92)	11	6	3.46 (9.84) / 3.38 (3.81)	8.93 [-6.33; 24.19]	0.2023	0.85 [-0.47; 2.17]	
Age										
< 18 years										
Baseline	5	3	53.59 (9.55)	6	4	52.60 (7.27)				
Week 24	5	4	48.89 (7.82)	6	5	54.98 (6.77)				
Change from baseline to week 24	5	3	-6.93 (9.07) / -2.63 (6.21)	6	4	2.23 (11.47) / 5.32 (5.91)	7.95 [NE; NE]	NE	0.59 [-0.94; 2.11]	NE
>= 18 years										
Baseline	5	2	46.66 (0.00)	6	3	40.72 (2.98)				
Week 24	3	2	37.74 (12.61)	5	4	47.40 (8.18)				
Change from baseline to week 24	3	0	NA (NA) / NE (NE)	5	2	5.94 (8.40) / -1.24 (8.49)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

55: Change from baseline to week 24 in SF-36v2 mental component score - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	41.81 (6.28)		17	17	45.84 (9.52)					
Week 24	6	6	43.74 (11.47)		17	15	49.55 (9.36)					
Change from baseline to week 24	6	4	-4.90 (8.69)	-5.11 (3.48)	17	15	3.23 (8.16)	3.52 (1.77)	8.63 [0.61; 16.65]	0.0356	1.13 [0.07; 2.18]	
Age												
< 18 years												
Baseline	1	1	43.33 (NA)		10	10	47.50 (9.91)					
Week 24	1	1	49.39 (NA)		10	9	50.34 (7.69)					
Change from baseline to week 24	1	1	6.06 (NA)	6.37 (6.73)	10	9	3.02 (9.77)	3.66 (2.29)	-2.71 [-17.43; 12.00]	0.7082	-0.34 [-2.40; 1.72]	0.4356
>= 18 years												
Baseline	8	4	41.44 (7.18)		7	7	43.46 (9.11)					
Week 24	5	5	42.61 (12.45)		7	6	48.38 (12.17)					
Change from baseline to week 24	5	3	-8.55 (5.76)	-8.77 (3.92)	7	6	3.56 (5.77)	3.36 (2.71)	12.14 [2.44; 21.83]	0.0161	1.50 [0.12; 2.88]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 mental component score - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	42.44 (7.84)		5	5	46.71 (11.93)					
Week 24	4	4	42.48 (8.27)		5	3	50.45 (10.48)					
Change from baseline to week 24	4	3	-2.08 (8.10)	-2.08 (4.20)	5	3	0.75 (3.84)	3.36 (4.18)	5.44 [-6.50; 17.38]	0.3580	0.54 [-0.91; 2.00]	0.8849
low titer												
Baseline	3	2	40.87 (5.63)		12	12	45.47 (8.91)					
Week 24	2	2	46.24 (20.84)		12	12	49.33 (9.55)					
Change from baseline to week 24	2	1	-13.34 (NA)	-13.36 (6.95)	12	12	3.85 (8.94)	3.62 (2.09)	16.98 [1.99; 31.97]	0.0279	2.13 [0.43; 3.82]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

56: Change from baseline to week 24 in SF-36v2 mental component score - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	44.35 (4.34)	12	7	50.71 (5.81)				
Week 24	8	6	46.19 (8.73)	11	9	50.86 (10.89)				
Change from baseline to week 24	8	3	-4.47 (9.62) / -4.40 (5.19)	11	6	1.07 (9.61) / -1.98 (7.40)	2.42 [-19.16; 24.00]	0.7931	0.14 [-1.13; 1.41]	
Age										
< 18 years										
Baseline	5	3	47.28 (2.24)	6	4	52.67 (4.30)				
Week 24	5	4	46.65 (10.31)	6	5	52.41 (11.15)				
Change from baseline to week 24	5	3	-4.47 (9.62) / -4.31 (6.29)	6	4	0.15 (10.88) / -5.77 (10.35)	-1.46 [NE; NE]	NE	-0.07 [-1.57; 1.43]	NE
>= 18 years										
Baseline	5	2	39.96 (0.91)	6	3	48.09 (7.46)				
Week 24	3	2	45.25 (7.74)	5	4	48.93 (11.89)				
Change from baseline to week 24	3	0	NA (NA) / NE (NE)	5	2	2.91 (9.82) / 1.46 (10.30)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

57: Change from baseline to week 24 in SF-36v2 physical component score - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	33.97 (4.39)		17	17	40.98 (7.98)					
Week 24	6	6	35.69 (8.22)		17	15	47.55 (9.97)					
Change from baseline to week 24	6	4	2.77 (8.18)	2.27 (3.56)	17	15	7.09 (7.51)	7.38 (1.73)	5.11 [-3.15; 13.38]	0.2174	0.67 [-0.34; 1.69]	
Age												
< 18 years												
Baseline	1	1	31.08 (NA)		10	10	41.90 (6.43)					
Week 24	1	1	33.70 (NA)		10	9	49.35 (5.72)					
Change from baseline to week 24	1	1	2.62 (NA)	1.21 (6.88)	10	9	7.35 (7.31)	8.37 (2.25)	7.16 [-7.98; 22.30]	0.3404	0.92 [-1.17; 3.01]	0.1033
>= 18 years												
Baseline	8	4	34.69 (4.71)		7	7	39.67 (10.22)					
Week 24	5	5	36.09 (9.12)		7	6	44.84 (14.54)					
Change from baseline to week 24	5	3	2.82 (10.02)	2.70 (3.88)	7	6	6.71 (8.48)	6.00 (2.64)	3.29 [-6.30; 12.89]	0.4872	0.42 [-0.82; 1.66]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 physical component score - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	31.40 (1.65)		5	5	37.31 (8.44)					
Week 24	4	4	30.81 (3.09)		5	3	45.55 (8.43)					
Change from baseline to week 24	4	3	-1.10 (3.24)	-1.82 (4.21)	5	3	13.30 (3.40)	11.55 (3.67)	13.38 [2.78; 23.97]	0.0153	1.47 [-0.13; 3.07]	0.0795
low titer												
Baseline	3	2	37.82 (4.70)		12	12	42.51 (7.62)					
Week 24	2	2	45.44 (4.86)		12	12	48.05 (10.59)					
Change from baseline to week 24	2	1	14.38 (NA)	14.78 (6.00)	12	12	5.54 (7.52)	5.92 (2.03)	-8.86 [-22.06; 4.34]	0.1797	-1.16 [-2.71; 0.40]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

58: Change from baseline to week 24 in SF-36v2 physical component score - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) CSE (SE)	N	n	Mean (SD) CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	38.55 (6.65)	12	7	38.45 (9.97)				
Week 24	8	6	35.78 (10.45)	11	9	47.91 (10.95)				
Change from baseline to week 24	8	3	5.14 (6.64) 4.76 (3.02)	11	6	4.56 (3.51) 4.64 (2.19)	-0.12 [-9.35; 9.11]	0.9755	-0.02 [-1.28; 1.25]	
Age										
< 18 years										
Baseline	5	3	36.68 (1.66)	6	4	44.52 (8.52)				
Week 24	5	4	37.39 (10.78)	6	5	52.11 (9.59)				
Change from baseline to week 24	5	3	5.14 (6.64) NE (NE)	6	4	5.51 (2.83) NE (NE)	NE [NE; NE]	NE	NE [NE; NE]	NE
>= 18 years										
Baseline	5	2	41.36 (12.05)	6	3	30.34 (4.13)				
Week 24	3	2	32.58 (12.90)	5	4	42.66 (11.45)				
Change from baseline to week 24	3	0	NA (NA) NE (NE)	5	2	2.67 (5.19) NE (NE)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

59: Change from baseline to week 24 in SF-36v2 bodily pain - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	9	5	37.64 (6.10)		17	17	42.26 (9.47)					
Week 24	6	6	39.29 (6.22)		17	15	52.40 (10.01)					
Change from baseline to week 24	6	4	2.12 (9.80)	-0.58 (4.42)	17	15	11.45 (9.24)	11.11 (2.20)	11.68 [1.60; 21.77]	0.0244	1.21 [0.15; 2.27]	
Age												
< 18 years												
Baseline	1	1	34.58 (NA)		10	10	43.57 (10.99)					
Week 24	1	1	34.58 (NA)		10	9	56.17 (7.04)					
Change from baseline to week 24	1	1	0.00 (NA)	-4.09 (8.64)	10	9	14.65 (8.35)	14.69 (2.83)	18.78 [-0.02; 37.58]	0.0502	1.92 [-0.29; 4.12]	0.3855
>= 18 years												
Baseline	8	4	38.41 (6.75)		7	7	40.40 (7.16)					
Week 24	5	5	40.23 (6.46)		7	6	46.74 (11.70)					
Change from baseline to week 24	5	3	2.83 (11.88)	-0.10 (4.89)	7	6	6.65 (9.01)	6.06 (3.37)	6.16 [-5.91; 18.23]	0.3042	0.61 [-0.64; 1.87]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 bodily pain - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	37.13 (2.22)		5	5	42.24 (11.55)					
Week 24	4	4	35.39 (1.89)		5	3	49.23 (11.99)					
Change from baseline to week 24	4	3	-2.69 (2.33)	-4.98 (5.31)	5	3	13.57 (12.57)	9.32 (4.89)	14.31 [0.03; 28.59]	0.0496	1.20 [-0.35; 2.74]	0.3479
low titer												
Baseline	3	2	38.41 (11.70)		12	12	42.27 (9.06)					
Week 24	2	2	47.08 (0.57)		12	12	53.19 (9.89)					
Change from baseline to week 24	2	1	16.54 (NA)	12.46 (8.49)	12	12	10.92 (8.85)	11.63 (2.62)	-0.83 [-19.16; 17.49]	0.9264	-0.08 [-1.58; 1.41]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

60: Change from baseline to week 24 in SF-36v2 bodily pain - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) CSE (SE)	N	n	Mean (SD) CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	10	5	37.48 (4.53)	12	7	47.08 (9.49)				
Week 24	8	6	40.70 (9.65)	11	9	51.69 (11.14)				
Change from baseline to week 24	8	3	4.70 (12.50) 4.82 (5.71)	11	6	3.76 (6.88) 3.74 (3.95)	-1.08 [-19.02; 16.86]	0.8878	-0.09 [-1.36; 1.17]	
Age										
< 18 years										
Baseline	5	3	38.21 (0.00)	6	4	52.62 (7.58)				
Week 24	5	4	41.84 (10.43)	6	5	58.13 (8.66)				
Change from baseline to week 24	5	3	4.70 (12.50) 2.73 (8.09)	6	4	4.54 (8.62) 7.96 (9.89)	5.23 [NE; NE]	NE	0.25 [-1.25; 1.75]	NE
>= 18 years										
Baseline	5	2	36.39 (8.84)	6	3	39.69 (6.38)				
Week 24	3	2	38.41 (11.12)	5	4	43.65 (8.71)				
Change from baseline to week 24	3	0	NA (NA) NE (NE)	5	2	2.21 (2.57) -1.12 (11.12)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

61: Change from baseline to week 24 in SF-36v2 physical functioning - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD) / CSE (SE)	N	n	Mean (SD) / CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)										
total										
Baseline	9	5	34.19 (8.05)	17	17	39.87 (10.30)				
Week 24	6	6	37.77 (11.72)	17	15	44.14 (11.51)				
Change from baseline to week 24	6	4	1.91 (8.26) / 0.70 (4.13)	17	15	3.19 (7.22) / 4.65 (2.18)	3.94 [-5.66; 13.55]	0.4104	0.42 [-0.58; 1.43]	
Age										
< 18 years										
Baseline	1	1	36.49 (NA)	10	10	39.93 (9.62)				
Week 24	1	1	42.23 (NA)	10	9	44.99 (10.40)				
Change from baseline to week 24	1	1	5.74 (NA) / 4.48 (8.25)	10	9	2.98 (8.13) / 5.38 (2.75)	0.90 [-17.06; 18.86]	0.9187	0.09 [-1.96; 2.15]	0.2469
>= 18 years										
Baseline	8	4	33.62 (9.18)	7	7	39.77 (11.99)				
Week 24	5	5	36.87 (12.87)	7	6	42.87 (13.94)				
Change from baseline to week 24	5	3	0.64 (9.63) / -0.11 (4.55)	7	6	3.51 (6.34) / 3.52 (3.25)	3.63 [-7.87; 15.13]	0.5224	0.38 [-0.86; 1.62]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

Change from baseline to week 24 in SF-36v2 physical functioning - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)				Concizumab PPX (arm 2)				Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
Disease severity												
high titer												
Baseline	6	3	32.02 (6.15)		5	5	34.19 (11.35)					
Week 24	4	4	31.70 (7.73)		5	3	40.95 (7.97)					
Change from baseline to week 24	4	3	-0.64 (7.96)	-2.77 (5.27)	5	3	5.10 (5.85)	5.92 (4.55)	8.69 [-4.92; 22.30]	0.2012	0.77 [-0.71; 2.25]	0.6796
low titer												
Baseline	3	2	37.44 (12.18)		12	12	42.23 (9.30)					
Week 24	2	2	49.89 (8.12)		12	12	44.94 (12.39)					
Change from baseline to week 24	2	1	9.57 (NA)	8.41 (7.80)	12	12	2.71 (7.67)	3.81 (2.65)	-4.61 [-21.34; 12.13]	0.5767	-0.46 [-1.97; 1.04]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

62: Change from baseline to week 24 in SF-36v2 physical functioning - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)			Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n	Mean (SD)	CSE (SE)	N	n	Mean (SD)	CSE (SE)	DE [95% CI]	p-value	Hedges' g [95% CI]	p-value interact.
All subjects (Total)												
total												
Baseline	10	5	38.40 (12.48)		12	7	34.30 (12.67)					
Week 24	8	6	32.98 (11.83)		11	9	43.08 (12.98)					
Change from baseline to week 24	8	3	1.28 (15.94)	1.10 (4.94)	11	6	2.87 (3.15)	3.46 (3.68)	2.36 [-12.55; 17.26]	0.7121	0.23 [-1.04; 1.50]	
Age												
< 18 years												
Baseline	5	3	36.49 (11.95)		6	4	39.36 (14.78)					
Week 24	5	4	35.53 (12.55)		6	5	45.68 (16.32)					
Change from baseline to week 24	5	3	1.28 (15.94)	1.74 (5.89)	6	4	3.35 (3.62)	9.01 (7.84)	7.26 [NE; NE]	NE	0.44 [-1.07; 1.96]	NE
>= 18 years												
Baseline	5	2	41.27 (17.59)		6	3	27.56 (5.84)					
Week 24	3	2	27.88 (12.18)		5	4	39.84 (8.32)					
Change from baseline to week 24	3	0	NA (NA)	NE (NE)	5	2	1.91 (2.71)	-3.00 (8.86)	NE [NE; NE]	NE	NE [NE; NE]	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, NE: not estimable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation, SE: Standard error, CI: confidence interval,p-value: unadjusted two-sided p-value for test of no difference from X (t-test), p-value int.: unadjusted two-sided p-value for test of no treatment by subgroup interaction (F-test), CSE: Change score estimate, DE: Difference estimate. Change from baseline values have been analysed using a mixed model for repeated measurements (MMRM), with treatment and bleeding frequency prior to screening as factors, and baseline value as a covariate, all nested within week (week 4, 8, 16 and 24). For subgroup analyses the subgroup variable is added as a factor, in addition to the interaction with treatment. A compound symmetry covariance matrix is used to describe the variability for the repeated measurements for a subject. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2).

63: Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	33.33 (11.79)	17	9	37.04 (19.59)
Week 4	8	3	5.56 (9.62)	17	9	46.30 (28.29)
Week 8	8	3	5.56 (9.62)	17	9	41.67 (28.57)
Week 16	6	3	16.67 (16.67)	17	7	30.95 (24.87)
Week 24	6	3	13.89 (4.81)	17	7	35.71 (20.81)
Week 32				17	5	31.67 (25.28)
Age						
< 18 years						
Baseline				10	2	54.17 (29.46)
Week 4				10	2	62.50 (17.68)
Week 8				10	3	72.22 (25.46)
Week 16				10	2	45.83 (5.89)
Week 24				10	1	66.67 (NA)
Week 32				10	2	54.17 (17.68)
>= 18 years						
Baseline	8	5	33.33 (11.79)	7	7	32.14 (15.54)
Week 4	7	3	5.56 (9.62)	7	7	41.67 (30.05)
Week 8	7	3	5.56 (9.62)	7	6	26.39 (14.35)
Week 16	5	3	16.67 (16.67)	7	5	25.00 (27.64)
Week 24	5	3	13.89 (4.81)	7	6	30.56 (17.21)
Week 32				7	3	16.67 (16.67)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	37.50 (8.33)	5	3	38.89 (9.62)
Week 4	5	2	8.33 (11.79)	5	2	41.67 (11.79)
Week 8	5	3	5.56 (9.62)	5	2	41.67 (11.79)
Week 16	4	2	16.67 (23.57)	5	3	25.00 (22.05)
Week 24	4	2	16.67 (0.00)	5	2	29.17 (5.89)
Week 32				5	2	37.50 (5.89)
low titer						
Baseline	3	1	16.67 (NA)	12	6	36.11 (23.96)
Week 4	3	1	0.00 (NA)	12	7	47.62 (32.17)
Week 8				12	7	41.67 (32.63)
Week 16	2	1	16.67 (NA)	12	4	35.42 (29.17)
Week 24	2	1	8.33 (NA)	12	5	38.33 (24.72)
Week 32				12	3	27.78 (34.69)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

64: Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	38.89 (29.27)	12	5	21.67 (13.94)
Week 4	9	1	91.67 (NA)	12	3	27.78 (12.73)
Week 8	9	1	25.00 (NA)	11	3	22.22 (25.46)
Week 16				11	4	22.92 (7.98)
Week 24	8	1	33.33 (NA)	11	3	16.67 (16.67)
Week 32				11	4	22.92 (15.77)
Age						
< 18 years						
Baseline	5	1	41.67 (NA)	6	1	33.33 (NA)
Week 24	5	1	33.33 (NA)			
>= 18 years						
Baseline	5	2	37.50 (41.25)	6	4	18.75 (14.23)
Week 4	4	1	91.67 (NA)	6	3	27.78 (12.73)
Week 8	4	1	25.00 (NA)	5	3	22.22 (25.46)
Week 16				5	4	22.92 (7.98)
Week 24				5	3	16.67 (16.67)
Week 32				5	4	22.92 (15.77)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

65: Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	58.75 (28.50)	17	9	31.94 (24.30)
Week 4	8	3	70.83 (25.26)	17	9	31.25 (32.48)
Week 8	8	3	68.75 (22.53)	17	9	13.89 (31.06)
Week 16	6	3	62.50 (31.25)	17	7	29.46 (33.41)
Week 24	6	3	72.92 (28.18)	17	7	25.00 (30.41)
Week 32				17	5	30.00 (35.19)
Age						
< 18 years						
Baseline				10	2	28.12 (22.10)
Week 4				10	2	12.50 (8.84)
Week 8				10	3	0.00 (0.00)
Week 16				10	2	12.50 (17.68)
Week 24				10	1	25.00 (NA)
Week 32				10	2	18.75 (26.52)
>= 18 years						
Baseline	8	5	58.75 (28.50)	7	7	33.04 (26.45)
Week 4	7	3	70.83 (25.26)	7	7	36.61 (35.25)
Week 8	7	3	68.75 (22.53)	7	6	20.83 (37.01)
Week 16	5	3	62.50 (31.25)	7	5	36.25 (37.34)
Week 24	5	3	72.92 (28.18)	7	6	25.00 (33.31)
Week 32				7	3	37.50 (43.75)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	65.62 (27.72)	5	3	47.92 (37.67)
Week 4	5	2	84.38 (13.26)	5	2	62.50 (35.36)
Week 8	5	3	68.75 (22.53)	5	2	46.88 (66.29)
Week 16	4	2	78.12 (22.10)	5	3	43.75 (47.19)
Week 24	4	2	87.50 (17.68)	5	2	62.50 (35.36)
Week 32				5	2	43.75 (61.87)
low titer						
Baseline	3	1	31.25 (NA)	12	6	23.96 (12.13)
Week 4	3	1	43.75 (NA)	12	7	22.32 (27.92)
Week 8				12	7	4.46 (9.35)
Week 16	2	1	31.25 (NA)	12	4	18.75 (19.76)
Week 24	2	1	43.75 (NA)	12	5	10.00 (9.48)
Week 32				12	3	20.83 (15.73)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

66: Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	52.08 (23.66)	12	5	57.50 (33.19)
Week 4	9	1	0.00 (NA)	12	3	35.42 (19.09)
Week 8	9	1	0.00 (NA)	11	3	33.33 (14.43)
Week 16				11	4	29.69 (21.27)
Week 24	8	1	0.00 (NA)	11	3	29.17 (26.02)
Week 32				11	4	25.00 (22.82)
Age						
< 18 years						
Baseline	5	1	68.75 (NA)	6	1	18.75 (NA)
Week 24	5	1	0.00 (NA)			
>= 18 years						
Baseline	5	2	43.75 (26.52)	6	4	67.19 (29.04)
Week 4	4	1	0.00 (NA)	6	3	35.42 (19.09)
Week 8	4	1	0.00 (NA)	5	3	33.33 (14.43)
Week 16				5	4	29.69 (21.27)
Week 24				5	3	29.17 (26.02)
Week 32				5	4	25.00 (22.82)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

67: Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	54.00 (14.75)	17	9	41.67 (21.21)
Week 4	8	3	63.33 (15.28)	17	9	43.89 (24.97)
Week 8	8	3	63.33 (17.56)	17	9	33.89 (28.04)
Week 16	6	3	61.67 (23.63)	17	7	39.29 (25.57)
Week 24	6	3	61.67 (20.21)	17	7	40.71 (19.67)
Week 32				17	5	44.00 (27.48)
Age						
< 18 years						
Baseline				10	2	17.50 (3.54)
Week 4				10	2	27.50 (24.75)
Week 8				10	3	16.67 (2.89)
Week 16				10	2	22.50 (31.82)
Week 24				10	1	35.00 (NA)
Week 32				10	2	20.00 (21.21)
>= 18 years						
Baseline	8	5	54.00 (14.75)	7	7	48.57 (18.64)
Week 4	7	3	63.33 (15.28)	7	7	48.57 (24.78)
Week 8	7	3	63.33 (17.56)	7	6	42.50 (31.42)
Week 16	5	3	61.67 (23.63)	7	5	46.00 (23.02)
Week 24	5	3	61.67 (20.21)	7	6	41.67 (21.37)
Week 32				7	3	60.00 (18.03)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	60.00 (7.07)	5	3	40.00 (22.91)
Week 4	5	2	70.00 (14.14)	5	2	52.50 (38.89)
Week 8	5	3	63.33 (17.56)	5	2	45.00 (42.43)
Week 16	4	2	75.00 (7.07)	5	3	36.67 (37.53)
Week 24	4	2	72.50 (10.61)	5	2	50.00 (28.28)
Week 32				5	2	42.50 (53.03)
low titer						
Baseline	3	1	30.00 (NA)	12	6	42.50 (22.53)
Week 4	3	1	50.00 (NA)	12	7	41.43 (23.40)
Week 8				12	7	30.71 (26.37)
Week 16	2	1	35.00 (NA)	12	4	41.25 (18.87)
Week 24	2	1	40.00 (NA)	12	5	37.00 (17.89)
Week 32				12	3	45.00 (10.00)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

68: Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	58.33 (23.63)	12	5	64.00 (32.09)
Week 4	9	1	20.00 (NA)	12	3	61.67 (18.93)
Week 8	9	1	25.00 (NA)	11	3	60.00 (13.23)
Week 16				11	4	51.25 (30.65)
Week 24	8	1	30.00 (NA)	11	3	60.00 (35.00)
Week 32				11	4	48.75 (28.39)
Age						
< 18 years						
Baseline	5	1	50.00 (NA)	6	1	10.00 (NA)
Week 24	5	1	30.00 (NA)			
>= 18 years						
Baseline	5	2	62.50 (31.82)	6	4	77.50 (12.58)
Week 4	4	1	20.00 (NA)	6	3	61.67 (18.93)
Week 8	4	1	25.00 (NA)	5	3	60.00 (13.23)
Week 16				5	4	51.25 (30.65)
Week 24				5	3	60.00 (35.00)
Week 32				5	4	48.75 (28.39)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

69: Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	36.67 (22.52)	17	9	16.67 (10.21)
Week 4	8	3	19.44 (17.35)	17	8	11.46 (17.22)
Week 8	8	3	19.44 (12.73)	17	8	11.46 (23.12)
Week 16	6	3	41.67 (14.43)	17	7	19.05 (26.23)
Week 24	6	3	25.00 (16.67)	17	7	17.86 (25.65)
Week 32				17	5	23.33 (23.12)
Age						
< 18 years						
Baseline				10	2	20.83 (5.89)
Week 4				10	1	8.33 (NA)
Week 8				10	2	4.17 (5.89)
Week 16				10	2	16.67 (23.57)
Week 24				10	1	50.00 (NA)
Week 32				10	2	12.50 (17.68)
>= 18 years						
Baseline	8	5	36.67 (22.52)	7	7	15.48 (11.21)
Week 4	7	3	19.44 (17.35)	7	7	11.90 (18.54)
Week 8	7	3	19.44 (12.73)	7	6	13.89 (26.70)
Week 16	5	3	41.67 (14.43)	7	5	20.00 (29.81)
Week 24	5	3	25.00 (16.67)	7	6	12.50 (23.42)
Week 32				7	3	30.56 (26.79)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	39.58 (24.88)	5	3	25.00 (8.33)
Week 4	5	2	12.50 (17.68)	5	2	33.33 (23.57)
Week 8	5	3	19.44 (12.73)	5	2	33.33 (47.14)
Week 16	4	2	37.50 (17.68)	5	3	33.33 (33.33)
Week 24	4	2	25.00 (23.57)	5	2	29.17 (41.25)
Week 32				5	2	20.83 (29.46)
low titer						
Baseline	3	1	25.00 (NA)	12	6	12.50 (8.74)
Week 4	3	1	33.33 (NA)	12	6	4.17 (6.97)
Week 8				12	6	4.17 (6.97)
Week 16	2	1	50.00 (NA)	12	4	8.33 (16.67)
Week 24	2	1	25.00 (NA)	12	5	13.33 (21.73)
Week 32				12	3	25.00 (25.00)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

70: Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	25.00 (22.05)	12	5	45.00 (38.91)
Week 4	9	1	16.67 (NA)	12	3	25.00 (43.30)
Week 8	9	1	0.00 (NA)	11	3	25.00 (43.30)
Week 16				11	4	41.67 (50.00)
Week 24	8	1	0.00 (NA)	11	3	33.33 (38.19)
Week 32				11	4	33.33 (47.14)
Age						
< 18 years						
Baseline	5	1	41.67 (NA)	6	1	25.00 (NA)
Week 24	5	1	0.00 (NA)			
>= 18 years						
Baseline	5	2	16.67 (23.57)	6	4	50.00 (43.03)
Week 4	4	1	16.67 (NA)	6	3	25.00 (43.30)
Week 8	4	1	0.00 (NA)	5	3	25.00 (43.30)
Week 16				5	4	41.67 (50.00)
Week 24				5	3	33.33 (38.19)
Week 32				5	4	33.33 (47.14)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

71: Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	72.00 (9.75)	17	9	47.22 (28.95)
Week 4	8	3	68.33 (14.43)	17	9	36.67 (30.82)
Week 8	8	3	80.00 (18.03)	17	9	30.00 (35.53)
Week 16	6	3	65.00 (21.79)	17	7	41.43 (40.69)
Week 24	6	3	63.33 (12.58)	17	7	32.14 (34.26)
Week 32				17	5	42.00 (33.28)
Age						
< 18 years						
Baseline				10	2	22.50 (3.54)
Week 4				10	2	12.50 (17.68)
Week 8				10	3	10.00 (17.32)
Week 16				10	2	20.00 (0.00)
Week 24				10	1	35.00 (NA)
Week 32				10	2	20.00 (28.28)
>= 18 years						
Baseline	8	5	72.00 (9.75)	7	7	54.29 (29.22)
Week 4	7	3	68.33 (14.43)	7	7	43.57 (31.05)
Week 8	7	3	80.00 (18.03)	7	6	40.00 (39.24)
Week 16	5	3	65.00 (21.79)	7	5	50.00 (46.50)
Week 24	5	3	63.33 (12.58)	7	6	31.67 (37.51)
Week 32				7	3	56.67 (31.75)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	73.75 (10.31)	5	3	48.33 (40.72)
Week 4	5	2	72.50 (17.68)	5	2	70.00 (35.36)
Week 8	5	3	80.00 (18.03)	5	2	62.50 (45.96)
Week 16	4	2	77.50 (3.54)	5	3	53.33 (38.19)
Week 24	4	2	70.00 (7.07)	5	2	45.00 (28.28)
Week 32				5	2	37.50 (53.03)
low titer						
Baseline	3	1	65.00 (NA)	12	6	46.67 (26.01)
Week 4	3	1	60.00 (NA)	12	7	27.14 (24.13)
Week 8				12	7	20.71 (29.64)
Week 16	2	1	40.00 (NA)	12	4	32.50 (45.73)
Week 24	2	1	50.00 (NA)	12	5	27.00 (38.01)
Week 32				12	3	45.00 (27.84)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

72: Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	46.67 (42.52)	12	5	67.00 (16.81)
Week 4	9	1	0.00 (NA)	12	3	50.00 (5.00)
Week 8	9	1	0.00 (NA)	11	3	45.00 (8.66)
Week 16				11	4	31.25 (20.97)
Week 24	8	1	40.00 (NA)	11	3	30.00 (30.00)
Week 32				11	4	26.25 (19.31)
Age						
< 18 years						
Baseline	5	1	45.00 (NA)	6	1	45.00 (NA)
Week 24	5	1	40.00 (NA)			
>= 18 years						
Baseline	5	2	47.50 (60.10)	6	4	72.50 (13.23)
Week 4	4	1	0.00 (NA)	6	3	50.00 (5.00)
Week 8	4	1	0.00 (NA)	5	3	45.00 (8.66)
Week 16				5	4	31.25 (20.97)
Week 24				5	3	30.00 (30.00)
Week 32				5	4	26.25 (19.31)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

73: Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	79.75 (18.12)	17	8	67.03 (17.58)
Week 4	8	3	73.33 (27.54)	17	7	55.89 (31.00)
Week 8	8	3	77.22 (19.74)	17	6	50.00 (29.66)
Week 16	6	3	79.17 (8.78)	17	5	53.75 (33.93)
Week 24	6	3	87.92 (15.83)	17	5	45.25 (22.02)
Week 32				17	3	66.67 (32.53)
Age						
< 18 years						
Baseline				10	2	55.00 (35.36)
Week 4				10	2	27.50 (3.54)
Week 8				10	3	41.67 (34.03)
Week 16				10	2	50.00 (49.50)
Week 24				10	1	35.00 (NA)
Week 32				10	2	50.00 (21.21)
>= 18 years						
Baseline	8	5	79.75 (18.12)	7	6	71.04 (10.26)
Week 4	7	3	73.33 (27.54)	7	5	67.25 (29.56)
Week 8	7	3	77.22 (19.74)	7	3	58.33 (28.87)
Week 16	5	3	79.17 (8.78)	7	3	56.25 (32.48)
Week 24	5	3	87.92 (15.83)	7	4	47.81 (24.55)
Week 32				7	1	100.00 (NA)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	85.94 (13.52)	5	3	73.33 (7.64)
Week 4	5	2	72.50 (38.89)	5	2	75.00 (21.21)
Week 8	5	3	77.22 (19.74)	5	2	77.50 (3.54)
Week 16	4	2	75.00 (7.07)	5	3	78.33 (5.77)
Week 24	4	2	85.00 (21.21)	5	2	65.62 (22.10)
Week 32				5	2	82.50 (24.75)
low titer						
Baseline	3	1	55.00 (NA)	12	5	63.25 (21.53)
Week 4	3	1	75.00 (NA)	12	5	48.25 (32.76)
Week 8				12	4	36.25 (26.58)
Week 16	2	1	87.50 (NA)	12	2	16.88 (2.65)
Week 24	2	1	93.75 (NA)	12	3	31.67 (5.77)
Week 32				12	1	35.00 (NA)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

74: Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	56.67 (32.53)	12	3	81.67 (23.63)
Week 4				12	2	80.00 (7.07)
Week 8				11	2	90.00 (0.00)
Week 16				11	2	82.50 (3.54)
Week 24				11	2	50.00 (70.71)
Week 32				11	2	72.50 (24.75)
Age						
< 18 years						
Baseline	5	1	55.00 (NA)	6	1	55.00 (NA)
>= 18 years						
Baseline	5	2	57.50 (45.96)	6	2	95.00 (7.07)
Week 4				6	2	80.00 (7.07)
Week 8				5	2	90.00 (0.00)
Week 16				5	2	82.50 (3.54)
Week 24				5	2	50.00 (70.71)
Week 32				5	2	72.50 (24.75)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

75: Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	55.52 (13.90)	17	9	40.32 (12.82)
Week 4	8	3	54.31 (17.42)	17	9	38.16 (19.47)
Week 8	8	3	60.59 (12.13)	17	9	31.39 (18.71)
Week 16	6	3	59.57 (10.61)	17	7	35.09 (20.75)
Week 24	6	3	59.30 (14.90)	17	7	31.85 (18.26)
Week 32				17	5	36.92 (21.97)
Age						
< 18 years						
Baseline				10	2	30.71 (1.92)
Week 4				10	2	25.43 (7.85)
Week 8				10	3	27.74 (4.05)
Week 16				10	2	27.72 (9.99)
Week 24				10	1	38.89 (NA)
Week 32				10	2	27.17 (18.45)
>= 18 years						
Baseline	8	5	55.52 (13.90)	7	7	43.07 (13.37)
Week 4	7	3	54.31 (17.42)	7	7	41.80 (20.63)
Week 8	7	3	60.59 (12.13)	7	6	33.21 (23.28)
Week 16	5	3	59.57 (10.61)	7	5	38.04 (24.14)
Week 24	5	3	59.30 (14.90)	7	6	30.68 (19.72)
Week 32				7	3	43.41 (25.24)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	59.74 (11.78)	5	3	44.57 (21.40)
Week 4	5	2	59.76 (20.72)	5	2	53.44 (26.38)
Week 8	5	3	60.59 (12.13)	5	2	49.33 (32.10)
Week 16	4	2	63.74 (10.98)	5	3	42.65 (26.06)
Week 24	4	2	65.78 (13.86)	5	2	47.16 (22.12)
Week 32				5	2	41.66 (38.93)
low titer						
Baseline	3	1	38.64 (NA)	12	6	38.19 (7.96)
Week 4	3	1	43.42 (NA)	12	7	33.80 (17.01)
Week 8				12	7	26.26 (12.54)
Week 16	2	1	51.22 (NA)	12	4	29.42 (17.56)
Week 24	2	1	46.34 (NA)	12	5	25.72 (14.63)
Week 32				12	3	33.76 (13.04)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

76: Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	47.84 (17.62)	12	5	55.93 (21.01)
Week 4	9	1	16.28 (NA)	12	3	44.95 (14.38)
Week 8	9	1	10.47 (NA)	11	3	44.83 (14.26)
Week 16				11	4	39.68 (20.38)
Week 24	8	1	27.03 (NA)	11	3	38.30 (23.68)
Week 32				11	4	36.50 (16.93)
Age						
< 18 years						
Baseline	5	1	52.33 (NA)	6	1	29.35 (NA)
Week 24	5	1	27.03 (NA)			
>= 18 years						
Baseline	5	2	45.59 (24.30)	6	4	62.57 (17.15)
Week 4	4	1	16.28 (NA)	6	3	44.95 (14.38)
Week 8	4	1	10.47 (NA)	5	3	44.83 (14.26)
Week 16				5	4	39.68 (20.38)
Week 24				5	3	38.30 (23.68)
Week 32				5	4	36.50 (16.93)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

77: Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	53.75 (14.89)	17	9	38.54 (21.88)
Week 4	8	3	56.25 (29.81)	17	9	37.15 (26.26)
Week 8	8	3	73.96 (18.04)	17	9	32.64 (25.20)
Week 16	6	3	67.71 (14.77)	17	7	32.59 (25.70)
Week 24	6	3	64.58 (23.45)	17	7	26.79 (19.42)
Week 32				17	5	32.50 (19.47)
Age						
< 18 years						
Baseline				10	2	25.00 (0.00)
Week 4				10	2	20.31 (6.63)
Week 8				10	3	28.12 (24.41)
Week 16				10	2	20.31 (6.63)
Week 24				10	1	31.25 (NA)
Week 32				10	2	25.00 (22.10)
>= 18 years						
Baseline	8	5	53.75 (14.89)	7	7	42.41 (23.65)
Week 4	7	3	56.25 (29.81)	7	7	41.96 (28.12)
Week 8	7	3	73.96 (18.04)	7	6	34.90 (27.56)
Week 16	5	3	67.71 (14.77)	7	5	37.50 (29.56)
Week 24	5	3	64.58 (23.45)	7	6	26.04 (21.16)
Week 32				7	3	37.50 (20.49)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	57.81 (13.62)	5	3	39.58 (30.83)
Week 4	5	2	70.31 (24.31)	5	2	46.88 (35.36)
Week 8	5	3	73.96 (18.04)	5	2	46.88 (44.19)
Week 16	4	2	70.31 (19.89)	5	3	36.46 (36.08)
Week 24	4	2	76.56 (15.47)	5	2	46.88 (17.68)
Week 32				5	2	32.81 (33.15)
low titer						
Baseline	3	1	37.50 (NA)	12	6	38.02 (19.61)
Week 4	3	1	28.12 (NA)	12	7	34.38 (25.90)
Week 8				12	7	28.57 (20.84)
Week 16	2	1	62.50 (NA)	12	4	29.69 (20.65)
Week 24	2	1	40.62 (NA)	12	5	18.75 (14.32)
Week 32				12	3	32.29 (14.43)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

78: Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	46.88 (16.54)	12	5	46.88 (29.89)
Week 4	9	1	0.00 (NA)	12	3	35.42 (17.21)
Week 8	9	1	0.00 (NA)	11	3	26.04 (6.51)
Week 16				11	4	32.03 (25.82)
Week 24	8	1	37.50 (NA)	11	3	27.08 (19.09)
Week 32				11	4	32.03 (10.33)
Age						
< 18 years						
Baseline	5	1	59.38 (NA)	6	1	28.12 (NA)
Week 24	5	1	37.50 (NA)			
>= 18 years						
Baseline	5	2	40.62 (17.68)	6	4	51.56 (32.33)
Week 4	4	1	0.00 (NA)	6	3	35.42 (17.21)
Week 8	4	1	0.00 (NA)	5	3	26.04 (6.51)
Week 16				5	4	32.03 (25.82)
Week 24				5	3	27.08 (19.09)
Week 32				5	4	32.03 (10.33)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

79: Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	68.00 (18.57)	17	9	43.89 (8.94)
Week 4	8	3	65.00 (22.91)	17	9	49.44 (22.70)
Week 8	8	3	75.00 (27.84)	17	9	36.11 (15.37)
Week 16	6	3	73.33 (15.28)	17	7	41.43 (18.19)
Week 24	6	3	81.67 (17.56)	17	7	38.57 (19.73)
Week 32				17	5	47.00 (26.12)
Age						
< 18 years						
Baseline				10	2	37.50 (3.54)
Week 4				10	2	40.00 (0.00)
Week 8				10	3	35.00 (5.00)
Week 16				10	2	35.00 (14.14)
Week 24				10	1	50.00 (NA)
Week 32				10	2	37.50 (24.75)
>= 18 years						
Baseline	8	5	68.00 (18.57)	7	7	45.71 (9.32)
Week 4	7	3	65.00 (22.91)	7	7	52.14 (25.47)
Week 8	7	3	75.00 (27.84)	7	6	36.67 (19.15)
Week 16	5	3	73.33 (15.28)	7	5	44.00 (20.43)
Week 24	5	3	81.67 (17.56)	7	6	36.67 (20.90)
Week 32				7	3	53.33 (30.14)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	73.75 (15.48)	5	3	43.33 (10.41)
Week 4	5	2	75.00 (21.21)	5	2	55.00 (0.00)
Week 8	5	3	75.00 (27.84)	5	2	47.50 (17.68)
Week 16	4	2	80.00 (14.14)	5	3	46.67 (18.93)
Week 24	4	2	90.00 (14.14)	5	2	55.00 (21.21)
Week 32				5	2	52.50 (45.96)
low titer						
Baseline	3	1	45.00 (NA)	12	6	44.17 (9.17)
Week 4	3	1	45.00 (NA)	12	7	47.86 (25.96)
Week 8				12	7	32.86 (14.39)
Week 16	2	1	60.00 (NA)	12	4	37.50 (19.36)
Week 24	2	1	65.00 (NA)	12	5	32.00 (16.81)
Week 32				12	3	43.33 (16.07)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

80: Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	53.33 (15.28)	12	5	59.00 (18.84)
Week 4	9	1	0.00 (NA)	12	3	53.33 (7.64)
Week 8	9	1	15.00 (NA)	11	3	51.67 (18.93)
Week 16				11	4	48.75 (20.97)
Week 24	8	1	25.00 (NA)	11	3	45.00 (22.91)
Week 32				11	4	46.25 (21.75)
Age						
< 18 years						
Baseline	5	1	50.00 (NA)	6	1	30.00 (NA)
Week 24	5	1	25.00 (NA)			
>= 18 years						
Baseline	5	2	55.00 (21.21)	6	4	66.25 (11.09)
Week 4	4	1	0.00 (NA)	6	3	53.33 (7.64)
Week 8	4	1	15.00 (NA)	5	3	51.67 (18.93)
Week 16				5	4	48.75 (20.97)
Week 24				5	3	45.00 (22.91)
Week 32				5	4	46.25 (21.75)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

81: Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	42.50 (19.47)	17	8	41.41 (11.54)
Week 4	8	2	46.88 (4.42)	17	8	34.90 (12.44)
Week 8	8	3	52.08 (15.73)	17	9	34.72 (21.90)
Week 16	6	3	58.33 (7.22)	17	7	24.11 (22.94)
Week 24	6	3	49.31 (16.97)	17	6	30.21 (15.52)
Week 32				17	5	22.92 (22.44)
Age						
< 18 years						
Baseline				10	2	43.75 (8.84)
Week 4				10	2	28.12 (4.42)
Week 8				10	3	52.08 (15.73)
Week 16				10	2	37.50 (35.36)
Week 24				10	1	43.75 (NA)
Week 32				10	2	25.00 (35.36)
>= 18 years						
Baseline	8	5	42.50 (19.47)	7	6	40.62 (12.96)
Week 4	7	2	46.88 (4.42)	7	6	37.15 (13.72)
Week 8	7	3	52.08 (15.73)	7	6	26.04 (19.93)
Week 16	5	3	58.33 (7.22)	7	5	18.75 (18.75)
Week 24	5	3	49.31 (16.97)	7	5	27.50 (15.69)
Week 32				7	3	21.53 (19.36)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	4	43.75 (22.24)	5	3	47.92 (13.01)
Week 4	5	2	46.88 (4.42)	5	2	40.62 (4.42)
Week 8	5	3	52.08 (15.73)	5	2	40.62 (4.42)
Week 16	4	2	56.25 (8.84)	5	3	27.08 (15.73)
Week 24	4	2	53.12 (22.10)	5	2	34.38 (4.42)
Week 32				5	2	21.88 (30.94)
low titer						
Baseline	3	1	37.50 (NA)	12	5	37.50 (9.88)
Week 4				12	6	32.99 (13.97)
Week 8				12	7	33.04 (24.93)
Week 16	2	1	62.50 (NA)	12	4	21.88 (29.54)
Week 24	2	1	41.67 (NA)	12	4	28.12 (19.43)
Week 32				12	3	23.61 (22.95)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

82: Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	4	25.00 (33.85)	17	4	12.50 (15.31)
Week 4	8	1	0.00 (NA)	17	4	10.94 (7.86)
Week 8	8	2	25.00 (35.36)	17	4	8.33 (16.67)
Week 16	6	1	0.00 (NA)	17	4	18.75 (22.24)
Week 24	6	1	0.00 (NA)	17	3	17.36 (16.71)
Week 32				17	2	9.38 (13.26)
Age						
< 18 years						
Baseline				10	2	9.38 (13.26)
Week 4				10	1	18.75 (NA)
Week 8				10	2	16.67 (23.57)
Week 16				10	2	21.88 (30.94)
Week 24				10	1	33.33 (NA)
Week 32				10	2	9.38 (13.26)
>= 18 years						
Baseline	8	4	25.00 (33.85)	7	2	15.62 (22.10)
Week 4	7	1	0.00 (NA)	7	3	8.33 (7.22)
Week 8	7	2	25.00 (35.36)	7	2	0.00 (0.00)
Week 16	5	1	0.00 (NA)	7	2	15.62 (22.10)
Week 24	5	1	0.00 (NA)	7	2	9.38 (13.26)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	29.17 (40.18)	5	2	15.62 (22.10)
Week 4	5	1	0.00 (NA)	5	1	12.50 (NA)
Week 8	5	2	25.00 (35.36)	5	1	0.00 (NA)
Week 16	4	1	0.00 (NA)	5	2	15.62 (22.10)
Week 24	4	1	0.00 (NA)	5	1	18.75 (NA)
Week 32				5	1	0.00 (NA)
low titer						
Baseline	3	1	12.50 (NA)	12	2	9.38 (13.26)
Week 4				12	3	10.42 (9.55)
Week 8				12	3	11.11 (19.25)
Week 16				12	2	21.88 (30.94)
Week 24				12	2	16.67 (23.57)
Week 32				12	1	18.75 (NA)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits. These data are included in the descriptive statistics.

83: Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	2	42.71 (33.88)	12	3	45.14 (39.11)
Week 4	9	1	37.50 (NA)	12	2	40.62 (48.61)
Week 8	9	1	25.00 (NA)	11	2	62.50 (53.03)
Week 16				11	3	41.67 (52.04)
Week 24				11	1	33.33 (NA)
Week 32				11	2	20.83 (29.46)
Age						
< 18 years						
Baseline				6	1	0.00 (NA)
>= 18 years						
Baseline	5	2	42.71 (33.88)	6	2	67.71 (1.47)
Week 4	4	1	37.50 (NA)	6	2	40.62 (48.61)
Week 8	4	1	25.00 (NA)	5	2	62.50 (53.03)
Week 16				5	3	41.67 (52.04)
Week 24				5	1	33.33 (NA)
Week 32				5	2	20.83 (29.46)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

84: Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	3	43.06 (6.36)	12	3	72.92 (28.18)
Week 4	9	1	31.25 (NA)	12	2	50.00 (35.36)
Week 8	9	1	18.75 (NA)	11	2	71.88 (4.42)
Week 16				11	2	53.12 (30.94)
Week 24	8	1	31.25 (NA)	11	1	87.50 (NA)
Week 32				11	2	58.33 (47.14)
Age						
< 18 years						
Baseline	5	1	50.00 (NA)	6	1	43.75 (NA)
Week 24	5	1	31.25 (NA)			
>= 18 years						
Baseline	5	2	39.58 (2.95)	6	2	87.50 (17.68)
Week 4	4	1	31.25 (NA)	6	2	50.00 (35.36)
Week 8	4	1	18.75 (NA)	5	2	71.88 (4.42)
Week 16				5	2	53.12 (30.94)
Week 24				5	1	87.50 (NA)
Week 32				5	2	58.33 (47.14)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at baseline and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

85: Hemo-TEM Total Score by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	35.38 (11.25)	17	16	25.46 (20.48)
Week 24	6	5	35.17 (20.34)	17	14	11.20 (11.55)
Week 32				17	16	11.01 (9.69)
Age						
< 18 years						
Baseline	1	1	46.85 (NA)	10	9	24.83 (18.57)
Week 24	1	1	62.74 (NA)	10	9	15.91 (12.08)
Week 32				10	9	13.78 (11.53)
>= 18 years						
Baseline	8	4	32.51 (10.67)	7	7	26.28 (24.23)
Week 24	5	4	28.27 (15.32)	7	5	2.73 (1.46)
Week 32				7	7	7.47 (5.60)
Disease severity						
high titer						
Baseline	6	3	36.88 (13.57)	5	5	33.36 (24.85)
Week 24	4	4	35.65 (23.45)	5	3	17.06 (13.40)
Week 32				5	4	11.29 (3.20)
low titer						
Baseline	3	2	33.12 (10.99)	12	11	21.87 (18.35)
Week 24	2	1	33.21 (NA)	12	11	9.60 (11.15)
Week 32				12	12	10.92 (11.19)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

86: Hemo-TEM Total Score by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	24.52 (6.07)	12	7	26.65 (13.63)
Week 24	8	6	27.57 (18.46)	11	9	9.28 (10.26)
Week 32				11	10	10.90 (10.17)
Age						
< 18 years						
Baseline	5	2	23.57 (9.51)	6	4	21.29 (16.48)
Week 24	5	4	26.96 (18.49)	6	5	4.45 (6.91)
Week 32				6	6	8.90 (8.84)
>= 18 years						
Baseline	5	2	25.48 (4.04)	6	3	33.79 (4.00)
Week 24	3	2	28.78 (25.97)	5	4	15.31 (11.38)
Week 32				5	4	13.88 (12.66)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

87: Hemo-TEM ease of use by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	53.33 (20.92)	17	16	29.69 (33.74)
Week 24	6	5	36.67 (25.41)	17	14	10.71 (11.98)
Week 32				17	16	14.06 (19.89)
Age						
< 18 years						
Baseline	1	1	75.00 (NA)	10	9	30.56 (36.32)
Week 24	1	1	66.67 (NA)	10	9	16.67 (11.02)
Week 32				10	9	20.37 (23.98)
>= 18 years						
Baseline	8	4	47.92 (19.69)	7	7	28.57 (32.93)
Week 24	5	4	29.17 (22.05)	7	5	0.00 (0.00)
Week 32				7	7	5.95 (9.27)
Disease severity						
high titer						
Baseline	6	3	52.78 (20.97)	5	5	40.00 (32.49)
Week 24	4	4	35.42 (29.17)	5	3	16.67 (16.67)
Week 32				5	4	10.42 (7.98)
low titer						
Baseline	3	2	54.17 (29.46)	12	11	25.00 (34.76)
Week 24	2	1	41.67 (NA)	12	11	9.09 (10.84)
Week 32				12	12	15.28 (22.71)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

88: Hemo-TEM ease of use by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	41.67 (15.21)	12	7	33.33 (23.57)
Week 24	8	6	29.17 (35.65)	11	9	11.11 (13.82)
Week 32				11	10	16.67 (18.84)
Age						
< 18 years						
Baseline	5	2	45.83 (17.68)	6	4	29.17 (30.81)
Week 24	5	4	39.58 (40.47)	6	5	1.67 (3.73)
Week 32				6	6	11.11 (16.39)
>= 18 years						
Baseline	5	2	37.50 (17.68)	6	3	38.89 (12.73)
Week 24	3	2	8.33 (11.79)	5	4	22.92 (12.50)
Week 32				5	4	25.00 (21.52)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

89: Hemo-TEM emotional impact by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	30.83 (16.03)	17	16	27.86 (26.30)
Week 24	6	5	37.50 (24.30)	17	14	13.69 (14.93)
Week 32				17	16	10.73 (11.75)
Age						
< 18 years						
Baseline	1	1	50.00 (NA)	10	9	29.63 (27.67)
Week 24	1	1	66.67 (NA)	10	9	18.98 (16.29)
Week 32				10	9	13.52 (12.73)
>= 18 years						
Baseline	8	4	26.04 (13.77)	7	7	25.60 (26.40)
Week 24	5	4	30.21 (20.80)	7	5	4.17 (4.17)
Week 32				7	7	7.14 (10.12)
Disease severity						
high titer						
Baseline	6	3	37.50 (18.16)	5	5	40.00 (26.29)
Week 24	4	4	42.71 (24.62)	5	3	22.22 (12.73)
Week 32				5	4	16.67 (12.27)
low titer						
Baseline	3	2	20.83 (5.89)	12	11	22.35 (25.57)
Week 24	2	1	16.67 (NA)	12	11	11.36 (15.15)
Week 32				12	12	8.75 (11.41)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

90: Hemo-TEM emotional impact by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	21.88 (13.77)	12	7	22.62 (14.60)
Week 24	8	6	31.25 (16.82)	11	9	5.09 (11.37)
Week 32				11	10	11.00 (15.01)
Age						
< 18 years						
Baseline	5	2	10.42 (2.95)	6	4	18.75 (17.51)
Week 24	5	4	33.33 (14.83)	6	5	2.50 (5.59)
Week 32				6	6	12.78 (15.15)
>= 18 years						
Baseline	5	2	33.33 (5.89)	6	3	27.78 (10.49)
Week 24	3	2	27.08 (26.52)	5	4	8.33 (16.67)
Week 32				5	4	8.33 (16.67)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

91: Hemo-TEM interference by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	33.33 (23.98)	17	16	28.12 (24.26)
Week 24	6	5	37.50 (34.23)	17	14	8.93 (11.16)
Week 32				17	16	9.38 (11.18)
Age						
< 18 years						
Baseline	1	1	43.75 (NA)	10	9	26.39 (20.91)
Week 24	1	1	87.50 (NA)	10	9	13.19 (11.88)
Week 32				10	9	11.11 (12.01)
>= 18 years						
Baseline	8	4	30.73 (26.86)	7	7	30.36 (29.63)
Week 24	5	4	25.00 (22.82)	7	5	1.25 (2.80)
Week 32				7	7	7.14 (10.48)
Disease severity						
high titer						
Baseline	6	3	31.25 (27.24)	5	5	27.50 (32.36)
Week 24	4	4	34.38 (38.70)	5	3	12.50 (12.50)
Week 32				5	4	4.69 (5.98)
low titer						
Baseline	3	2	36.46 (27.99)	12	11	28.41 (21.54)
Week 24	2	1	50.00 (NA)	12	11	7.95 (11.21)
Week 32				12	12	10.94 (12.25)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

92: Hemo-TEM interference by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	15.62 (8.07)	12	7	25.00 (17.31)
Week 24	8	6	30.90 (26.53)	11	9	13.66 (15.06)
Week 32				11	10	8.54 (14.52)
Age						
< 18 years						
Baseline	5	2	12.50 (8.84)	6	4	23.44 (24.14)
Week 24	5	4	18.75 (22.24)	6	5	10.83 (18.07)
Week 32				6	6	6.25 (15.31)
>= 18 years						
Baseline	5	2	18.75 (8.84)	6	3	27.08 (3.61)
Week 24	3	2	55.21 (16.20)	5	4	17.19 (11.83)
Week 32				5	4	11.98 (14.67)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

93: Hemo-TEM physical impact by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	35.83 (20.54)	17	16	21.09 (15.10)
Week 24	6	5	34.17 (12.98)	17	14	10.42 (13.35)
Week 32				17	16	11.98 (14.97)
Age						
< 18 years						
Baseline	1	1	33.33 (NA)	10	9	21.30 (12.92)
Week 24	1	1	50.00 (NA)	10	9	14.81 (14.89)
Week 32				10	9	14.35 (17.93)
>= 18 years						
Baseline	8	4	36.46 (23.66)	7	7	20.83 (18.63)
Week 24	5	4	30.21 (10.96)	7	5	2.50 (3.73)
Week 32				7	7	8.93 (10.60)
Disease severity						
high titer						
Baseline	6	3	40.28 (12.03)	5	5	30.00 (15.42)
Week 24	4	4	35.42 (14.63)	5	3	20.83 (19.09)
Week 32				5	4	16.67 (7.61)
low titer						
Baseline	3	2	29.17 (35.36)	12	11	17.05 (13.75)
Week 24	2	1	29.17 (NA)	12	11	7.58 (10.84)
Week 32				12	12	10.42 (16.71)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

94: Hemo-TEM physical impact by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	22.92 (11.02)	12	7	33.93 (17.25)
Week 24	8	6	25.69 (20.65)	11	9	12.96 (16.06)
Week 32				11	10	15.42 (13.33)
Age						
< 18 years						
Baseline	5	2	31.25 (8.84)	6	4	27.08 (19.39)
Week 24	5	4	27.08 (18.79)	6	5	5.83 (9.13)
Week 32				6	6	13.19 (14.29)
>= 18 years						
Baseline	5	2	14.58 (2.95)	6	3	43.06 (10.49)
Week 24	3	2	22.92 (32.41)	5	4	21.88 (19.65)
Week 32				5	4	18.75 (12.95)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

95: Hemo-TEM treatment burden by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	23.57 (12.27)	17	16	20.54 (19.19)
Week 24	6	5	30.00 (14.85)	17	14	12.24 (14.94)
Week 32				17	16	8.93 (9.13)
Age						
< 18 years						
Baseline	1	1	32.14 (NA)	10	9	16.27 (10.28)
Week 24	1	1	42.86 (NA)	10	9	15.87 (17.69)
Week 32				10	9	9.52 (10.56)
>= 18 years						
Baseline	8	4	21.43 (13.04)	7	7	26.02 (26.78)
Week 24	5	4	26.79 (15.01)	7	5	5.71 (4.07)
Week 32				7	7	8.16 (7.64)
Disease severity						
high titer						
Baseline	6	3	22.62 (13.52)	5	5	29.29 (27.13)
Week 24	4	4	30.36 (17.13)	5	3	13.10 (13.52)
Week 32				5	4	8.04 (9.39)
low titer						
Baseline	3	2	25.00 (15.15)	12	11	16.56 (14.22)
Week 24	2	1	28.57 (NA)	12	11	12.01 (15.91)
Week 32				12	12	9.23 (9.44)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

96: Hemo-TEM treatment burden by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	20.54 (9.39)	12	7	18.37 (20.04)
Week 24	8	6	20.83 (27.14)	11	9	3.57 (5.05)
Week 32				11	10	2.86 (4.70)
Age						
< 18 years						
Baseline	5	2	17.86 (15.15)	6	4	8.04 (7.36)
Week 24	5	4	16.07 (22.87)	6	5	1.43 (3.19)
Week 32				6	6	1.19 (1.84)
>= 18 years						
Baseline	5	2	23.21 (2.53)	6	3	32.14 (25.00)
Week 24	3	2	30.36 (42.93)	5	4	6.25 (6.10)
Week 32				5	4	5.36 (6.84)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

97: PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	4.40 (2.70)	17	16	4.69 (2.91)
Week 4	8	8	5.50 (2.33)	17	11	3.36 (3.44)
Week 8	8	6	4.83 (3.49)	17	15	2.87 (2.83)
Week 16	6	4	4.25 (3.50)	17	16	2.94 (3.02)
Week 24	6	6	4.00 (2.00)	17	14	1.86 (2.98)
Week 32				17	16	3.44 (3.42)
Age						
< 18 years						
Baseline	1	1	6.00 (NA)	10	9	4.67 (2.55)
Week 4	1	1	6.00 (NA)	10	7	2.43 (3.21)
Week 8	1	1	4.00 (NA)	10	9	2.11 (2.52)
Week 16	1	1	8.00 (NA)	10	9	2.78 (3.07)
Week 24	1	1	5.00 (NA)	10	9	1.44 (2.60)
Week 32				10	9	3.22 (3.35)
>= 18 years						
Baseline	8	4	4.00 (2.94)	7	7	4.71 (3.55)
Week 4	7	7	5.43 (2.51)	7	4	5.00 (3.65)
Week 8	7	5	5.00 (3.87)	7	6	4.00 (3.10)
Week 16	5	3	3.00 (3.00)	7	7	3.14 (3.18)
Week 24	5	5	3.80 (2.17)	7	5	2.60 (3.78)
Week 32				7	7	3.71 (3.77)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	3.67 (3.21)	5	5	4.60 (0.89)
Week 4	5	5	6.40 (1.52)	5	3	3.33 (2.52)
Week 8	5	4	5.00 (2.58)	5	5	2.40 (1.52)
Week 16	4	3	5.67 (2.52)	5	5	2.00 (1.22)
Week 24	4	4	4.50 (1.73)	5	3	1.67 (1.53)
Week 32				5	4	2.50 (1.73)
low titer						
Baseline	3	2	5.50 (2.12)	12	11	4.73 (3.52)
Week 4	3	3	4.00 (3.00)	12	8	3.38 (3.89)
Week 8	3	2	4.50 (6.36)	12	10	3.10 (3.35)
Week 16	2	1	0.00 (NA)	12	11	3.36 (3.53)
Week 24	2	2	3.00 (2.83)	12	11	1.91 (3.33)
Week 32				12	12	3.75 (3.84)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

98: PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	4.80 (2.86)	12	7	2.43 (1.81)
Week 4	9	5	3.60 (3.58)	12	7	1.29 (1.98)
Week 8	9	6	3.83 (2.14)	11	8	1.88 (2.36)
Week 16	9	4	4.75 (3.30)	11	9	1.67 (1.87)
Week 24	8	6	4.50 (2.74)	11	9	1.78 (2.49)
Week 32				11	10	1.70 (2.41)
Age						
< 18 years						
Baseline	5	3	5.33 (2.52)	6	4	1.50 (1.73)
Week 4	5	3	4.00 (4.00)	6	4	0.75 (1.50)
Week 8	5	4	3.50 (2.38)	6	4	0.75 (0.96)
Week 16	5	3	4.00 (3.61)	6	5	1.00 (1.22)
Week 24	5	4	4.25 (3.10)	6	5	0.80 (1.79)
Week 32				6	6	0.67 (1.63)
>= 18 years						
Baseline	5	2	4.00 (4.24)	6	3	3.67 (1.15)
Week 4	4	2	3.00 (4.24)	6	3	2.00 (2.65)
Week 8	4	2	4.50 (2.12)	5	4	3.00 (2.94)
Week 16	4	1	7.00 (NA)	5	4	2.50 (2.38)
Week 24	3	2	5.00 (2.83)	5	4	3.00 (2.94)
Week 32				5	4	3.25 (2.75)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

99: PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	7	38.88 (11.04)	17	17	39.31 (8.69)
Week 4	8	7	37.66 (10.61)	17	11	37.86 (8.42)
Week 8	8	5	38.90 (10.87)	17	14	42.10 (9.65)
Week 16	6	4	42.82 (6.99)	17	15	42.32 (9.61)
Week 24	6	6	38.82 (10.84)	17	14	41.38 (8.82)
Week 32				17	16	43.06 (11.87)
Age						
< 18 years						
Baseline	1	1	36.17 (NA)	10	10	40.15 (10.22)
Week 4	1	1	37.15 (NA)	10	7	41.05 (7.60)
Week 8	1	1	34.86 (NA)	10	8	44.14 (10.72)
Week 16	1	1	39.79 (NA)	10	8	43.76 (8.35)
Week 24	1	1	36.17 (NA)	10	9	42.93 (9.44)
Week 32				10	9	42.71 (13.30)
>= 18 years						
Baseline	8	6	39.33 (12.02)	7	7	38.12 (6.48)
Week 4	7	6	37.74 (11.62)	7	4	32.28 (7.46)
Week 8	7	4	39.91 (12.27)	7	6	39.37 (8.11)
Week 16	5	3	43.83 (8.20)	7	7	40.69 (11.32)
Week 24	5	5	39.35 (12.03)	7	5	38.60 (7.71)
Week 32				7	7	43.51 (10.77)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	5	40.62 (11.89)	5	5	45.88 (9.67)
Week 4	5	4	39.64 (12.64)	5	3	38.68 (8.08)
Week 8	5	3	42.17 (13.89)	5	4	44.02 (9.34)
Week 16	4	3	41.93 (8.28)	5	4	41.94 (9.43)
Week 24	4	4	38.42 (13.55)	5	3	38.08 (7.83)
Week 32				5	4	42.63 (9.61)
low titer						
Baseline	3	2	34.54 (10.65)	12	12	36.58 (6.94)
Week 4	3	3	35.01 (8.93)	12	8	37.55 (9.07)
Week 8	3	2	33.98 (2.45)	12	10	41.33 (10.16)
Week 16	2	1	45.51 (NA)	12	11	42.46 (10.12)
Week 24	2	2	39.61 (5.86)	12	11	42.28 (9.21)
Week 32				12	12	43.20 (12.91)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

100: PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	4	41.08 (11.43)	12	7	41.31 (10.46)
Week 4	9	4	41.56 (12.14)	12	6	43.85 (8.87)
Week 8	9	5	36.90 (6.94)	11	7	45.19 (9.90)
Week 16	9	4	37.91 (13.67)	11	8	47.68 (10.18)
Week 24	8	6	36.30 (7.50)	11	8	45.60 (11.39)
Week 32				11	9	48.28 (8.64)
Age						
< 18 years						
Baseline	5	3	42.66 (13.45)	6	4	43.78 (10.96)
Week 4	5	3	45.61 (11.09)	6	4	45.06 (9.87)
Week 8	5	4	38.38 (7.05)	6	4	46.97 (12.95)
Week 16	5	3	41.09 (14.82)	6	5	49.05 (10.50)
Week 24	5	4	37.19 (8.74)	6	5	46.19 (12.52)
Week 32				6	6	48.40 (9.21)
>= 18 years						
Baseline	5	1	36.34 (NA)	6	3	38.01 (10.94)
Week 4	4	1	29.43 (NA)	6	2	41.43 (9.11)
Week 8	4	1	30.97 (NA)	5	3	42.81 (5.23)
Week 16	4	1	28.37 (NA)	5	3	45.39 (11.41)
Week 24	3	2	34.53 (6.55)	5	3	44.62 (11.75)
Week 32				5	3	48.05 (9.31)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

101: SF-36v2 general health by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	30.36 (4.25)	17	17	43.12 (8.52)
Week 4	8	8	35.41 (5.62)	17	11	48.21 (8.52)
Week 8	8	6	29.97 (5.52)	17	15	48.56 (9.15)
Week 16	6	4	28.10 (3.09)	17	16	48.37 (10.59)
Week 24	6	6	30.20 (4.77)	17	15	48.75 (9.10)
Week 32				17	16	49.77 (10.99)
Age						
< 18 years						
Baseline	1	1	23.71 (NA)	10	10	45.53 (6.79)
Week 4	1	1	33.22 (NA)	10	7	49.92 (8.34)
Week 8	1	1	34.17 (NA)	10	9	50.18 (8.06)
Week 16	1	1	28.46 (NA)	10	9	51.55 (9.63)
Week 24	1	1	30.84 (NA)	10	9	50.39 (8.54)
Week 32				10	9	51.97 (10.24)
>= 18 years						
Baseline	8	4	32.03 (2.38)	7	7	39.67 (10.04)
Week 4	7	7	35.73 (5.99)	7	4	45.22 (9.17)
Week 8	7	5	29.13 (5.72)	7	6	46.13 (10.89)
Week 16	5	3	27.99 (3.77)	7	7	44.29 (11.04)
Week 24	5	5	30.08 (5.32)	7	6	46.29 (10.15)
Week 32				7	7	46.94 (12.05)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 general health by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	30.05 (5.98)	5	5	43.96 (12.93)
Week 4	5	5	36.07 (7.01)	5	3	52.07 (8.46)
Week 8	5	4	29.30 (5.54)	5	5	52.24 (11.23)
Week 16	4	3	27.67 (3.63)	5	5	51.57 (13.60)
Week 24	4	4	29.06 (2.28)	5	3	52.39 (12.20)
Week 32				5	4	49.98 (13.74)
low titer						
Baseline	3	2	30.84 (0.00)	12	12	42.77 (6.66)
Week 4	3	3	34.32 (3.05)	12	8	46.77 (8.63)
Week 8	3	2	31.31 (7.40)	12	10	46.72 (7.93)
Week 16	2	1	29.41 (NA)	12	11	46.92 (9.31)
Week 24	2	2	32.50 (9.08)	12	12	47.84 (8.58)
Week 32				12	12	49.70 (10.63)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

102: SF-36v2 general health by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	40.06 (8.43)	12	7	41.23 (9.14)
Week 4	9	6	38.45 (7.01)	12	7	46.46 (10.17)
Week 8	9	6	39.48 (9.35)	11	8	45.94 (12.65)
Week 16	9	4	32.86 (7.55)	11	9	47.06 (11.27)
Week 24	8	6	38.68 (9.77)	11	9	51.39 (9.15)
Week 32				11	11	46.10 (11.41)
Age						
< 18 years						
Baseline	5	3	42.73 (10.36)	6	4	45.22 (9.30)
Week 4	5	4	39.40 (4.23)	6	4	53.19 (6.44)
Week 8	5	4	41.18 (8.22)	6	4	52.00 (13.79)
Week 16	5	3	35.12 (7.41)	6	5	50.14 (9.80)
Week 24	5	4	38.80 (7.55)	6	5	56.14 (5.16)
Week 32				6	6	51.84 (8.85)
>= 18 years						
Baseline	5	2	36.07 (4.03)	6	3	35.91 (6.83)
Week 4	4	2	36.54 (13.45)	6	3	37.50 (6.07)
Week 8	4	2	36.06 (14.12)	5	4	39.88 (9.22)
Week 16	4	1	26.08 (NA)	5	4	43.20 (13.23)
Week 24	3	2	38.44 (17.49)	5	4	45.46 (10.16)
Week 32				5	5	39.20 (10.89)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

103: SF-36v2 mental health by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	41.97 (8.60)	17	17	44.56 (10.87)
Week 4	8	8	45.31 (7.19)	17	11	50.63 (8.31)
Week 8	8	6	42.58 (6.70)	17	15	48.43 (9.09)
Week 16	6	4	42.37 (2.51)	17	16	49.89 (11.42)
Week 24	6	6	43.02 (9.79)	17	15	50.00 (8.60)
Week 32				17	16	50.21 (8.36)
Age						
< 18 years						
Baseline	1	1	40.40 (NA)	10	10	44.33 (10.91)
Week 4	1	1	50.87 (NA)	10	7	48.63 (9.24)
Week 8	1	1	37.79 (NA)	10	9	51.45 (8.56)
Week 16	1	1	45.64 (NA)	10	9	51.16 (12.30)
Week 24	1	1	50.87 (NA)	10	9	50.87 (8.58)
Week 32				10	9	53.19 (7.90)
>= 18 years						
Baseline	8	4	42.37 (9.88)	7	7	44.89 (11.67)
Week 4	7	7	44.51 (7.38)	7	4	54.14 (5.80)
Week 8	7	5	43.54 (7.02)	7	6	43.89 (8.55)
Week 16	5	3	41.27 (1.51)	7	7	48.25 (10.89)
Week 24	5	5	41.45 (10.06)	7	6	48.69 (9.27)
Week 32				7	7	46.38 (7.81)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 mental health by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	41.28 (9.19)	5	5	43.54 (13.52)
Week 4	5	5	46.68 (6.30)	5	3	52.61 (6.58)
Week 8	5	4	39.75 (1.30)	5	5	51.39 (13.77)
Week 16	4	3	43.02 (2.62)	5	5	51.39 (16.06)
Week 24	4	4	40.41 (7.70)	5	3	53.49 (9.06)
Week 32				5	4	52.18 (11.00)
low titer						
Baseline	3	2	43.02 (11.10)	12	12	44.98 (10.23)
Week 4	3	3	43.02 (9.43)	12	8	49.89 (9.16)
Week 8	3	2	48.25 (11.10)	12	10	46.94 (6.07)
Week 16	2	1	40.40 (NA)	12	11	49.20 (9.52)
Week 24	2	2	48.25 (14.80)	12	12	49.12 (8.66)
Week 32				12	12	49.56 (7.77)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

104: SF-36v2 mental health by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	44.06 (6.02)	12	7	50.12 (4.71)
Week 4	9	6	46.51 (8.22)	12	7	50.87 (8.41)
Week 8	9	6	45.64 (11.34)	11	8	48.58 (8.09)
Week 16	9	4	43.02 (10.24)	11	9	50.00 (7.85)
Week 24	8	6	41.71 (10.30)	11	9	49.42 (8.39)
Week 32				11	11	47.30 (9.81)
Age						
< 18 years						
Baseline	5	3	48.25 (0.00)	6	4	52.83 (3.29)
Week 4	5	4	50.87 (5.65)	6	4	52.83 (8.37)
Week 8	5	4	50.87 (9.31)	6	4	49.56 (11.41)
Week 16	5	3	46.51 (9.19)	6	5	52.96 (8.15)
Week 24	5	4	43.02 (12.63)	6	5	52.44 (8.40)
Week 32				6	6	47.82 (12.65)
>= 18 years						
Baseline	5	2	37.78 (3.70)	6	3	46.51 (4.00)
Week 4	4	2	37.78 (3.70)	6	3	48.25 (9.43)
Week 8	4	2	35.17 (7.40)	5	4	47.60 (4.47)
Week 16	4	1	32.56 (NA)	5	4	46.29 (6.54)
Week 24	3	2	39.09 (5.55)	5	4	45.64 (7.70)
Week 32				5	5	46.68 (6.30)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

105: SF-36v2 role emotional by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	36.67 (5.83)	17	17	42.04 (10.48)
Week 4	8	8	40.07 (6.15)	17	11	44.14 (10.94)
Week 8	8	6	38.18 (11.94)	17	15	42.47 (11.28)
Week 16	6	4	40.50 (4.49)	17	16	46.16 (10.85)
Week 24	6	6	40.50 (11.18)	17	15	47.12 (9.74)
Week 32				17	16	46.38 (10.19)
Age						
< 18 years						
Baseline	1	1	42.24 (NA)	10	10	43.63 (11.74)
Week 4	1	1	42.24 (NA)	10	7	43.24 (12.99)
Week 8	1	1	35.28 (NA)	10	9	39.53 (12.03)
Week 16	1	1	42.24 (NA)	10	9	45.72 (12.19)
Week 24	1	1	42.24 (NA)	10	9	48.04 (10.45)
Week 32				10	9	47.66 (9.39)
>= 18 years						
Baseline	8	4	35.28 (5.69)	7	7	39.75 (8.70)
Week 4	7	7	39.76 (6.58)	7	4	45.72 (7.52)
Week 8	7	5	38.76 (13.26)	7	6	46.89 (9.26)
Week 16	5	3	39.92 (5.32)	7	7	46.72 (9.79)
Week 24	5	5	40.15 (12.46)	7	6	45.72 (9.34)
Week 32				7	7	44.73 (11.67)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 role emotional by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	37.60 (8.04)	5	5	44.33 (10.33)
Week 4	5	5	38.06 (4.54)	5	3	48.04 (4.02)
Week 8	5	4	37.02 (8.28)	5	5	40.15 (9.72)
Week 16	4	3	41.08 (5.32)	5	5	47.81 (10.62)
Week 24	4	4	39.63 (8.70)	5	3	45.72 (9.21)
Week 32				5	4	44.85 (8.70)
low titer						
Baseline	3	2	35.28 (0.00)	12	12	41.08 (10.84)
Week 4	3	3	43.40 (8.04)	12	8	42.68 (12.55)
Week 8	3	2	40.50 (22.16)	12	10	43.64 (12.31)
Week 16	2	1	38.76 (NA)	12	11	45.41 (11.39)
Week 24	2	2	42.24 (19.70)	12	12	47.46 (10.23)
Week 32				12	12	46.88 (10.94)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

106: SF-36v2 role emotional by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	38.06 (10.56)	12	7	43.23 (12.01)
Week 4	9	6	42.82 (10.43)	12	7	47.22 (10.99)
Week 8	9	6	41.08 (4.75)	11	8	47.47 (9.49)
Week 16	9	4	37.02 (6.67)	11	9	48.82 (9.28)
Week 24	8	6	42.24 (7.63)	11	9	49.21 (9.05)
Week 32				11	11	44.77 (9.98)
Age						
< 18 years						
Baseline	5	3	39.92 (14.50)	6	4	44.85 (11.85)
Week 4	5	4	46.59 (11.15)	6	4	48.34 (9.16)
Week 8	5	4	41.37 (4.38)	6	4	47.47 (10.45)
Week 16	5	3	39.92 (4.02)	6	5	49.90 (9.34)
Week 24	5	4	43.11 (8.70)	6	5	51.30 (9.08)
Week 32				6	6	46.30 (11.74)
>= 18 years						
Baseline	5	2	35.28 (0.00)	6	3	41.08 (14.50)
Week 4	4	2	35.28 (0.00)	6	3	45.72 (15.18)
Week 8	4	2	40.50 (7.38)	5	4	47.47 (10.05)
Week 16	4	1	28.31 (NA)	5	4	47.47 (10.45)
Week 24	3	2	40.50 (7.38)	5	4	46.59 (9.59)
Week 32				5	5	42.94 (8.31)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

107: SF-36v2 role physical by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	36.50 (8.31)	17	17	40.65 (6.87)
Week 4	8	8	37.51 (8.72)	17	11	39.60 (6.65)
Week 8	8	6	36.94 (12.54)	17	15	44.13 (9.68)
Week 16	6	4	33.58 (9.79)	17	16	47.19 (9.06)
Week 24	6	6	38.44 (8.36)	17	15	46.98 (9.02)
Week 32				17	16	45.23 (10.17)
Age						
< 18 years						
Baseline	1	1	34.70 (NA)	10	10	40.77 (6.95)
Week 4	1	1	39.19 (NA)	10	7	38.87 (7.03)
Week 8	1	1	43.68 (NA)	10	9	42.43 (9.47)
Week 16	1	1	41.44 (NA)	10	9	46.93 (10.24)
Week 24	1	1	36.95 (NA)	10	9	47.43 (9.26)
Week 32				10	9	46.43 (10.46)
>= 18 years						
Baseline	8	4	36.95 (9.53)	7	7	40.47 (7.32)
Week 4	7	7	37.27 (9.39)	7	4	40.88 (6.71)
Week 8	7	5	35.60 (13.53)	7	6	46.68 (10.31)
Week 16	5	3	30.96 (10.13)	7	7	47.53 (8.07)
Week 24	5	5	38.74 (9.31)	7	6	46.30 (9.47)
Week 32				7	7	43.68 (10.37)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 role physical by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	32.45 (3.89)	5	5	36.95 (7.28)
Week 4	5	5	34.25 (5.59)	5	3	36.95 (5.94)
Week 8	5	4	36.38 (8.48)	5	5	38.74 (8.16)
Week 16	4	3	34.70 (11.67)	5	5	45.48 (9.18)
Week 24	4	4	34.14 (4.63)	5	3	46.68 (7.22)
Week 32				5	4	42.56 (11.23)
low titer						
Baseline	3	2	42.56 (11.12)	12	12	42.19 (6.37)
Week 4	3	3	42.93 (11.52)	12	8	40.59 (6.99)
Week 8	3	2	38.07 (23.82)	12	10	46.83 (9.60)
Week 16	2	1	30.21 (NA)	12	11	47.97 (9.34)
Week 24	2	2	47.05 (7.93)	12	12	47.05 (9.69)
Week 32				12	12	46.12 (10.15)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

108: SF-36v2 role physical by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	39.19 (4.76)	12	7	41.44 (10.21)
Week 4	9	6	40.69 (5.62)	12	7	43.68 (11.52)
Week 8	9	6	40.31 (9.39)	11	8	45.65 (7.04)
Week 16	9	4	39.19 (7.10)	11	9	46.18 (7.05)
Week 24	8	6	37.32 (7.02)	11	9	48.92 (7.10)
Week 32				11	11	47.56 (7.18)
Age						
< 18 years						
Baseline	5	3	36.95 (3.89)	6	4	47.05 (8.30)
Week 4	5	4	39.75 (2.82)	6	4	49.30 (9.07)
Week 8	5	4	37.51 (5.61)	6	4	47.61 (7.42)
Week 16	5	3	41.44 (6.74)	6	5	50.42 (6.74)
Week 24	5	4	38.63 (7.86)	6	5	51.32 (7.21)
Week 32				6	6	48.92 (6.46)
>= 18 years						
Baseline	5	2	42.56 (4.77)	6	3	33.95 (7.89)
Week 4	4	2	42.56 (11.12)	6	3	36.20 (11.30)
Week 8	4	2	45.93 (15.88)	5	4	43.68 (7.10)
Week 16	4	1	32.46 (NA)	5	4	40.88 (2.15)
Week 24	3	2	34.70 (6.35)	5	4	45.93 (6.61)
Week 32				5	5	45.93 (8.40)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

109: SF-36v2 social function by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	36.28 (4.20)	17	17	42.59 (8.02)
Week 4	8	8	33.53 (7.46)	17	11	41.85 (9.09)
Week 8	8	6	39.79 (12.18)	17	15	47.31 (8.04)
Week 16	6	4	38.54 (11.11)	17	16	46.38 (8.82)
Week 24	6	6	38.96 (13.70)	17	15	45.64 (9.02)
Week 32				17	16	45.43 (11.27)
Age						
< 18 years						
Baseline	1	1	32.27 (NA)	10	10	44.31 (7.91)
Week 4	1	1	27.26 (NA)	10	7	39.44 (5.68)
Week 8	1	1	42.30 (NA)	10	9	47.31 (5.60)
Week 16	1	1	47.31 (NA)	10	9	43.97 (8.31)
Week 24	1	1	42.30 (NA)	10	9	46.20 (7.84)
Week 32				10	9	45.64 (13.50)
>= 18 years						
Baseline	8	4	37.29 (4.09)	7	7	40.15 (8.11)
Week 4	7	7	34.42 (7.58)	7	4	46.06 (13.19)
Week 8	7	5	39.29 (13.55)	7	6	47.31 (11.43)
Week 16	5	3	35.62 (11.58)	7	7	49.46 (9.09)
Week 24	5	5	38.29 (15.21)	7	6	44.81 (11.32)
Week 32				7	7	45.16 (8.61)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 social function by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	33.94 (2.90)	5	5	37.29 (10.03)
Week 4	5	5	30.27 (7.60)	5	3	35.62 (2.90)
Week 8	5	4	36.03 (13.19)	5	5	42.30 (8.68)
Week 16	4	3	37.29 (13.26)	5	5	40.30 (6.73)
Week 24	4	4	33.53 (13.81)	5	3	40.63 (7.66)
Week 32				5	4	39.80 (14.47)
low titer						
Baseline	3	2	39.80 (3.54)	12	12	44.81 (6.23)
Week 4	3	3	38.96 (2.89)	12	8	44.18 (9.64)
Week 8	3	2	47.31 (7.09)	12	10	49.82 (6.79)
Week 16	2	1	42.30 (NA)	12	11	49.14 (8.47)
Week 24	2	2	49.82 (3.55)	12	12	46.89 (9.19)
Week 32				12	12	47.31 (10.03)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

110: SF-36v2 social function by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	38.29 (8.97)	12	7	46.60 (9.79)
Week 4	9	6	43.13 (7.38)	12	7	45.17 (13.22)
Week 8	9	6	46.48 (10.71)	11	8	48.57 (8.79)
Week 16	9	4	41.05 (7.52)	11	9	47.87 (8.10)
Week 24	8	6	43.14 (9.73)	11	9	48.43 (9.64)
Week 32				11	11	46.86 (9.37)
Age						
< 18 years						
Baseline	5	3	33.95 (5.79)	6	4	51.07 (7.52)
Week 4	5	4	43.55 (8.56)	6	4	48.57 (10.33)
Week 8	5	4	46.06 (11.12)	6	4	48.57 (8.56)
Week 16	5	3	42.30 (8.68)	6	5	50.32 (7.60)
Week 24	5	4	41.05 (8.56)	6	5	48.31 (10.28)
Week 32				6	6	46.48 (9.20)
>= 18 years						
Baseline	5	2	44.81 (10.63)	6	3	40.63 (10.44)
Week 4	4	2	42.30 (7.09)	6	3	40.63 (17.60)
Week 8	4	2	47.31 (14.18)	5	4	48.57 (10.33)
Week 16	4	1	37.29 (NA)	5	4	44.81 (8.68)
Week 24	3	2	47.31 (14.18)	5	4	48.57 (10.33)
Week 32				5	5	47.31 (10.64)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

111: SF-36v2 vitality by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	43.09 (6.44)	17	17	48.23 (8.79)
Week 4	8	8	43.32 (8.17)	17	11	50.98 (10.49)
Week 8	8	6	43.19 (10.86)	17	15	52.01 (7.46)
Week 16	6	4	43.69 (6.42)	17	16	52.04 (10.36)
Week 24	6	6	44.18 (8.49)	17	15	52.00 (8.86)
Week 32				17	16	53.53 (9.62)
Age						
< 18 years						
Baseline	1	1	46.66 (NA)	10	10	51.71 (8.97)
Week 4	1	1	43.69 (NA)	10	7	54.30 (5.90)
Week 8	1	1	40.72 (NA)	10	9	54.58 (5.75)
Week 16	1	1	52.60 (NA)	10	9	53.92 (9.29)
Week 24	1	1	46.66 (NA)	10	9	53.92 (7.14)
Week 32				10	9	58.87 (7.78)
>= 18 years						
Baseline	8	4	42.20 (7.08)	7	7	43.26 (6.05)
Week 4	7	7	43.26 (8.82)	7	4	45.17 (15.05)
Week 8	7	5	43.68 (12.07)	7	6	48.14 (8.56)
Week 16	5	3	40.72 (2.98)	7	7	49.63 (11.88)
Week 24	5	5	43.69 (9.40)	7	6	49.13 (11.02)
Week 32				7	7	46.66 (7.28)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 vitality by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	43.69 (7.86)	5	5	48.44 (9.99)
Week 4	5	5	41.31 (7.10)	5	3	54.58 (6.18)
Week 8	5	4	39.97 (2.85)	5	5	55.57 (6.97)
Week 16	4	3	44.68 (7.48)	5	5	54.97 (15.06)
Week 24	4	4	42.20 (5.69)	5	3	52.60 (12.95)
Week 32				5	4	57.80 (11.47)
low titer						
Baseline	3	2	42.20 (6.31)	12	12	48.14 (8.73)
Week 4	3	3	46.66 (10.29)	12	8	49.63 (11.78)
Week 8	3	2	49.62 (21.01)	12	10	50.22 (7.38)
Week 16	2	1	40.72 (NA)	12	11	50.71 (8.00)
Week 24	2	2	48.14 (14.71)	12	12	51.86 (8.32)
Week 32				12	12	52.10 (9.03)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

112: SF-36v2 vitality by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	50.82 (7.74)	12	7	47.51 (8.35)
Week 4	9	6	47.65 (8.75)	12	7	52.17 (7.16)
Week 8	9	6	46.66 (11.43)	11	8	51.49 (8.24)
Week 16	9	4	45.17 (8.58)	11	9	51.94 (7.97)
Week 24	8	6	45.17 (10.08)	11	9	51.61 (8.00)
Week 32				11	11	52.33 (10.91)
Age						
< 18 years						
Baseline	5	3	53.59 (9.55)	6	4	52.60 (7.27)
Week 4	5	4	52.60 (2.42)	6	4	55.57 (4.20)
Week 8	5	4	51.86 (8.53)	6	4	54.83 (9.81)
Week 16	5	3	48.64 (6.18)	6	5	55.57 (7.27)
Week 24	5	4	48.89 (7.82)	6	5	54.98 (6.77)
Week 32				6	6	54.58 (14.14)
>= 18 years						
Baseline	5	2	46.66 (0.00)	6	3	40.72 (2.98)
Week 4	4	2	37.74 (8.41)	6	3	47.65 (8.58)
Week 8	4	2	36.26 (10.51)	5	4	48.14 (5.69)
Week 16	4	1	34.77 (NA)	5	4	47.40 (7.02)
Week 24	3	2	37.74 (12.61)	5	4	47.40 (8.18)
Week 32				5	5	49.63 (5.56)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

113: SF-36v2 mental component score by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	41.81 (6.28)	17	17	45.84 (9.52)
Week 4	8	8	44.42 (6.12)	17	11	49.52 (9.03)
Week 8	8	6	43.64 (10.08)	17	15	48.39 (7.29)
Week 16	6	4	45.06 (4.75)	17	16	48.88 (10.46)
Week 24	6	6	43.74 (11.47)	17	15	49.55 (9.36)
Week 32				17	16	50.45 (7.89)
Age						
< 18 years						
Baseline	1	1	43.33 (NA)	10	10	47.50 (9.91)
Week 4	1	1	45.12 (NA)	10	7	47.53 (10.56)
Week 8	1	1	36.99 (NA)	10	9	48.69 (7.60)
Week 16	1	1	50.40 (NA)	10	9	47.77 (10.95)
Week 24	1	1	49.39 (NA)	10	9	50.34 (7.69)
Week 32				10	9	53.01 (8.31)
>= 18 years						
Baseline	8	4	41.44 (7.18)	7	7	43.46 (9.11)
Week 4	7	7	44.32 (6.60)	7	4	53.02 (4.78)
Week 8	7	5	44.97 (10.67)	7	6	47.94 (7.46)
Week 16	5	3	43.28 (3.85)	7	7	50.30 (10.46)
Week 24	5	5	42.61 (12.45)	7	6	48.38 (12.17)
Week 32				7	7	47.16 (6.40)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 mental component score by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	42.44 (7.84)	5	5	46.71 (11.93)
Week 4	5	5	44.31 (3.99)	5	3	51.93 (6.11)
Week 8	5	4	41.03 (6.16)	5	5	49.41 (9.63)
Week 16	4	3	46.55 (4.52)	5	5	49.34 (11.94)
Week 24	4	4	42.48 (8.27)	5	3	50.45 (10.48)
Week 32				5	4	51.11 (9.26)
low titer						
Baseline	3	2	40.87 (5.63)	12	12	45.47 (8.91)
Week 4	3	3	44.59 (9.95)	12	8	48.62 (10.11)
Week 8	3	2	48.86 (17.68)	12	10	47.89 (6.37)
Week 16	2	1	40.58 (NA)	12	11	48.67 (10.34)
Week 24	2	2	46.24 (20.84)	12	12	49.33 (9.55)
Week 32				12	12	50.24 (7.83)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

114: SF-36v2 mental component score by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	44.35 (4.34)	12	7	50.71 (5.81)
Week 4	9	6	47.83 (10.25)	12	7	50.75 (12.52)
Week 8	9	6	47.59 (8.24)	11	8	50.62 (11.50)
Week 16	9	4	44.17 (9.64)	11	9	50.78 (9.11)
Week 24	8	6	46.19 (8.73)	11	9	50.86 (10.89)
Week 32				11	11	48.02 (13.34)
Age						
< 18 years						
Baseline	5	3	47.28 (2.24)	6	4	52.67 (4.30)
Week 4	5	4	52.83 (8.63)	6	4	51.21 (13.23)
Week 8	5	4	51.78 (5.29)	6	4	49.45 (14.55)
Week 16	5	3	46.71 (10.05)	6	5	52.05 (10.21)
Week 24	5	4	46.65 (10.31)	6	5	52.41 (11.15)
Week 32				6	6	47.64 (17.28)
>= 18 years						
Baseline	5	2	39.96 (0.91)	6	3	48.09 (7.46)
Week 4	4	2	37.82 (1.09)	6	3	50.13 (14.37)
Week 8	4	2	39.19 (6.65)	5	4	51.80 (9.67)
Week 16	4	1	36.57 (NA)	5	4	49.20 (8.75)
Week 24	3	2	45.25 (7.74)	5	4	48.93 (11.89)
Week 32				5	5	48.47 (8.44)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

115: SF-36v2 physical component score by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	33.97 (4.39)	17	17	40.98 (7.98)
Week 4	8	8	33.25 (6.28)	17	11	42.38 (9.88)
Week 8	8	6	33.80 (7.95)	17	15	45.52 (9.50)
Week 16	6	4	30.77 (8.19)	17	16	48.27 (9.21)
Week 24	6	6	35.69 (8.22)	17	15	47.55 (9.97)
Week 32				17	16	45.44 (9.67)
Age						
< 18 years						
Baseline	1	1	31.08 (NA)	10	10	41.90 (6.43)
Week 4	1	1	32.55 (NA)	10	7	45.25 (6.70)
Week 8	1	1	43.39 (NA)	10	9	46.79 (7.61)
Week 16	1	1	33.54 (NA)	10	9	51.79 (5.53)
Week 24	1	1	33.70 (NA)	10	9	49.35 (5.72)
Week 32				10	9	47.15 (7.86)
>= 18 years						
Baseline	8	4	34.69 (4.71)	7	7	39.67 (10.22)
Week 4	7	7	33.35 (6.77)	7	4	37.36 (13.52)
Week 8	7	5	31.88 (7.16)	7	6	43.62 (12.36)
Week 16	5	3	29.84 (9.77)	7	7	43.74 (11.36)
Week 24	5	5	36.09 (9.12)	7	6	44.84 (14.54)
Week 32				7	7	43.25 (11.89)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 physical component score by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	31.40 (1.65)	5	5	37.31 (8.44)
Week 4	5	5	29.92 (5.38)	5	3	40.26 (6.36)
Week 8	5	4	32.29 (8.59)	5	5	43.06 (8.94)
Week 16	4	3	28.56 (8.46)	5	5	48.59 (9.81)
Week 24	4	4	30.81 (3.09)	5	3	45.55 (8.43)
Week 32				5	4	43.30 (8.72)
low titer						
Baseline	3	2	37.82 (4.70)	12	12	42.51 (7.62)
Week 4	3	3	38.80 (2.42)	12	8	43.17 (11.19)
Week 8	3	2	36.82 (8.19)	12	10	46.75 (9.99)
Week 16	2	1	37.38 (NA)	12	11	48.12 (9.42)
Week 24	2	2	45.44 (4.86)	12	12	48.05 (10.59)
Week 32				12	12	46.15 (10.23)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

116: SF-36v2 physical component score by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	38.55 (6.65)	12	7	38.45 (9.97)
Week 4	9	6	37.34 (8.71)	12	7	44.94 (12.48)
Week 8	9	6	38.09 (9.27)	11	8	44.81 (12.09)
Week 16	9	4	34.94 (11.70)	11	9	46.94 (8.55)
Week 24	8	6	35.78 (10.45)	11	9	47.91 (10.95)
Week 32				11	11	47.23 (12.71)
Age						
< 18 years						
Baseline	5	3	36.68 (1.66)	6	4	44.52 (8.52)
Week 4	5	4	35.97 (4.28)	6	4	51.92 (11.66)
Week 8	5	4	36.61 (7.53)	6	4	51.39 (14.60)
Week 16	5	3	37.97 (12.27)	6	5	51.51 (7.69)
Week 24	5	4	37.39 (10.78)	6	5	52.11 (9.59)
Week 32				6	6	52.18 (12.81)
>= 18 years						
Baseline	5	2	41.36 (12.05)	6	3	30.34 (4.13)
Week 4	4	2	40.08 (17.38)	6	3	35.62 (5.94)
Week 8	4	2	41.05 (15.27)	5	4	38.23 (3.49)
Week 16	4	1	25.86 (NA)	5	4	41.23 (6.14)
Week 24	3	2	32.58 (12.90)	5	4	42.66 (11.45)
Week 32				5	5	41.29 (10.85)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

117: Return rates of PGI-C on physical functioning by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
Age									
< 18 years	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
>= 18 years	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
Disease severity									
High titer	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
Low titer	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)

PGI-C: Patient Global Impression of Change, HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. There are no baseline results for PGI-C as the questionnaire is defined as "compared to baseline".

118: SF-36v2 bodily pain by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	37.64 (6.10)	17	17	42.26 (9.47)
Week 4	8	8	35.99 (10.64)	17	11	48.91 (9.81)
Week 8	8	6	38.68 (8.27)	17	15	47.32 (9.56)
Week 16	6	4	35.28 (3.83)	17	16	51.04 (11.59)
Week 24	6	6	39.29 (6.22)	17	15	52.40 (10.01)
Week 32				17	16	46.93 (11.89)
Age						
< 18 years						
Baseline	1	1	34.58 (NA)	10	10	43.57 (10.99)
Week 4	1	1	26.52 (NA)	10	7	52.09 (5.30)
Week 8	1	1	42.24 (NA)	10	9	49.01 (9.55)
Week 16	1	1	34.58 (NA)	10	9	54.83 (10.13)
Week 24	1	1	34.58 (NA)	10	9	56.17 (7.04)
Week 32				10	9	49.99 (11.61)
>= 18 years						
Baseline	8	4	38.41 (6.75)	7	7	40.40 (7.16)
Week 4	7	7	37.35 (10.72)	7	4	43.35 (14.12)
Week 8	7	5	37.97 (9.04)	7	6	44.80 (9.88)
Week 16	5	3	35.52 (4.66)	7	7	46.16 (12.24)
Week 24	5	5	40.23 (6.46)	7	6	46.74 (11.70)
Week 32				7	7	42.99 (11.88)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 bodily pain by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	37.13 (2.22)	5	5	42.24 (11.55)
Week 4	5	5	32.65 (8.53)	5	3	44.93 (6.04)
Week 8	5	4	37.50 (5.94)	5	5	43.53 (7.82)
Week 16	4	3	34.31 (4.04)	5	5	53.05 (11.46)
Week 24	4	4	35.39 (1.89)	5	3	49.23 (11.99)
Week 32				5	4	44.96 (8.31)
low titer						
Baseline	3	2	38.41 (11.70)	12	12	42.27 (9.06)
Week 4	3	3	41.57 (13.26)	12	8	50.41 (10.84)
Week 8	3	2	41.03 (14.82)	12	10	49.22 (10.15)
Week 16	2	1	38.21 (NA)	12	11	50.12 (12.09)
Week 24	2	2	47.08 (0.57)	12	12	53.19 (9.89)
Week 32				12	12	47.58 (13.11)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

119: Return rates of PGI-S on physical functioning by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	5 (50.0)	12	7 (58.3)
	Week 24	6	6 (100)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	5 (100)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	2 (100)	12	11 (91.7)	3	3 (100)	9	8 (88.9)

PGI-S: Patient Global Impression of Severity, HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, L ow titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

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120: SF-36v2 bodily pain by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	37.48 (4.53)	12	7	47.08 (9.49)
Week 4	9	6	37.00 (4.14)	12	7	52.44 (7.27)
Week 8	9	6	41.30 (8.26)	11	8	49.35 (9.20)
Week 16	9	4	39.32 (11.76)	11	9	52.63 (9.77)
Week 24	8	6	40.70 (9.65)	11	9	51.69 (11.14)
Week 32				11	11	51.41 (11.17)
Age						
< 18 years						
Baseline	5	3	38.21 (0.00)	6	4	52.62 (7.58)
Week 4	5	4	37.20 (2.02)	6	4	55.55 (7.71)
Week 8	5	4	43.65 (8.20)	6	4	53.94 (6.49)
Week 16	5	3	43.58 (9.91)	6	5	53.77 (8.27)
Week 24	5	4	41.84 (10.43)	6	5	58.13 (8.66)
Week 32				6	6	56.35 (9.65)
>= 18 years						
Baseline	5	2	36.39 (8.84)	6	3	39.69 (6.38)
Week 4	4	2	36.59 (8.55)	6	3	48.29 (4.91)
Week 8	4	2	36.59 (8.55)	5	4	44.76 (9.97)
Week 16	4	1	26.52 (NA)	5	4	51.21 (12.59)
Week 24	3	2	38.41 (11.12)	5	4	43.65 (8.71)
Week 32				5	5	45.47 (10.71)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

121: Return rates of Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

122: SF-36v2 physical functioning by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	9	5	34.19 (8.05)	17	17	39.87 (10.30)
Week 4	8	8	33.14 (9.69)	17	11	39.97 (12.89)
Week 8	8	6	33.94 (8.95)	17	15	42.74 (11.03)
Week 16	6	4	34.09 (11.84)	17	16	46.42 (10.58)
Week 24	6	6	37.77 (11.72)	17	15	44.14 (11.51)
Week 32				17	16	43.78 (11.19)
Age						
< 18 years						
Baseline	1	1	36.49 (NA)	10	10	39.93 (9.62)
Week 4	1	1	42.23 (NA)	10	7	42.23 (12.55)
Week 8	1	1	42.23 (NA)	10	9	44.99 (10.04)
Week 16	1	1	36.49 (NA)	10	9	50.52 (6.90)
Week 24	1	1	42.23 (NA)	10	9	44.99 (10.40)
Week 32				10	9	44.99 (11.08)
>= 18 years						
Baseline	8	4	33.62 (9.18)	7	7	39.77 (11.99)
Week 4	7	7	31.84 (9.68)	7	4	36.01 (14.35)
Week 8	7	5	32.28 (8.92)	7	6	39.36 (12.50)
Week 16	5	3	33.30 (14.37)	7	7	41.14 (12.59)
Week 24	5	5	36.87 (12.87)	7	6	42.87 (13.94)
Week 32				7	7	42.23 (12.00)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

SF-36v2 physical functioning by treatment week - Explorer 7 - HAwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Disease severity						
high titer						
Baseline	6	3	32.02 (6.15)	5	5	34.19 (11.35)
Week 4	5	5	29.98 (8.07)	5	3	40.31 (11.64)
Week 8	5	4	30.27 (8.89)	5	5	42.23 (9.76)
Week 16	4	3	29.47 (9.05)	5	5	46.44 (11.98)
Week 24	4	4	31.70 (7.73)	5	3	40.95 (7.97)
Week 32				5	4	42.23 (12.00)
low titer						
Baseline	3	2	37.44 (12.18)	12	12	42.23 (9.30)
Week 4	3	3	38.40 (11.48)	12	8	39.84 (14.09)
Week 8	3	2	41.27 (1.35)	12	10	42.99 (12.11)
Week 16	2	1	47.97 (NA)	12	11	46.40 (10.51)
Week 24	2	2	49.89 (8.12)	12	12	44.94 (12.39)
Week 32				12	12	44.30 (11.41)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

123: Return rates of Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

124: SF-36v2 physical functioning by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	10	5	38.40 (12.48)	12	7	34.30 (12.67)
Week 4	9	6	39.36 (10.18)	12	7	42.50 (12.95)
Week 8	9	6	36.49 (9.76)	11	8	42.23 (11.62)
Week 16	9	4	32.19 (13.66)	11	9	45.00 (10.36)
Week 24	8	6	32.98 (11.83)	11	9	43.08 (12.98)
Week 32				11	11	42.75 (9.87)
Age						
< 18 years						
Baseline	5	3	36.49 (11.95)	6	4	39.36 (14.78)
Week 4	5	4	39.84 (7.22)	6	4	49.41 (11.73)
Week 8	5	4	35.06 (8.75)	6	4	49.41 (11.73)
Week 16	5	3	35.85 (14.11)	6	5	51.42 (8.28)
Week 24	5	4	35.53 (12.55)	6	5	45.68 (16.32)
Week 32				6	6	47.01 (10.67)
>= 18 years						
Baseline	5	2	41.27 (17.59)	6	3	27.56 (5.84)
Week 4	4	2	38.41 (18.94)	6	3	33.30 (8.63)
Week 8	4	2	39.36 (14.88)	5	4	35.06 (6.33)
Week 16	4	1	21.18 (NA)	5	4	36.97 (6.33)
Week 24	3	2	27.88 (12.18)	5	4	39.84 (8.32)
Week 32				5	5	37.64 (6.43)

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, NA: not applicable, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

125: Return rates of Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

126: Return rates of Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	8 (47.1)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	8 (47.1)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	1 (10.0)				
	Week 8			10	2 (20.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	6 (50.0)			10	1 (10.0)
	Week 8			12	6 (50.0)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 B U, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

127: Return rates of Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 B U, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

128: Return rates of Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	8 (47.1)	10	3 (30.0)	12	3 (25.0)
	Week 4	8	3 (37.5)	17	7 (41.2)			12	2 (16.7)
	Week 8	8	3 (37.5)	17	6 (35.3)			11	2 (18.2)
	Week 16	6	3 (50.0)	17	5 (29.4)			11	2 (18.2)
	Week 24	6	3 (50.0)	17	5 (29.4)			11	2 (18.2)
	Week 32			17	3 (17.6)			11	2 (18.2)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	6 (85.7)	5	2 (40.0)	6	2 (33.3)
	Week 4	7	3 (42.9)	7	5 (71.4)			6	2 (33.3)
	Week 8	7	3 (42.9)	7	3 (42.9)			5	2 (40.0)
	Week 16	5	3 (60.0)	7	3 (42.9)			5	2 (40.0)
	Week 24	5	3 (60.0)	7	4 (57.1)			5	2 (40.0)
	Week 32			7	1 (14.3)			5	2 (40.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)				
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)			1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)			1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	5 (41.7)	4	1 (25.0)	10	1 (10.0)
	Week 4	3	1 (33.3)	12	5 (41.7)				
	Week 8			12	4 (33.3)				
	Week 16	2	1 (50.0)	12	2 (16.7)				
	Week 24	2	1 (50.0)	12	3 (25.0)			9	1 (11.1)
	Week 32			12	1 (8.3)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

129: Return rates of Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 B U, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

130: Return rates of Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

131: Return rates of Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	9 (52.9)	10	3 (30.0)	12	5 (41.7)
	Week 4	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	12	3 (25.0)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	3 (27.3)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	4 (36.4)
	Week 24	6	3 (50.0)	17	7 (41.2)	8	1 (12.5)	11	3 (27.3)
	Week 32			17	5 (29.4)			11	4 (36.4)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	7 (100)	5	2 (40.0)	6	4 (66.7)
	Week 4	7	3 (42.9)	7	7 (100)	4	1 (25.0)	6	3 (50.0)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	4 (80.0)
	Week 24	5	3 (60.0)	7	6 (85.7)			5	3 (60.0)
	Week 32			7	3 (42.9)			5	4 (80.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	6 (50.0)	4	1 (25.0)	10	3 (30.0)
	Week 4	3	1 (33.3)	12	7 (58.3)			10	1 (10.0)
	Week 8			12	7 (58.3)			9	1 (11.1)
	Week 16	2	1 (50.0)	12	4 (33.3)			9	2 (22.2)
	Week 24	2	1 (50.0)	12	5 (41.7)	3	1 (33.3)	9	2 (22.2)
	Week 32			12	3 (25.0)			9	2 (22.2)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

132: Return rates of Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	8 (47.1)	10	3 (30.0)	12	3 (25.0)
	Week 4	8	2 (25.0)	17	8 (47.1)	9	1 (11.1)	12	2 (16.7)
	Week 8	8	3 (37.5)	17	9 (52.9)	9	1 (11.1)	11	2 (18.2)
	Week 16	6	3 (50.0)	17	7 (41.2)			11	2 (18.2)
	Week 24	6	3 (50.0)	17	6 (35.3)	8	1 (12.5)	11	1 (9.1)
	Week 32			17	5 (29.4)			11	2 (18.2)
Age									
>= 18 years	Baseline	8	5 (62.5)	7	6 (85.7)	5	2 (40.0)	6	2 (33.3)
	Week 4	7	2 (28.6)	7	6 (85.7)	4	1 (25.0)	6	2 (33.3)
	Week 8	7	3 (42.9)	7	6 (85.7)	4	1 (25.0)	5	2 (40.0)
	Week 16	5	3 (60.0)	7	5 (71.4)			5	2 (40.0)
	Week 24	5	3 (60.0)	7	5 (71.4)			5	1 (20.0)
	Week 32			7	3 (42.9)			5	2 (40.0)
< 18 years	Baseline			10	2 (20.0)	5	1 (20.0)	6	1 (16.7)
	Week 4			10	2 (20.0)				
	Week 8			10	3 (30.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)	5	1 (20.0)		
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	4 (66.7)	5	3 (60.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	2 (40.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	3 (60.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	2 (50.0)	5	3 (60.0)			1	1 (100)
	Week 24	4	2 (50.0)	5	2 (40.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	2 (40.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	5 (41.7)	4	1 (25.0)	10	2 (20.0)
	Week 4			12	6 (50.0)				
	Week 8			12	7 (58.3)				
	Week 16	2	1 (50.0)	12	4 (33.3)				
	Week 24	2	1 (50.0)	12	4 (33.3)	3	1 (33.3)		
	Week 32			12	3 (25.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

133: Return rates of Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	4 (44.4)	17	4 (23.5)	10	2 (20.0)	12	3 (25.0)
	Week 4	8	1 (12.5)	17	4 (23.5)	9	1 (11.1)	12	2 (16.7)
	Week 8	8	2 (25.0)	17	4 (23.5)	9	1 (11.1)	11	2 (18.2)
	Week 16	6	1 (16.7)	17	4 (23.5)			11	3 (27.3)
	Week 24	6	1 (16.7)	17	3 (17.6)			11	1 (9.1)
	Week 32			17	2 (11.8)			11	2 (18.2)
Age									
>= 18 years	Baseline	8	4 (50.0)	7	2 (28.6)	5	2 (40.0)	6	2 (33.3)
	Week 4	7	1 (14.3)	7	3 (42.9)	4	1 (25.0)	6	2 (33.3)
	Week 8	7	2 (28.6)	7	2 (28.6)	4	1 (25.0)	5	2 (40.0)
	Week 16	5	1 (20.0)	7	2 (28.6)			5	3 (60.0)
	Week 24	5	1 (20.0)	7	2 (28.6)			5	1 (20.0)
	Week 32							5	2 (40.0)
< 18 years	Baseline			10	2 (20.0)			6	1 (16.7)
	Week 4			10	1 (10.0)				
	Week 8			10	2 (20.0)				
	Week 16			10	2 (20.0)				
	Week 24			10	1 (10.0)				
	Week 32			10	2 (20.0)				
Disease severity									
High titer	Baseline	6	3 (50.0)	5	2 (40.0)	4	1 (25.0)	1	1 (100)
	Week 4	5	1 (20.0)	5	1 (20.0)	4	1 (25.0)	1	1 (100)
	Week 8	5	2 (40.0)	5	1 (20.0)	4	1 (25.0)	1	1 (100)
	Week 16	4	1 (25.0)	5	2 (40.0)			1	1 (100)
	Week 24	4	1 (25.0)	5	1 (20.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 B U, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

Return rates of Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 7 - HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
High titer	Week 32			5	1 (20.0)			1	1 (100)
Low titer	Baseline	3	1 (33.3)	12	2 (16.7)	4	1 (25.0)	10	2 (20.0)
	Week 4			12	3 (25.0)				
	Week 8			12	3 (25.0)				
	Week 16			12	2 (16.7)			9	1 (11.1)
	Week 24			12	2 (16.7)			9	1 (11.1)
	Week 32			12	1 (8.3)			9	1 (11.1)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32. One subject below the age of 17 filled out the questionnaire at post baseline visits and one other subject filled it out at post baseline visits. These data are included in the descriptive statistics.

134: Return rates of Hemo-TEM Total Score by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	4 (40.0)	12	7 (58.3)
	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	2 (40.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	1 (25.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

135: Return rates of Hemo-TEM ease of use by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	4 (40.0)	12	7 (58.3)
	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	2 (40.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	1 (25.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

136: Return rates of Hemo-TEM emotional impact by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	4 (40.0)	12	7 (58.3)
	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	2 (40.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	1 (25.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

137: Return rates of Hemo-TEM interference by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	4 (40.0)	12	7 (58.3)
	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	2 (40.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	1 (25.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

138: Return rates of Hemo-TEM physical impact by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	4 (40.0)	12	7 (58.3)
	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	2 (40.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	1 (25.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 B U, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

139: Return rates of Hemo-TEM treatment burden by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	4 (40.0)	12	7 (58.3)
	Week 24	6	5 (83.3)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	2 (40.0)	6	4 (66.7)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 24	5	4 (80.0)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	1 (25.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 24	2	1 (50.0)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

140: Return rates of PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	16 (94.1)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	5 (55.6)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	14 (82.4)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	10 (90.9)
Age									
< 18 years	Baseline	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	3 (60.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	5 (71.4)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	4 (80.0)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	3 (75.0)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	11 (91.7)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	11 (91.7)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

141: Return rates of PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	7 (77.8)	17	17 (100)	10	4 (40.0)	12	7 (58.3)
	Week 4	8	7 (87.5)	17	11 (64.7)	9	4 (44.4)	12	6 (50.0)
	Week 8	8	5 (62.5)	17	14 (82.4)	9	5 (55.6)	11	7 (63.6)
	Week 16	6	4 (66.7)	17	15 (88.2)	9	4 (44.4)	11	8 (72.7)
	Week 24	6	6 (100)	17	14 (82.4)	8	6 (75.0)	11	8 (72.7)
	Week 32			17	16 (94.1)			11	9 (81.8)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	3 (60.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	8 (80.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	8 (80.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	6 (75.0)	7	7 (100)	5	1 (20.0)	6	3 (50.0)
	Week 4	7	6 (85.7)	7	4 (57.1)	4	1 (25.0)	6	2 (33.3)
	Week 8	7	4 (57.1)	7	6 (85.7)	4	1 (25.0)	5	3 (60.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	3 (60.0)
	Week 24	5	5 (100)	7	5 (71.4)	3	2 (66.7)	5	3 (60.0)
	Week 32			7	7 (100)			5	3 (60.0)
Disease severity									
High titer	Baseline	6	5 (83.3)	5	5 (100)	4	1 (25.0)		
	Week 4	5	4 (80.0)	5	3 (60.0)	4	2 (50.0)		
	Week 8	5	3 (60.0)	5	4 (80.0)	4	3 (75.0)		
	Week 16	4	3 (75.0)	5	4 (80.0)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)				

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	6 (60.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	5 (50.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	6 (66.7)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	7 (77.8)
	Week 24	2	2 (100)	12	11 (91.7)	3	3 (100)	9	7 (77.8)
	Week 32			12	12 (100)			9	8 (88.9)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

142: Return rates of SF-36v2 general health by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 general health by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

143: Return rates of SF-36v2 mental health by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 mental health by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

144: Return rates of SF-36v2 role emotional by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 role emotional by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

145: Return rates of SF-36v2 role physical by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 role physical by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

146: Return rates of SF-36v2 social function by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 social function by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

147: Return rates of SF-36v2 vitality by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 vitality by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 B U, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

148: Return rates of SF-36v2 mental component score by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 mental component score by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

149: Return rates of SF-36v2 physical component score by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 physical component score by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

150: Return rates of SF-36v2 bodily pain by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 bodily pain by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

151: Return rates of SF-36v2 physical functioning by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Total									
All subjects	Baseline	9	5 (55.6)	17	17 (100)	10	5 (50.0)	12	7 (58.3)
	Week 4	8	8 (100)	17	11 (64.7)	9	6 (66.7)	12	7 (58.3)
	Week 8	8	6 (75.0)	17	15 (88.2)	9	6 (66.7)	11	8 (72.7)
	Week 16	6	4 (66.7)	17	16 (94.1)	9	4 (44.4)	11	9 (81.8)
	Week 24	6	6 (100)	17	15 (88.2)	8	6 (75.0)	11	9 (81.8)
	Week 32			17	16 (94.1)			11	11 (100)
Age									
< 18 years	Baseline	1	1 (100)	10	10 (100)	5	3 (60.0)	6	4 (66.7)
	Week 4	1	1 (100)	10	7 (70.0)	5	4 (80.0)	6	4 (66.7)
	Week 8	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	4 (66.7)
	Week 16	1	1 (100)	10	9 (90.0)	5	3 (60.0)	6	5 (83.3)
	Week 24	1	1 (100)	10	9 (90.0)	5	4 (80.0)	6	5 (83.3)
	Week 32			10	9 (90.0)			6	6 (100)
>= 18 years	Baseline	8	4 (50.0)	7	7 (100)	5	2 (40.0)	6	3 (50.0)
	Week 4	7	7 (100)	7	4 (57.1)	4	2 (50.0)	6	3 (50.0)
	Week 8	7	5 (71.4)	7	6 (85.7)	4	2 (50.0)	5	4 (80.0)
	Week 16	5	3 (60.0)	7	7 (100)	4	1 (25.0)	5	4 (80.0)
	Week 24	5	5 (100)	7	6 (85.7)	3	2 (66.7)	5	4 (80.0)
	Week 32			7	7 (100)			5	5 (100)
Disease severity									
High titer	Baseline	6	3 (50.0)	5	5 (100)	4	2 (50.0)		
	Week 4	5	5 (100)	5	3 (60.0)	4	4 (100)		
	Week 8	5	4 (80.0)	5	5 (100)	4	4 (100)		
	Week 16	4	3 (75.0)	5	5 (100)	4	3 (75.0)		
	Week 24	4	4 (100)	5	3 (60.0)	3	3 (100)		
	Week 32			5	4 (80.0)			1	1 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Return rates of SF-36v2 physical functioning by treatment week - Explorer 7 - HAwI and HBwI - On-treatment without data on initial regimen - Full analysis set

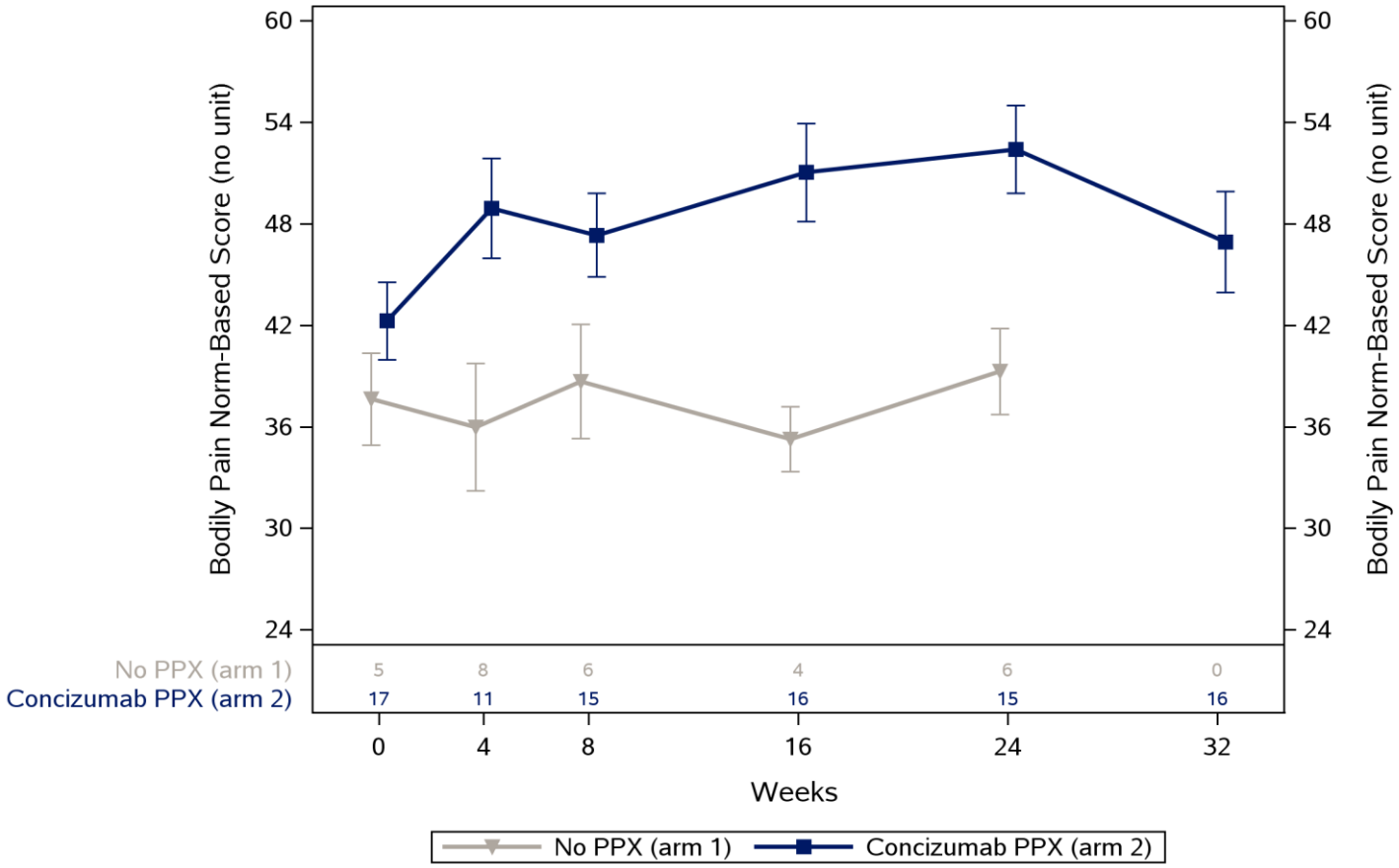
		HAwI				HBwI			
		No PPX		Concizumab PPX		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Low titer	Baseline	3	2 (66.7)	12	12 (100)	4	2 (50.0)	10	7 (70.0)
	Week 4	3	3 (100)	12	8 (66.7)	3	2 (66.7)	10	6 (60.0)
	Week 8	3	2 (66.7)	12	10 (83.3)	3	2 (66.7)	9	7 (77.8)
	Week 16	2	1 (50.0)	12	11 (91.7)	3	1 (33.3)	9	8 (88.9)
	Week 24	2	2 (100)	12	12 (100)	3	3 (100)	9	8 (88.9)
	Week 32			12	12 (100)			9	9 (100)

HAwI: haemophilia A with inhibitors, HBwI: haemophilia B with inhibitors, PPX: Prophylaxis, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, N: number of subjects in the analysis set who did not discontinue before the nominal week of the visit, n: number of subjects contributing to analysis, SD: Standard deviation. Baseline is visit 2/2a for no PPX (arm 1) and visit 2a for concizumab PPX (arms 2). Patients in arm 1 (No PPX) did not fill out the questionnaire at week 32.

Table of contents

Page

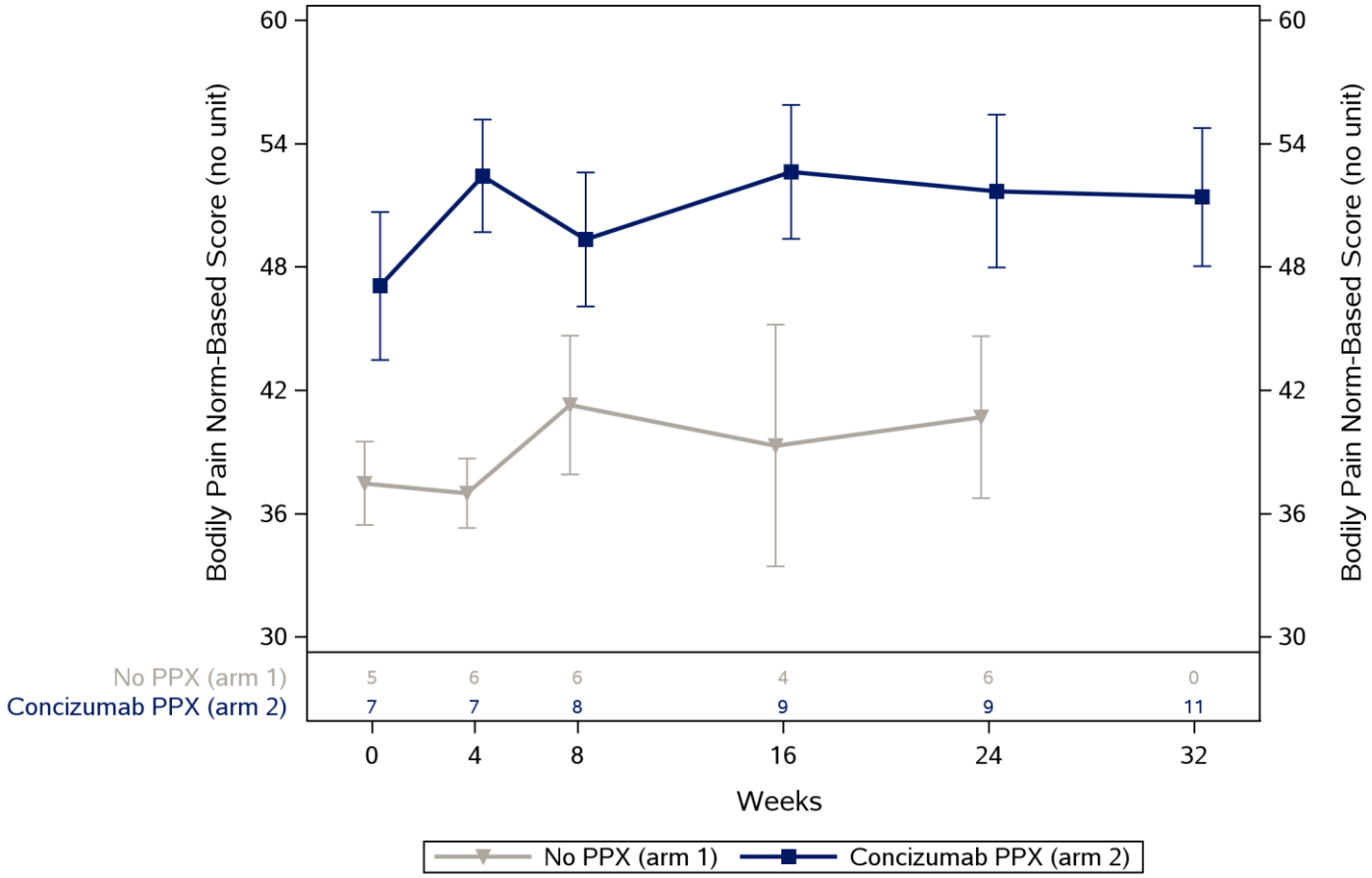
1: SF-36v2 (standard version) - bodily pain - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:38 - f-sf36mean.sas/f-sf36bpfasHA.png

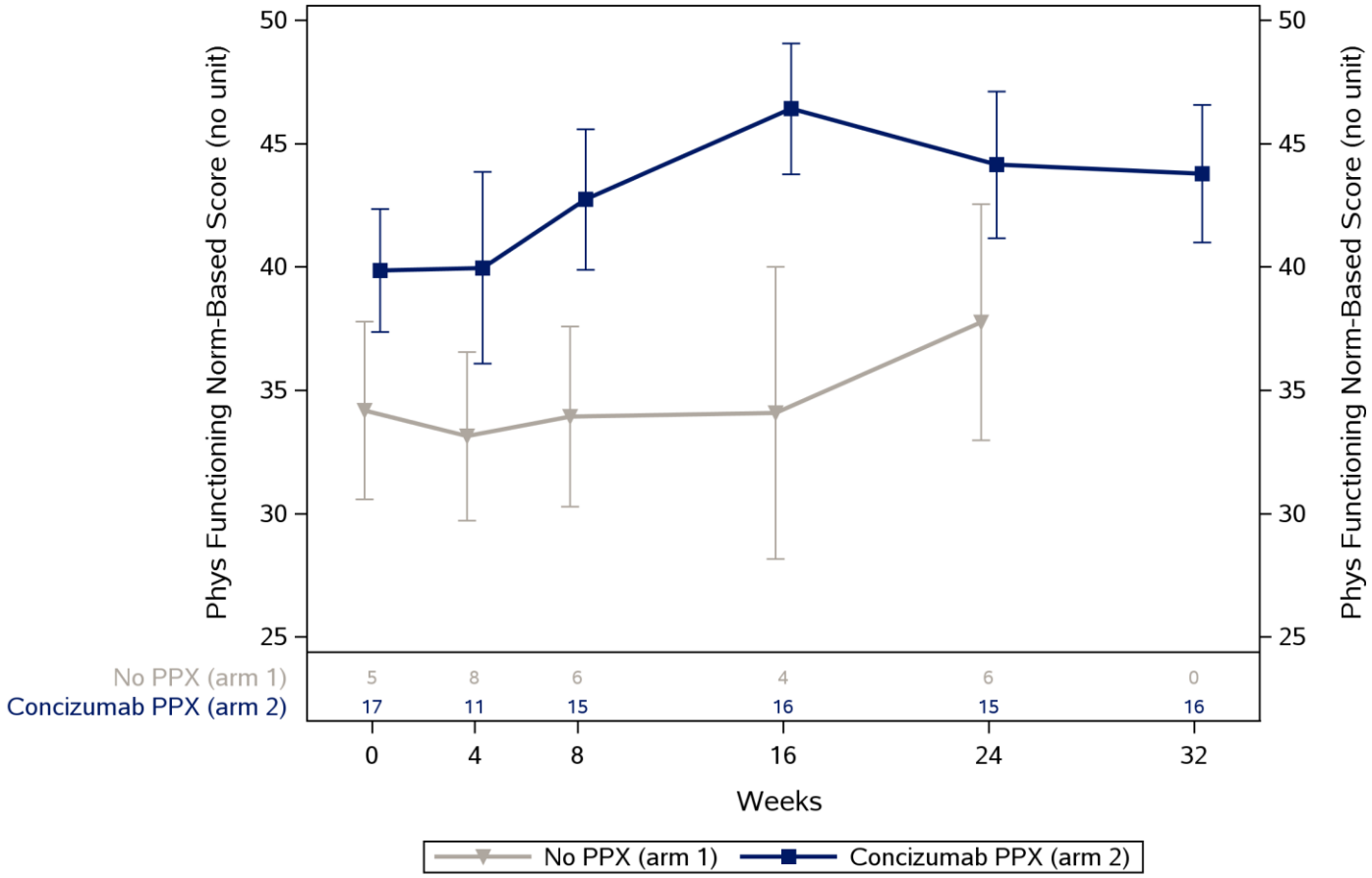
2: SF-36v2 (standard version) - bodily pain - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:43 - f-sf36mean.sas/f-sf36bpfasHB.png

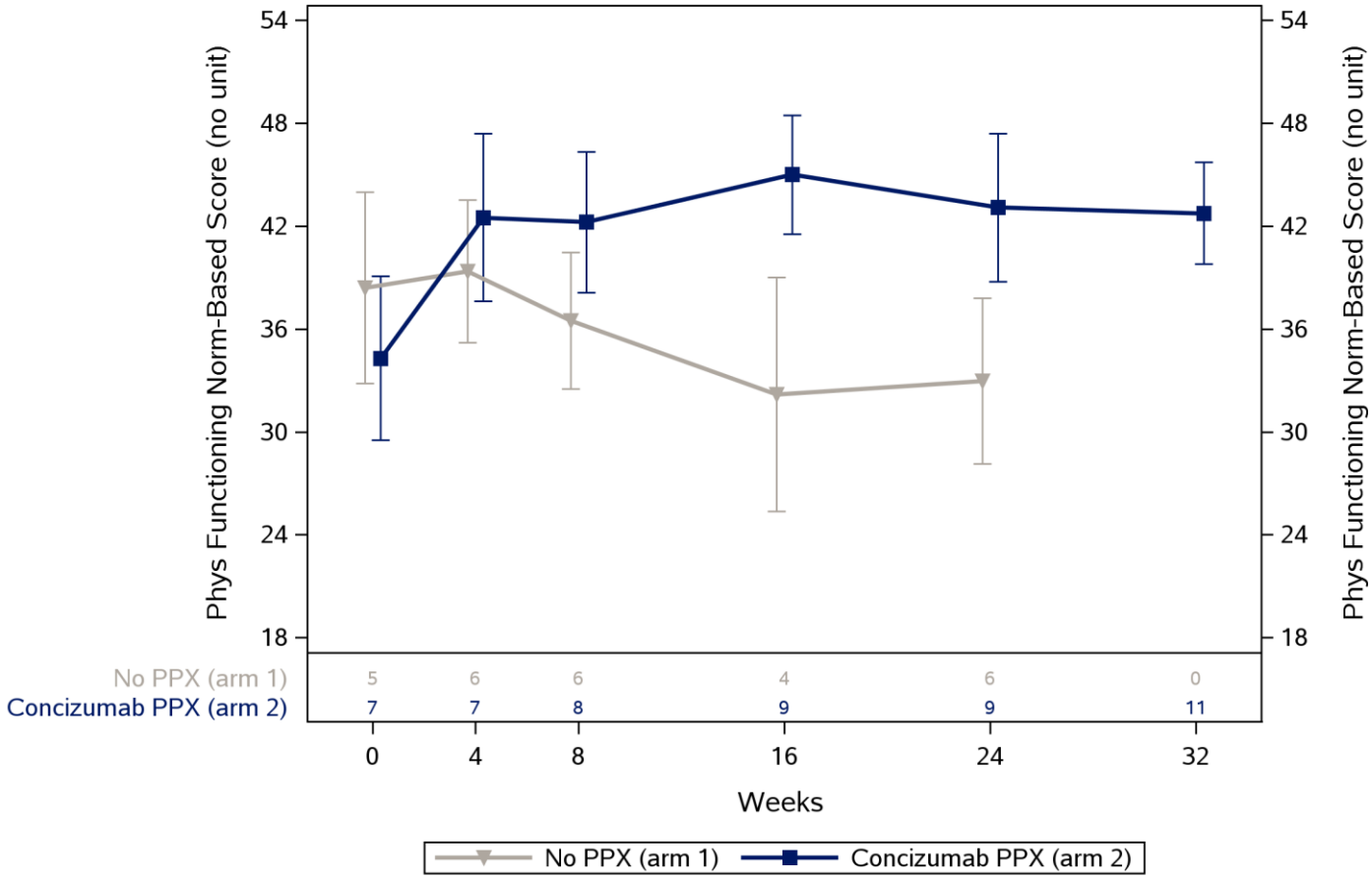
3: SF-36v2 (standard version) - physical functioning - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:45 - f-sf36mean.sas/f-sf36physfuncfasHA.png

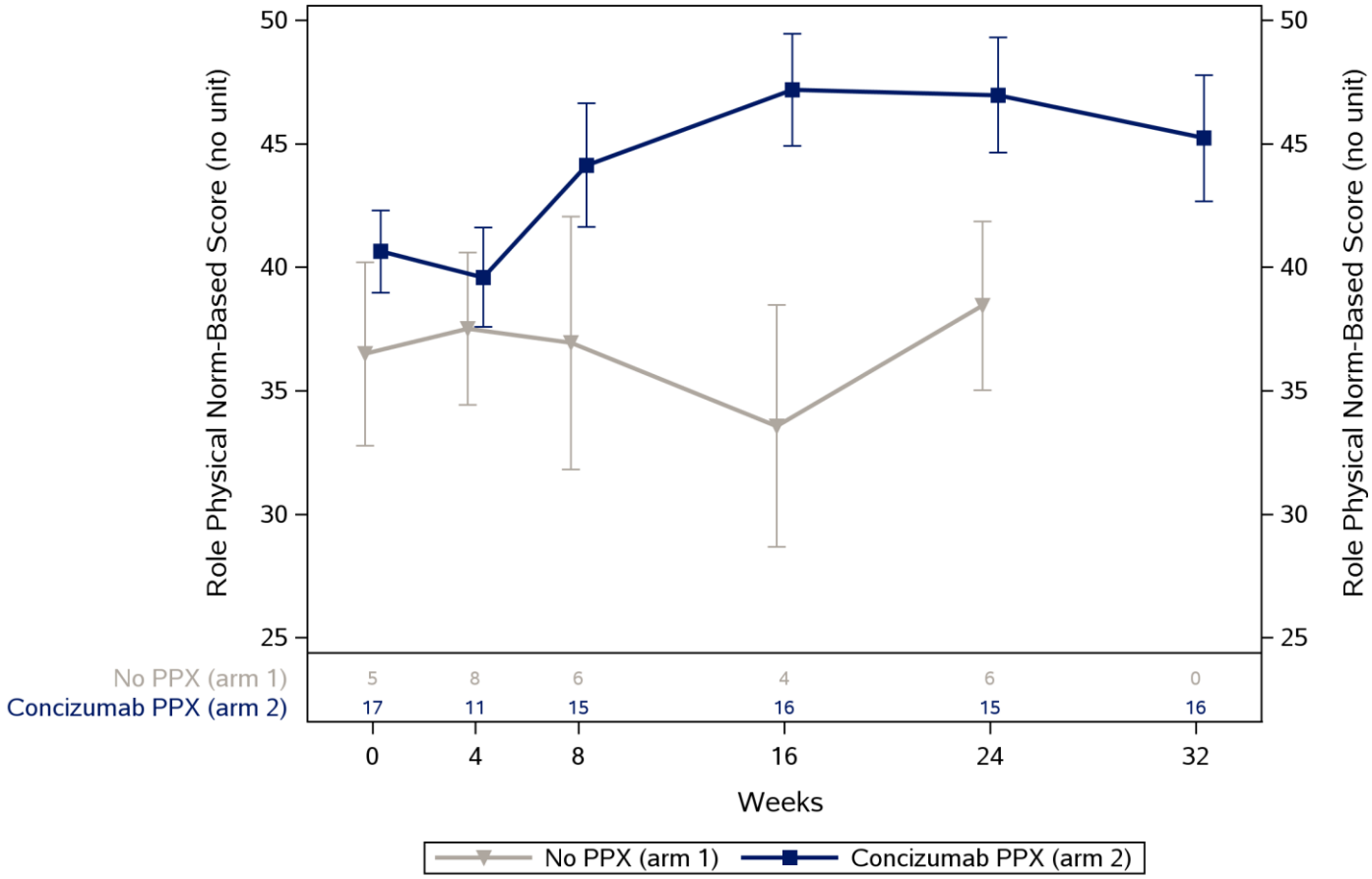
4: SF-36v2 (standard version) - physical functioning - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:46 - f-sf36mean.sas/f-sf36physfuncfasHB.png

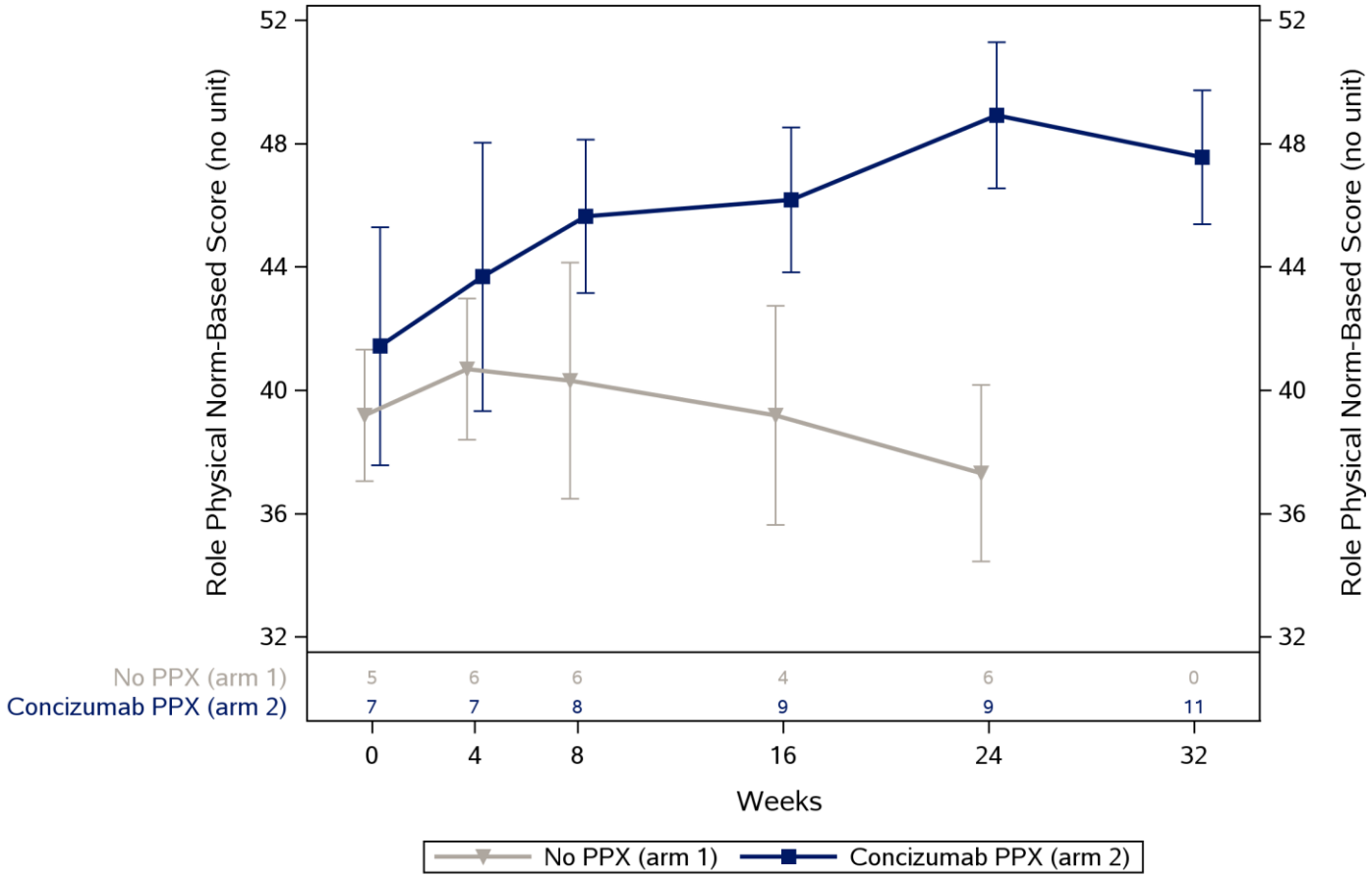
5: SF-36v2 (standard version) - role physical - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:50 - f-sf36mean.sas/f-sf36rolephysfasHA.png

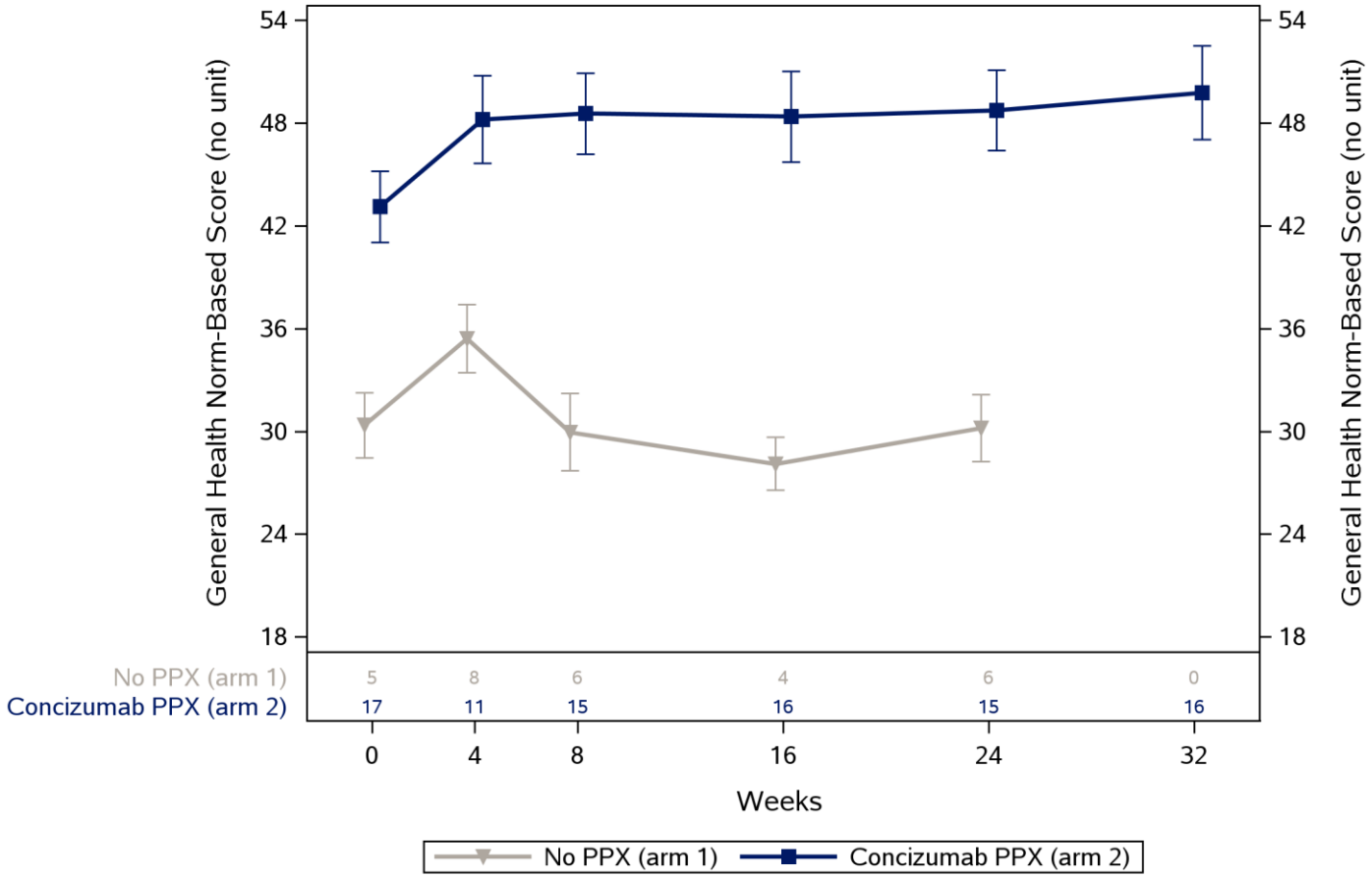
6: SF-36v2 (standard version) - role physical - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:52 - f-sf36mean.sas/f-sf36rolephysfasHB.png

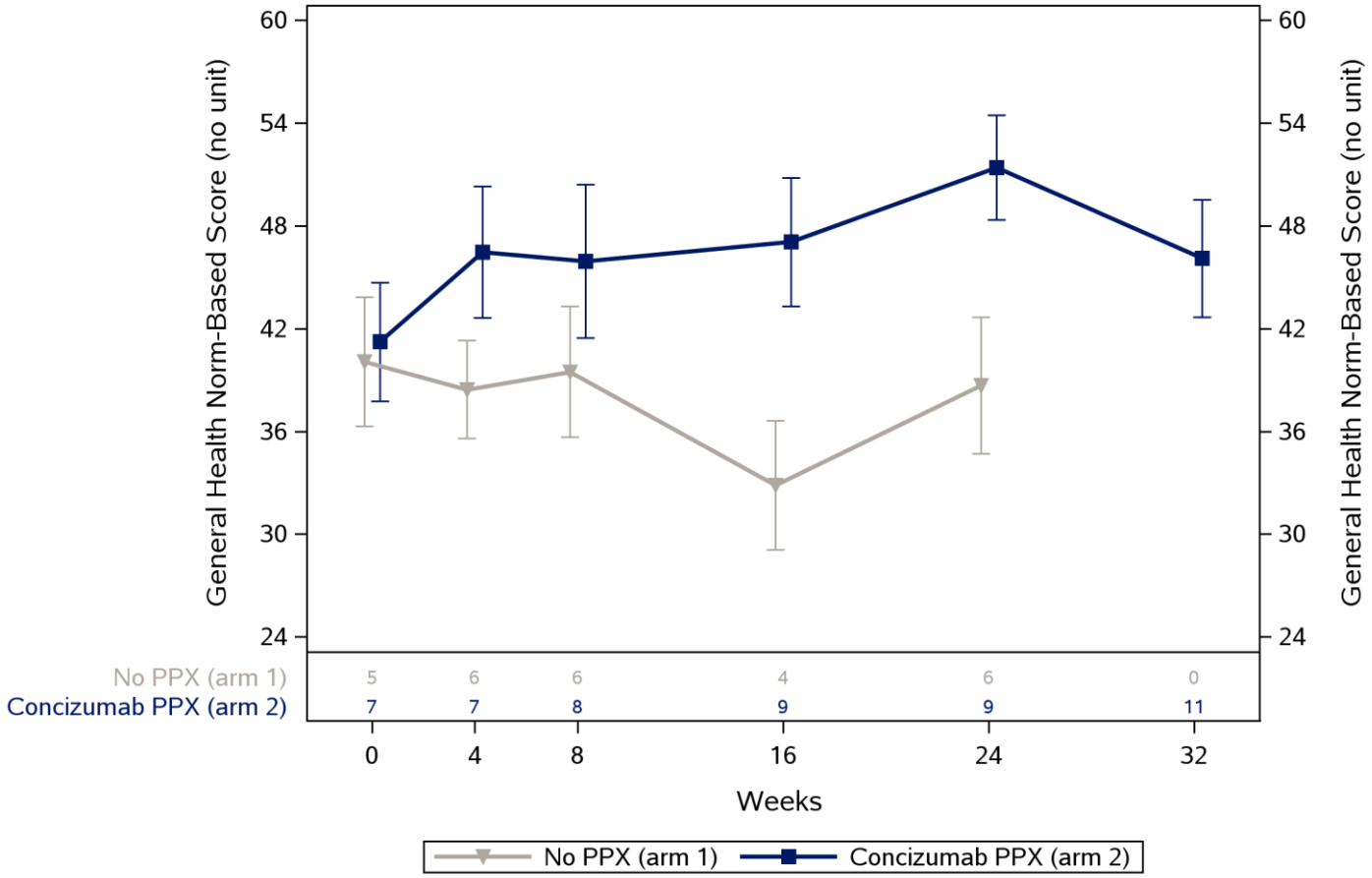
7: SF-36v2 (standard version) - general health - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:53 - f-sf36mean.sas/f-sf36ghelathfasHA.png

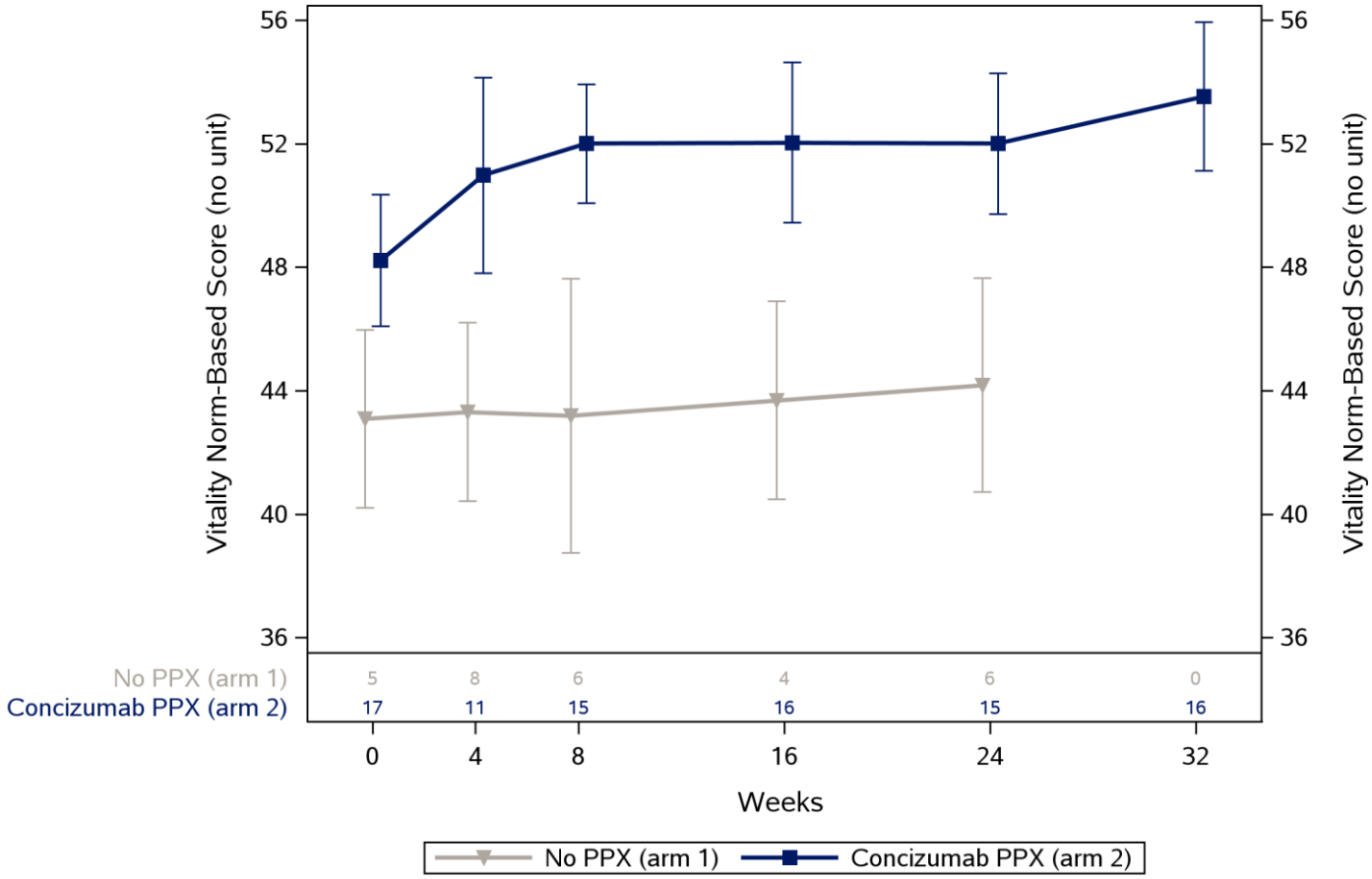
8: SF-36v2 (standard version) - general health - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:55 - f-sf36mean.sas/f-sf36ghelathfasHB.png

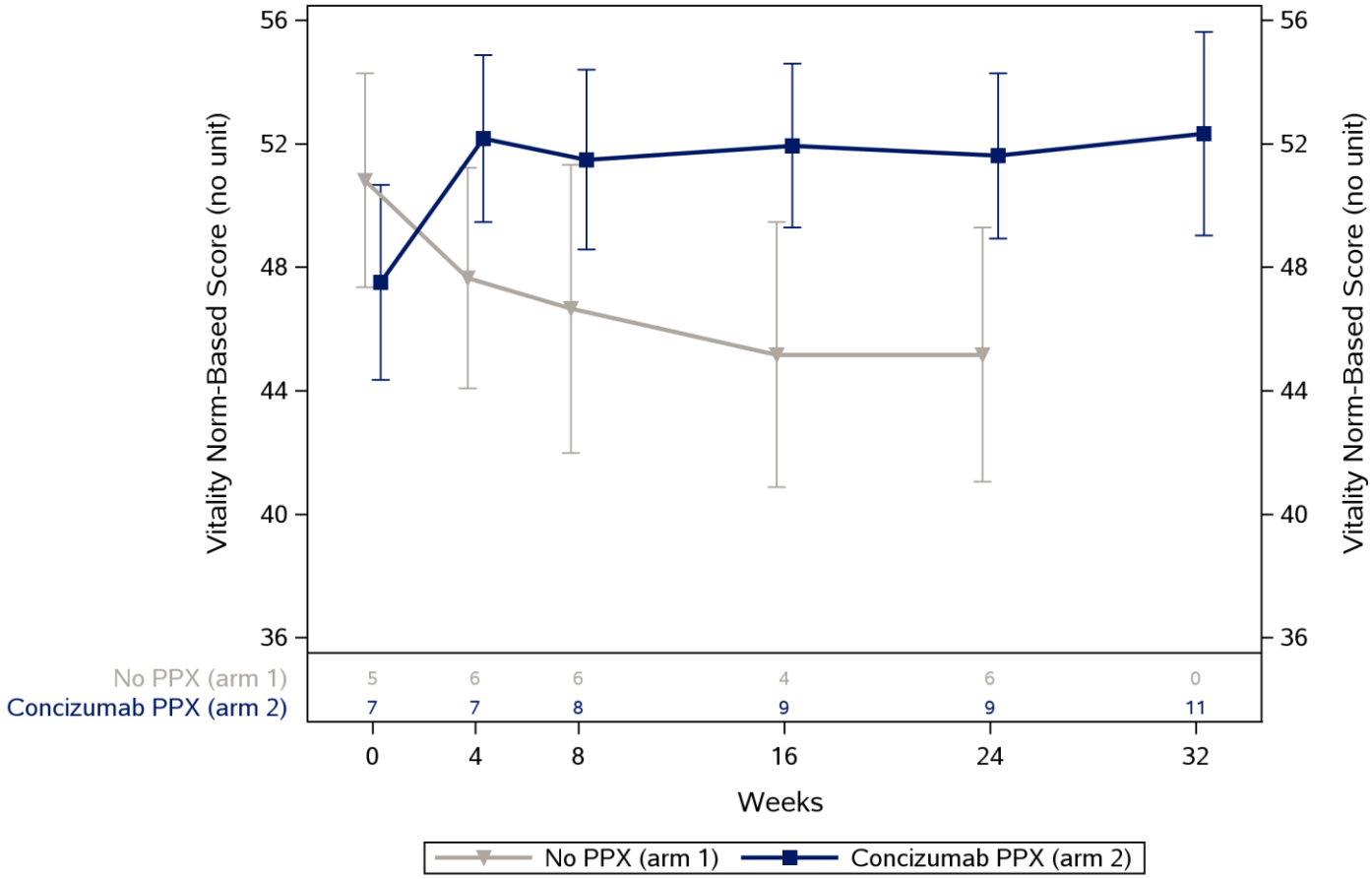
9: SF-36v2 (standard version) - vitality - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:56 - f-sf36mean.sas/f-sf36vitalityfasHA.png

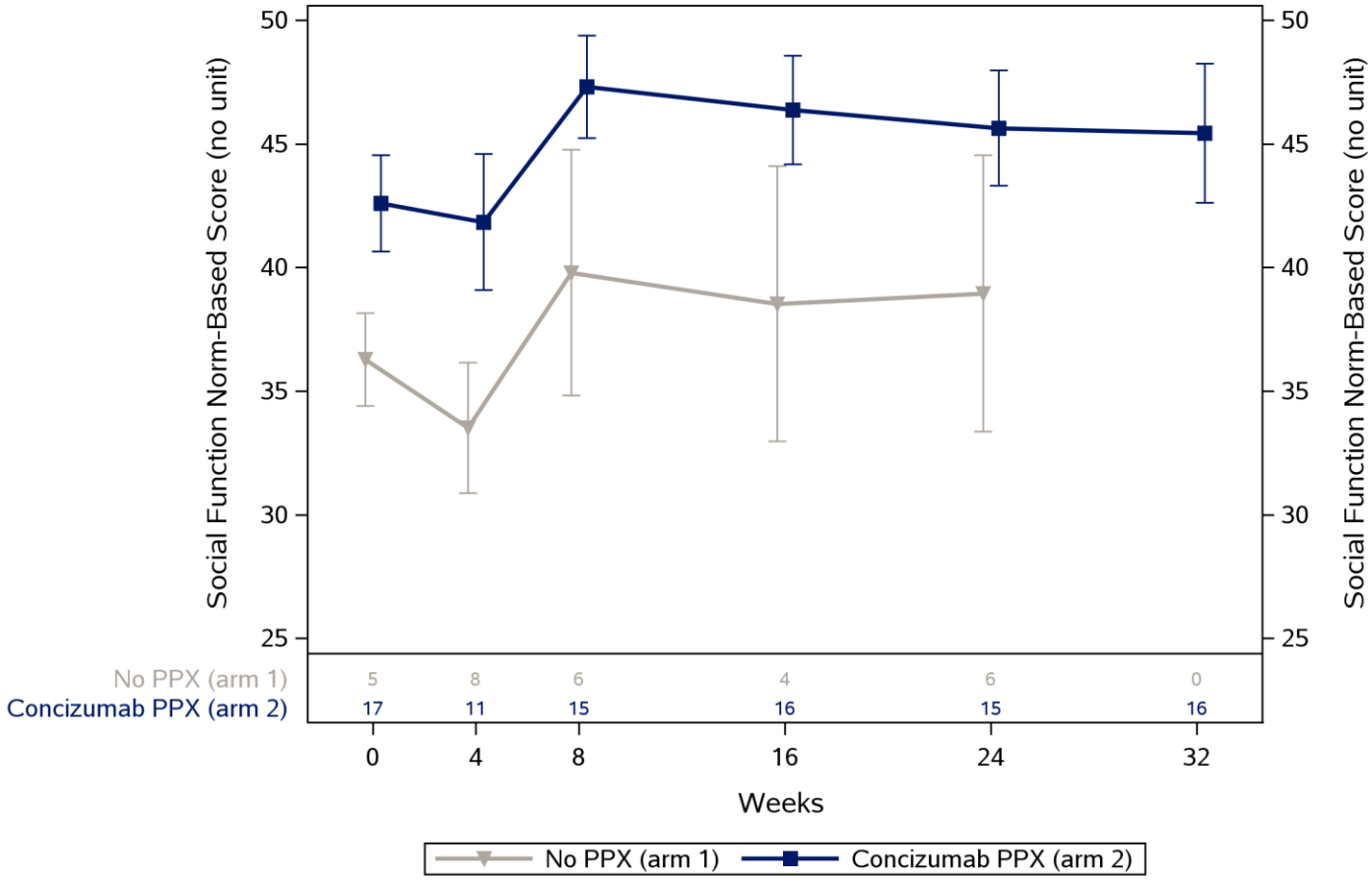
10: SF-36v2 (standard version) - vitality - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:37:58 - f-sf36mean.sas/f-sf36vitalityfasHB.png

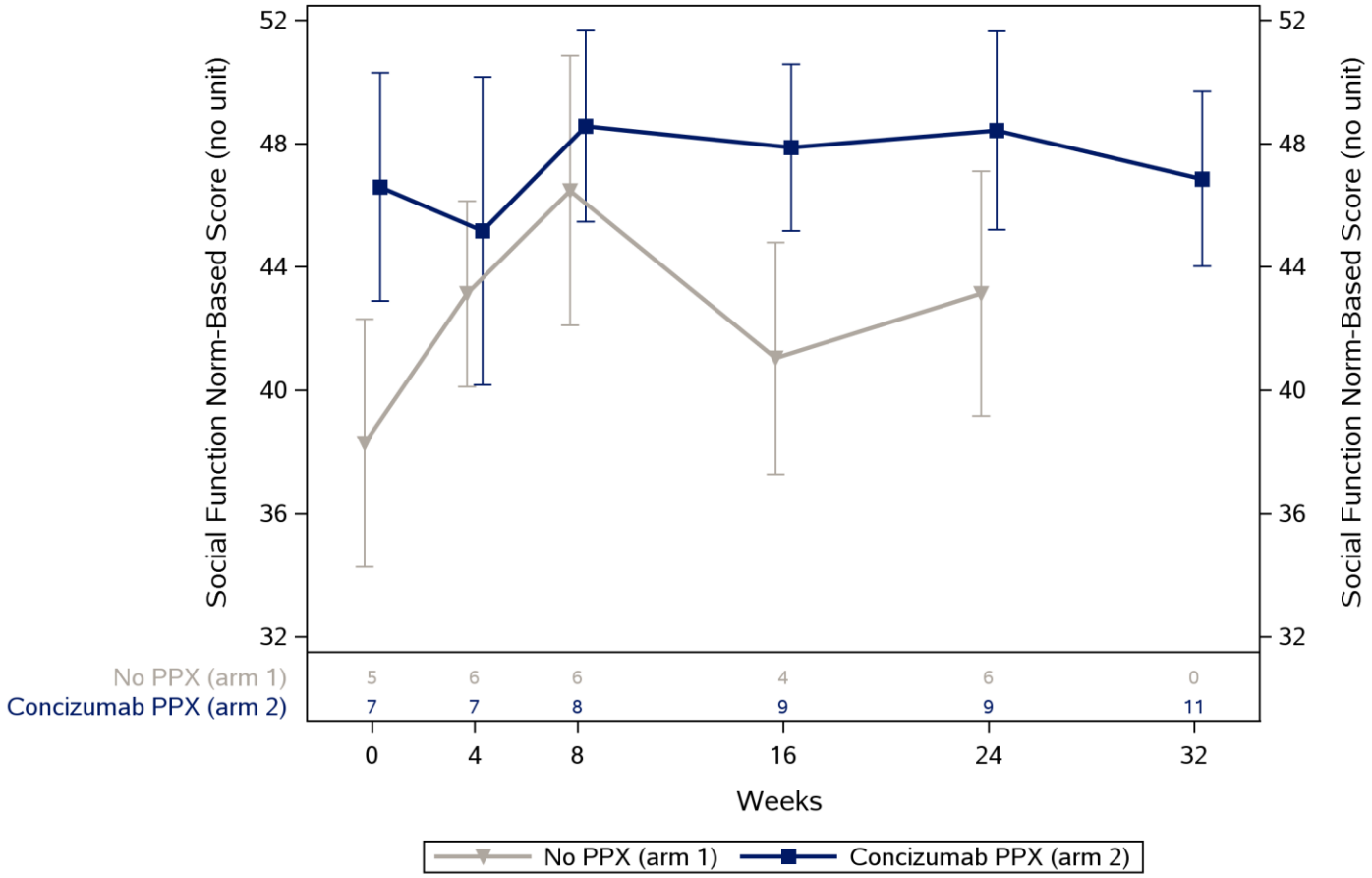
11: SF-36v2 (standard version) - social functioning - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:00 - f-sf36mean.sas/f-sf36socialfuncfasHA.png

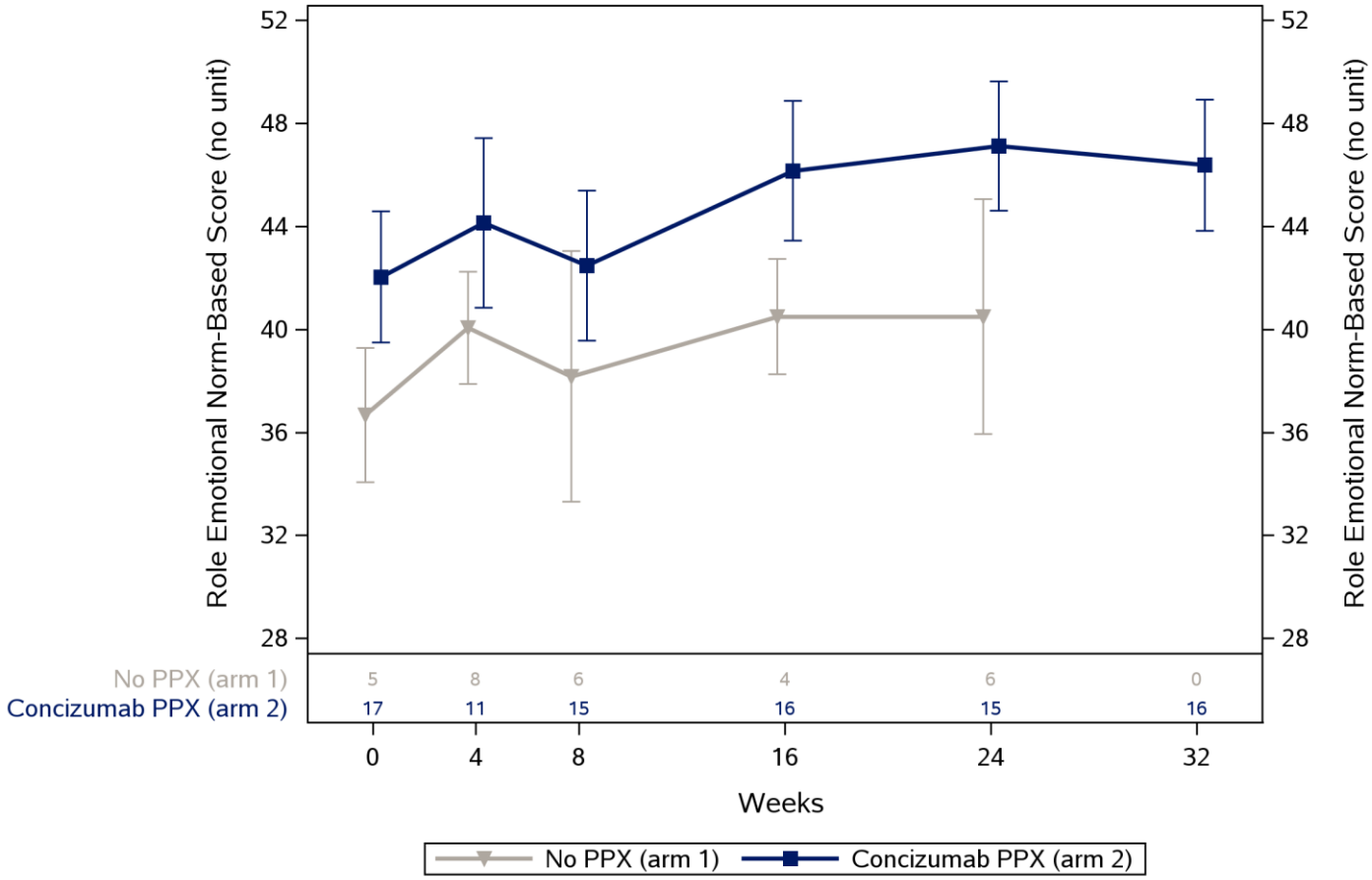
12: SF-36v2 (standard version) - social functioning - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:03 - f-sf36mean.sas/f-sf36socialfuncfasHB.png

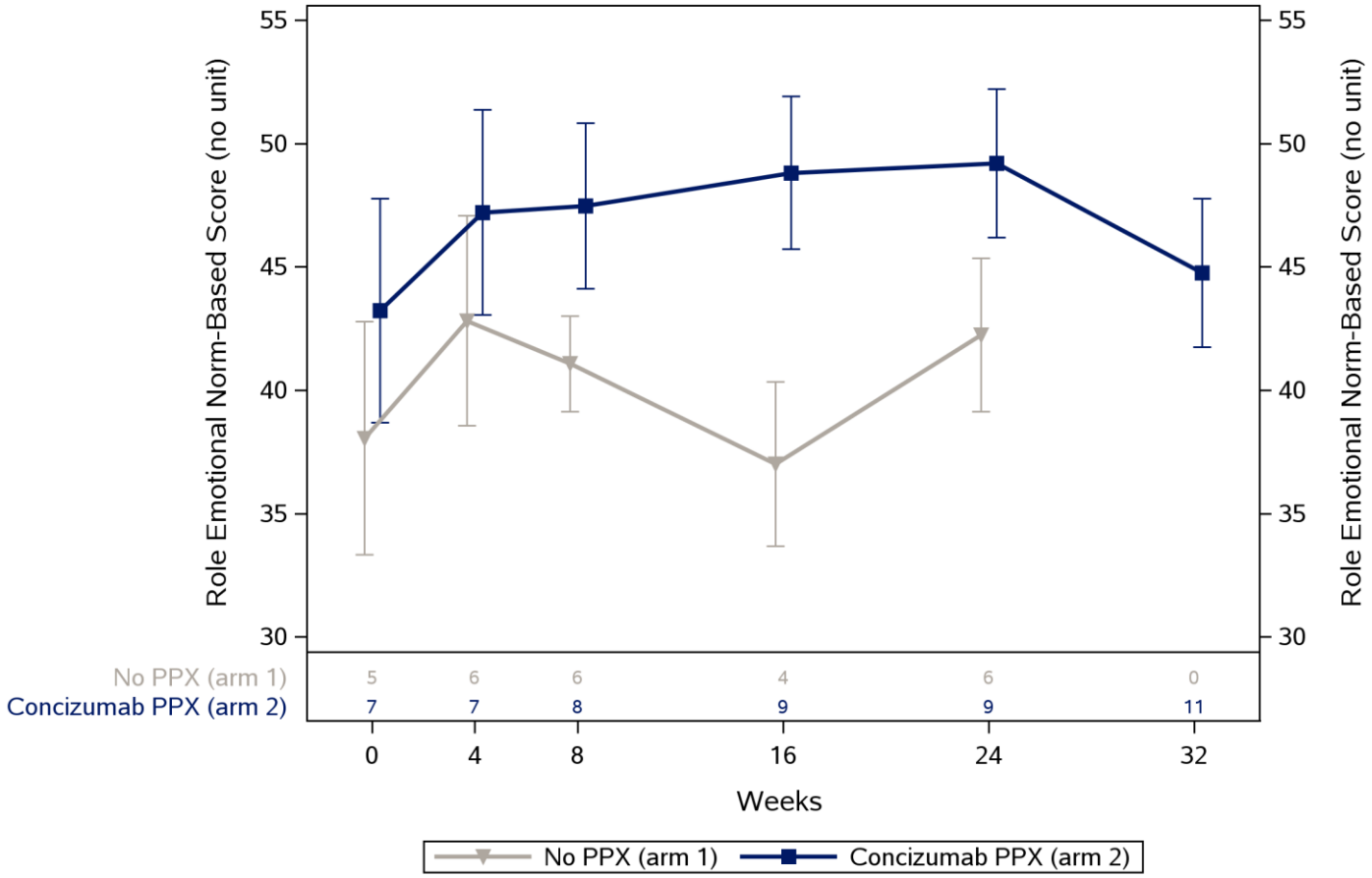
13: SF-36v2 (standard version) - role emotional - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:05 - f-sf36mean.sas/f-sf36roleemofasHA.png

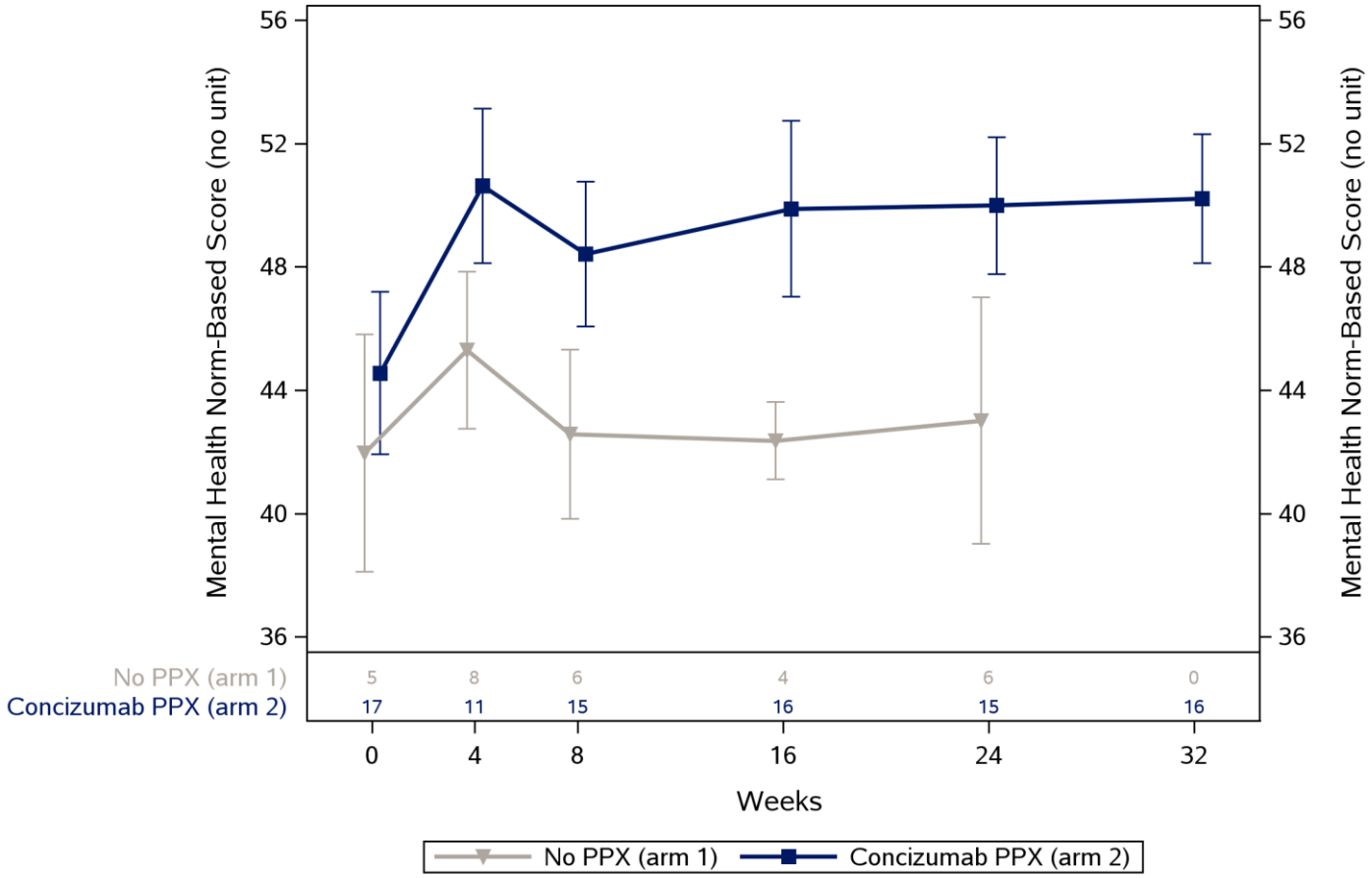
14: SF-36v2 (standard version) - role emotional - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:07 - f-sf36mean.sas/f-sf36roleemofasHB.png

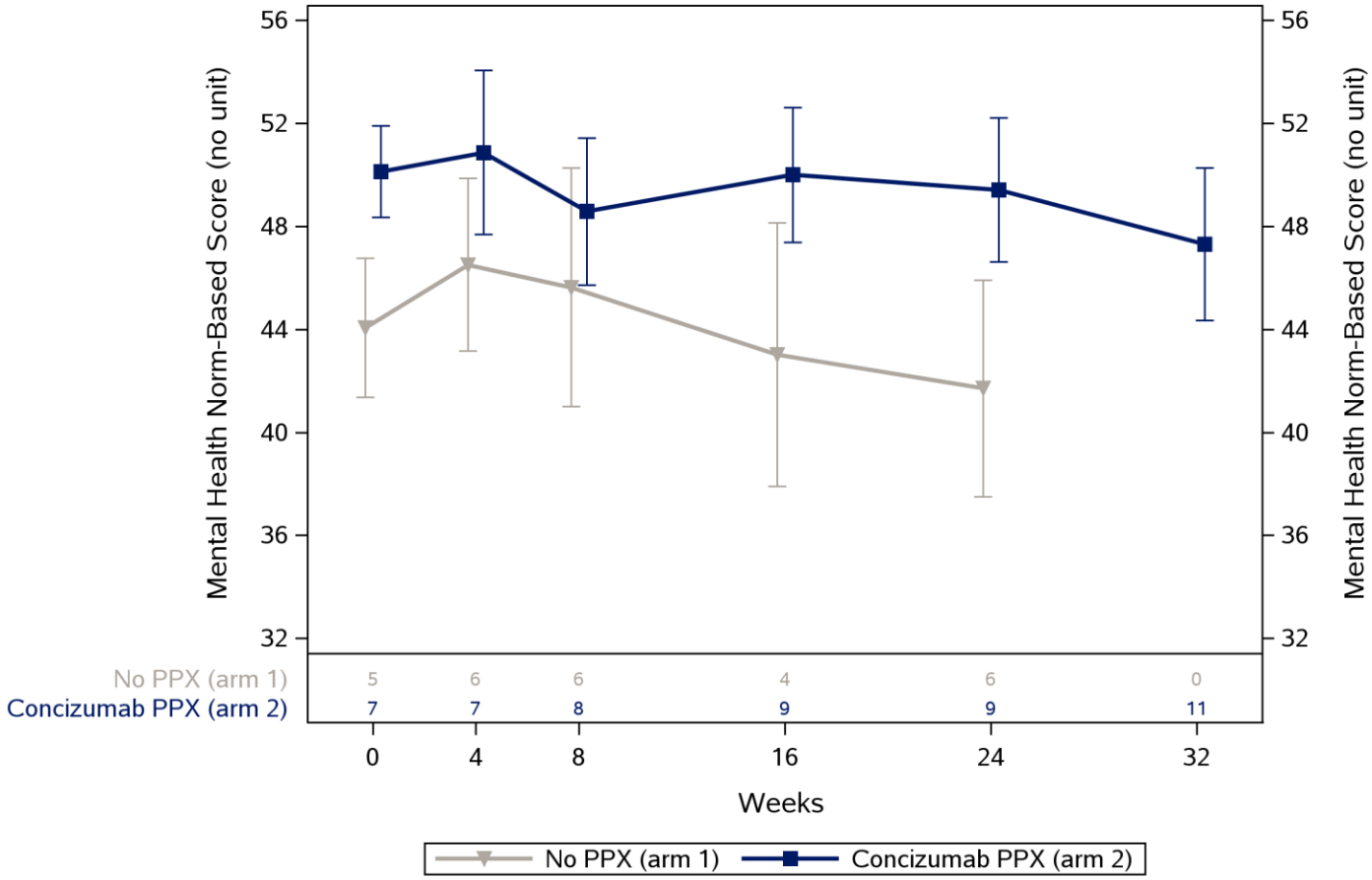
15: SF-36v2 (standard version) - mental health - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:08 - f-sf36mean.sas/f-sf36mentalhfasHA.png

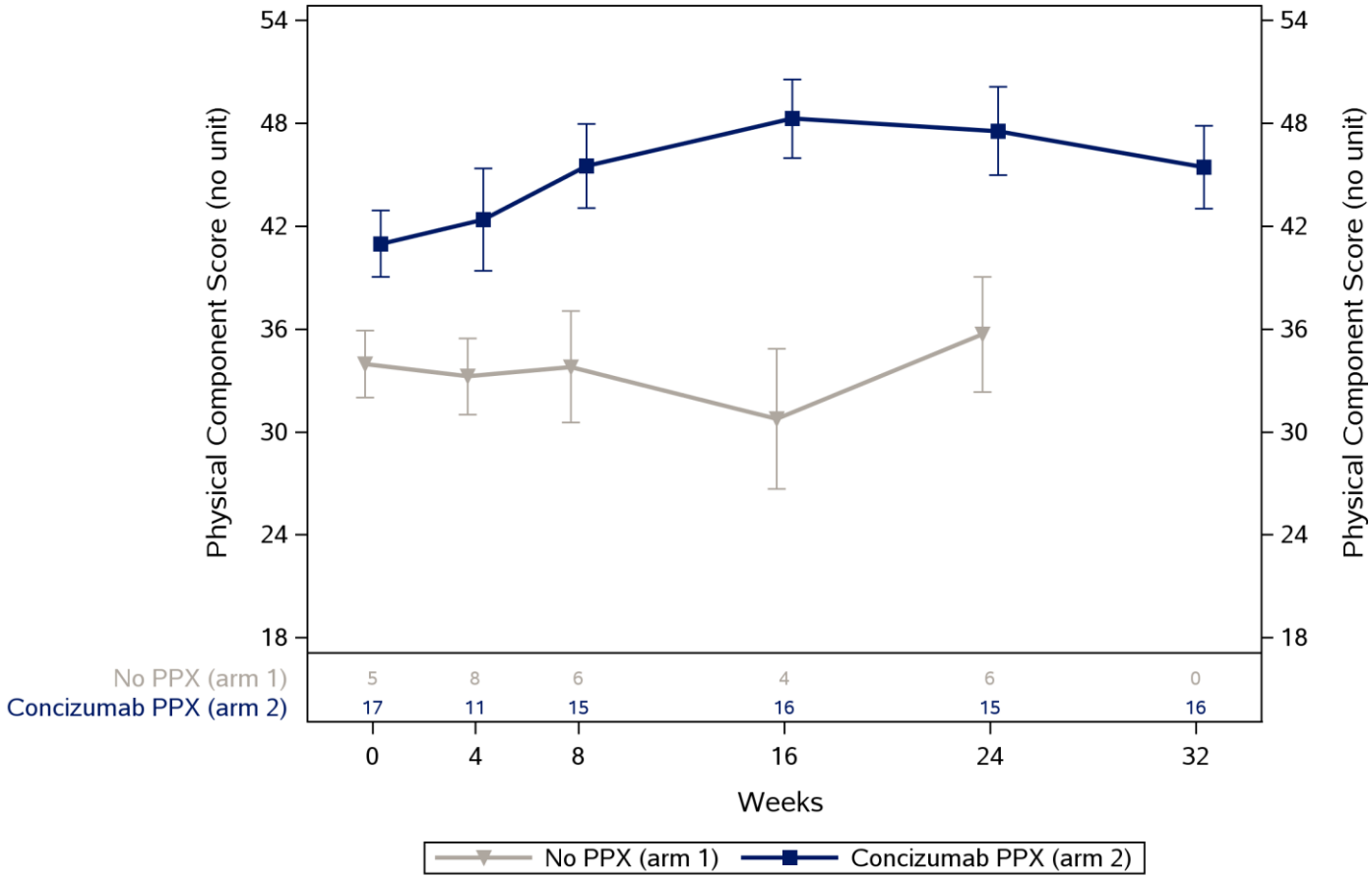
16: SF-36v2 (standard version) - mental health - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:10 - f-sf36mean.sas/f-sf36mentalhfasHB.png

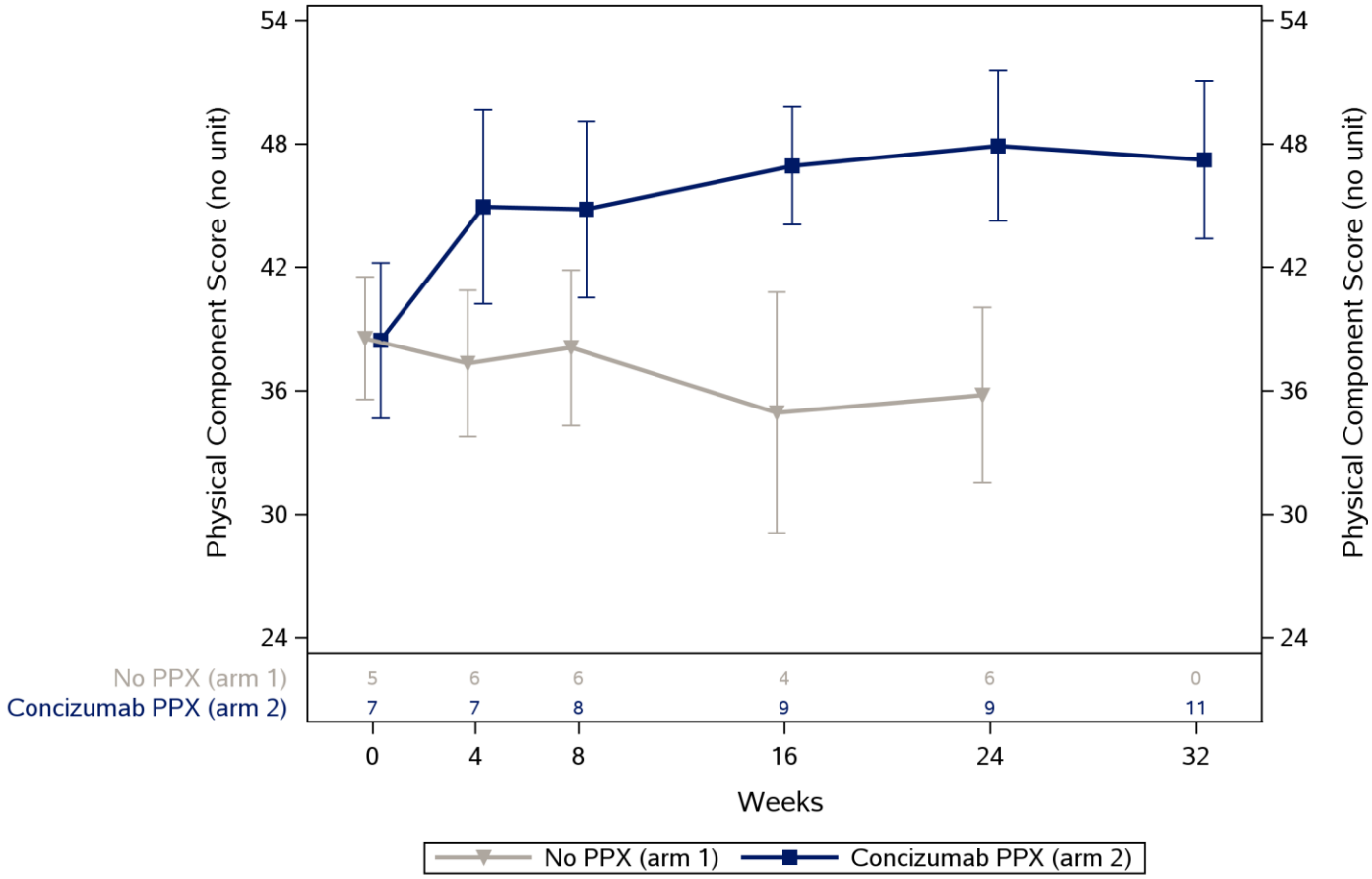
17: SF-36v2 (standard version) - physical component score - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:11 - f-sf36mean.sas/f-sf36physcompfasHA.png

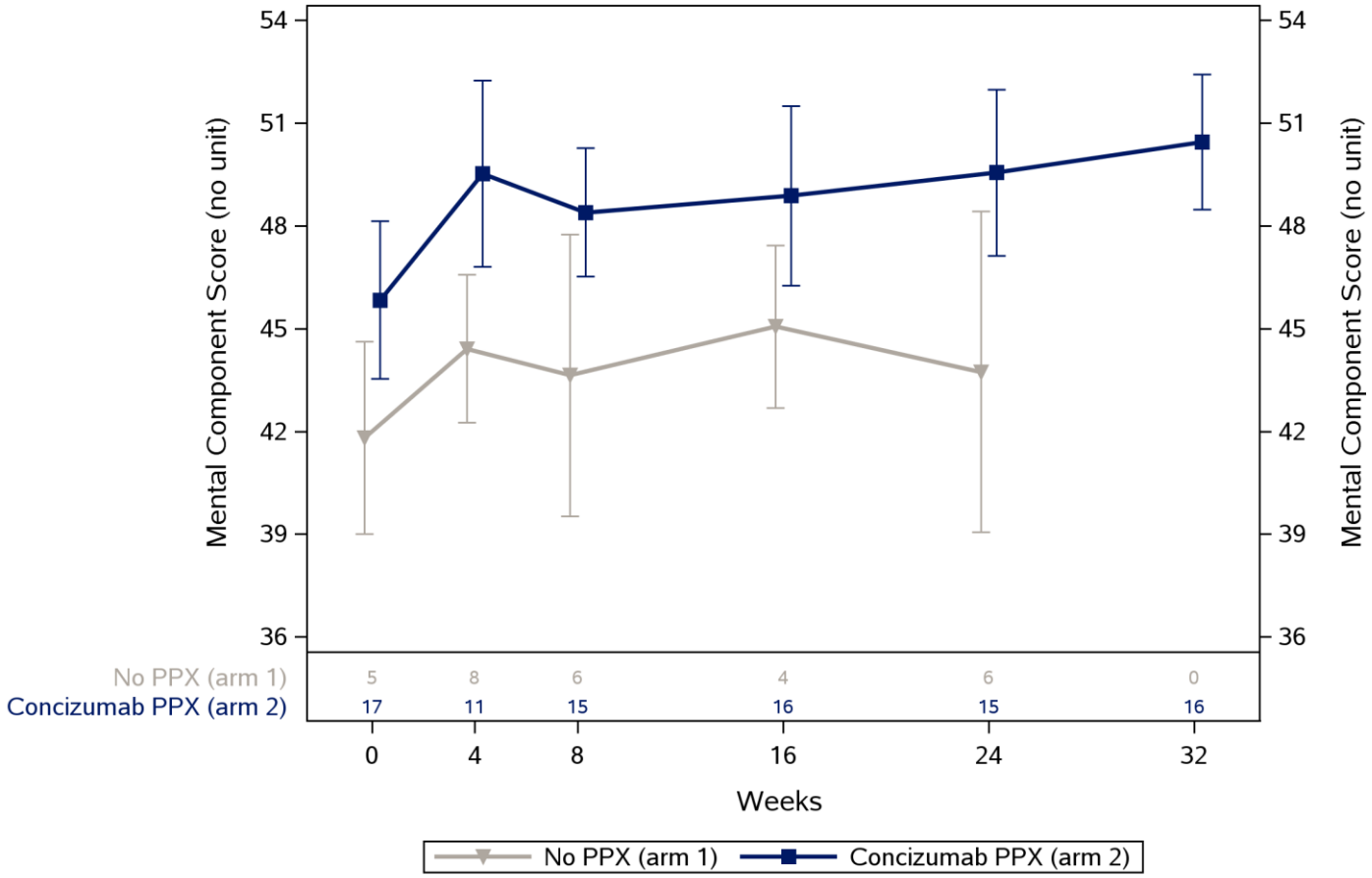
18: SF-36v2 (standard version) - physical component score - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:13 - f-sf36mean.sas/f-sf36physcompfasHB.png

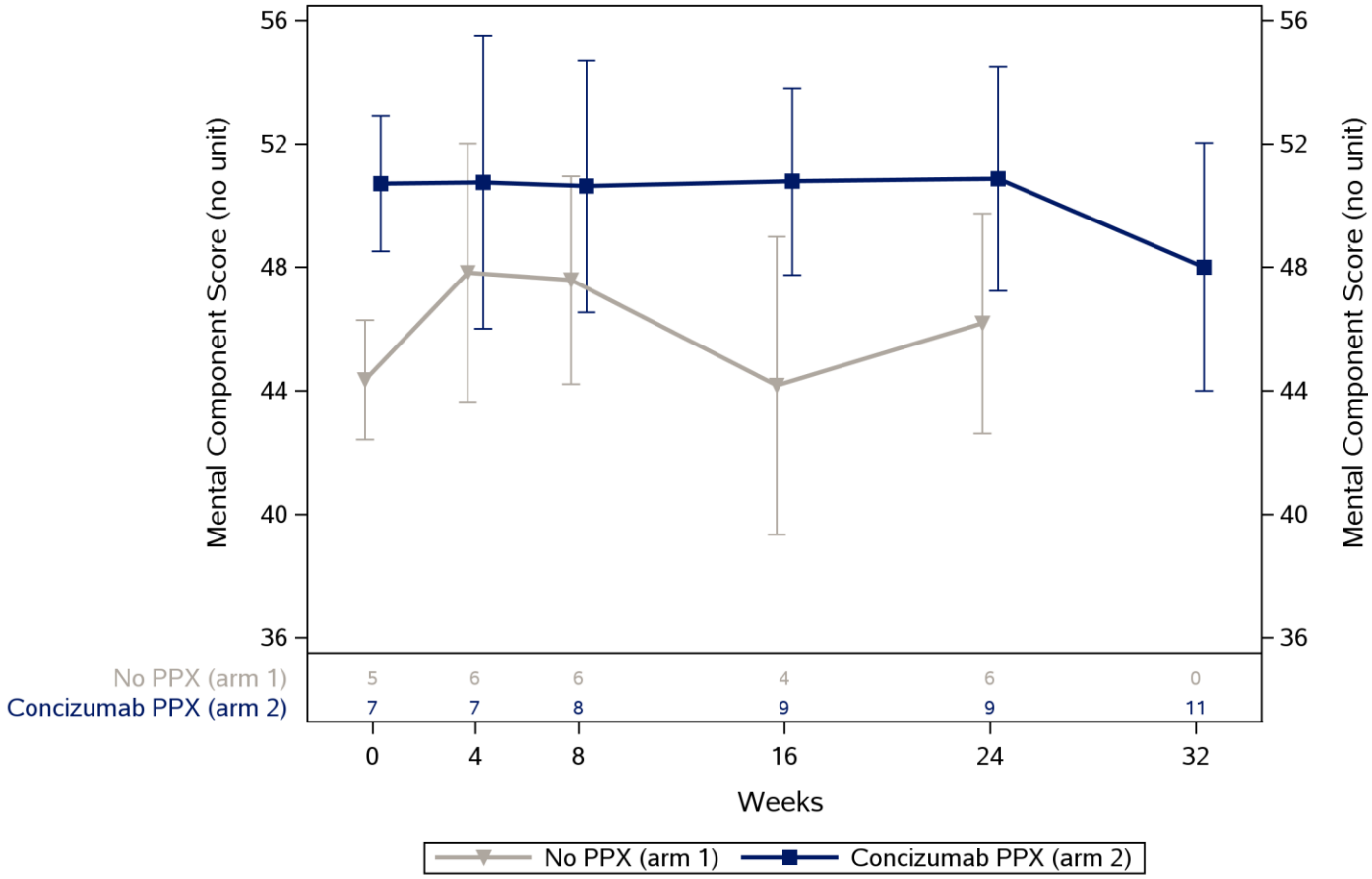
19: SF-36v2 (standard version) - mental component score - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:14 - f-sf36mean.sas/f-sf36hecompfasHA.png

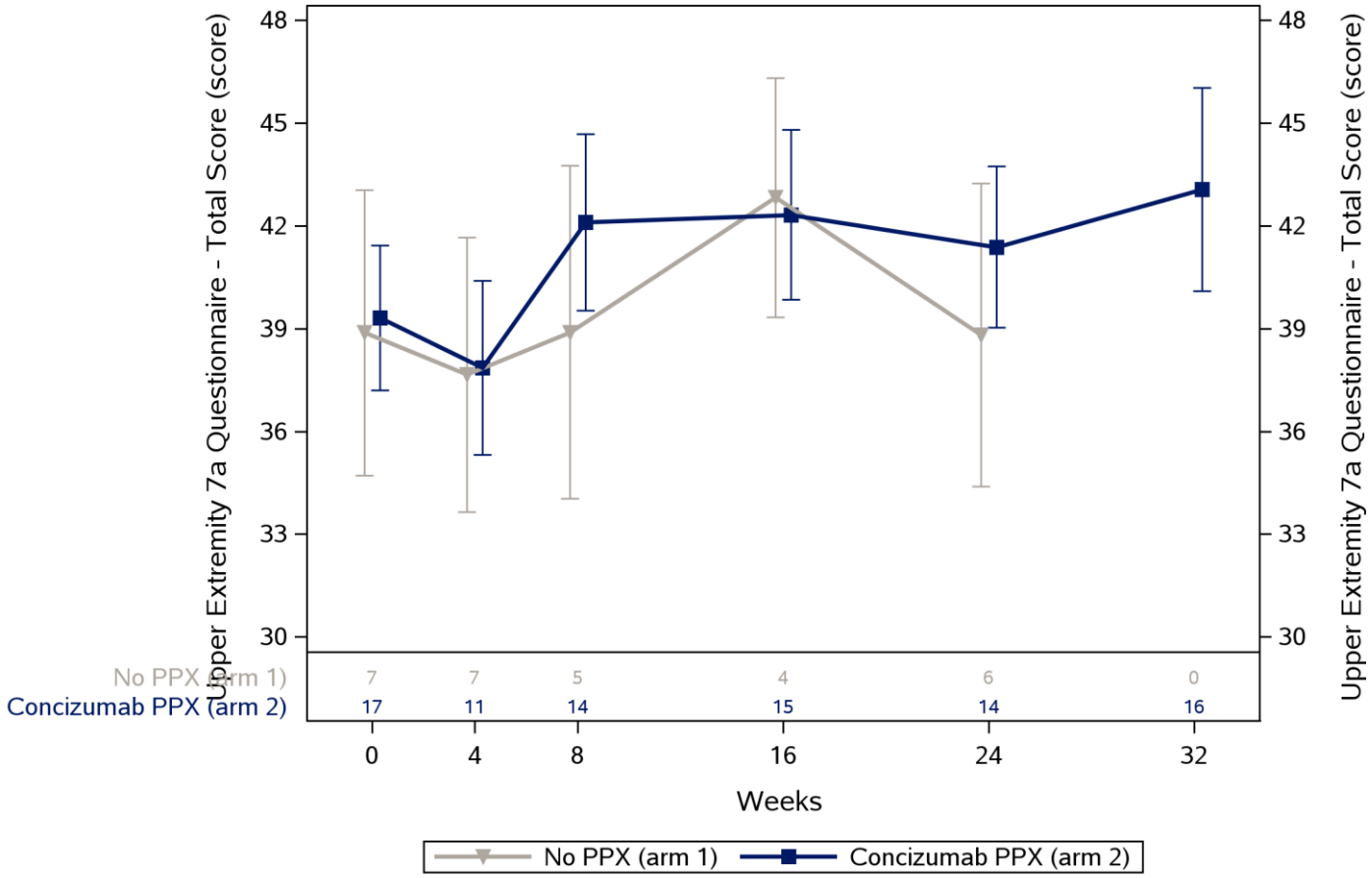
20: SF-36v2 (standard version) - mental component score - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:16 - f-sf36mean.sas/f-sf36hecompfasHB.png

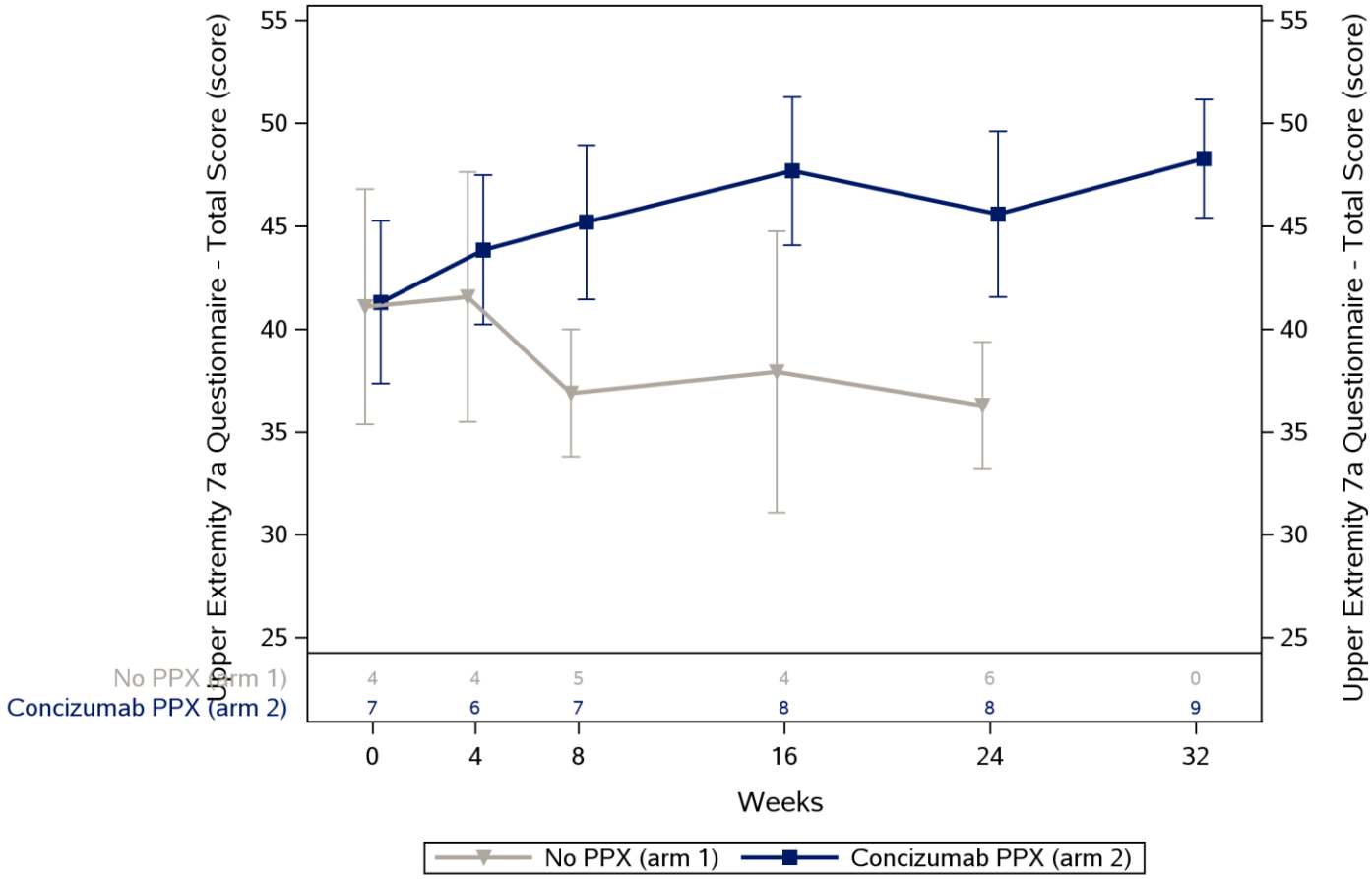
21: PROMIS Short Form v2.0 – Upper Extremity 7a - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:17 - f-sf36mean.sas/f-prom_upperexfasHA.png

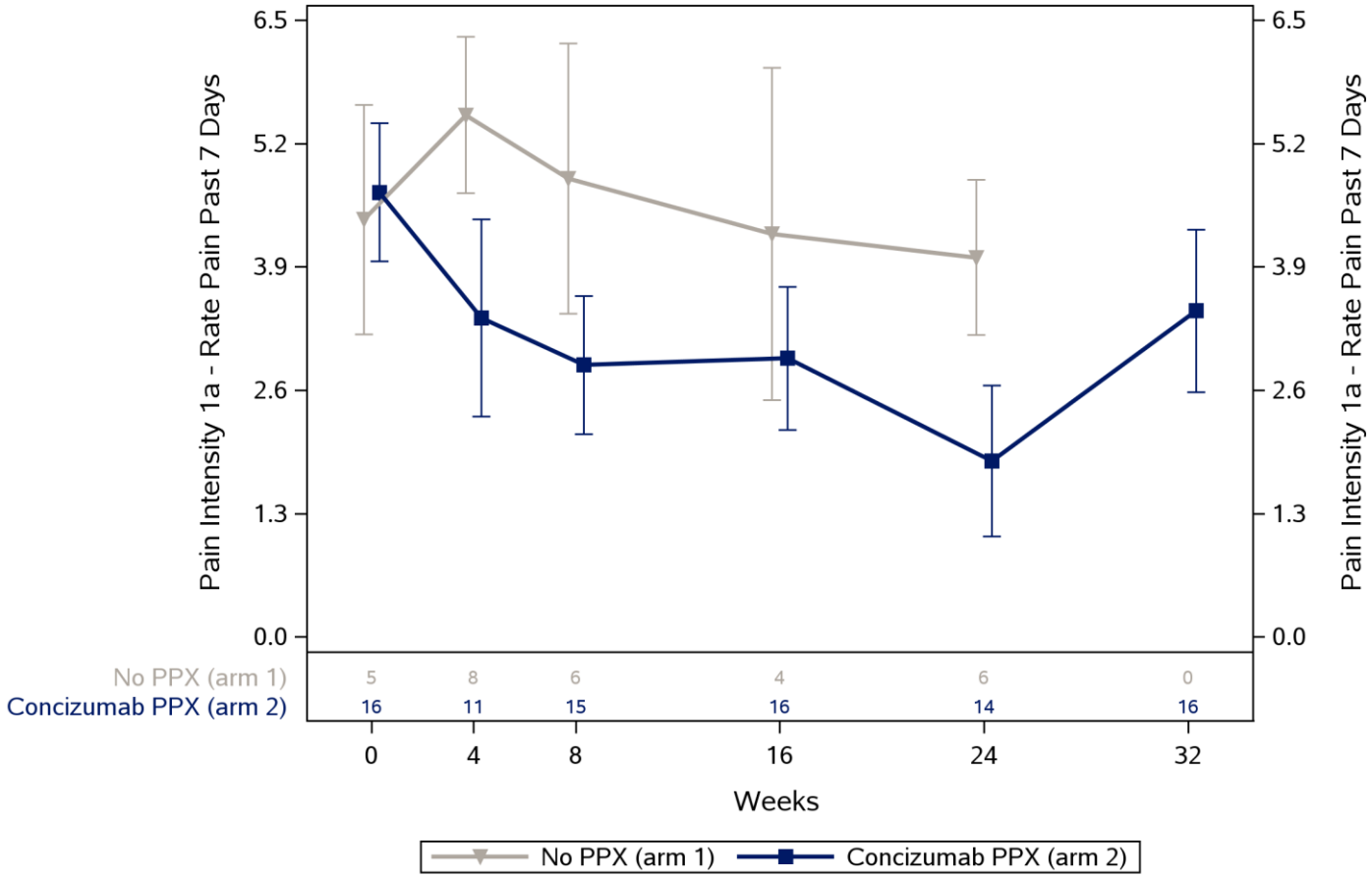
22: PROMIS Short Form v2.0 – Upper Extremity 7a - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:20 - f-sf36mean.sas/f-prom_upperexfasHB.png

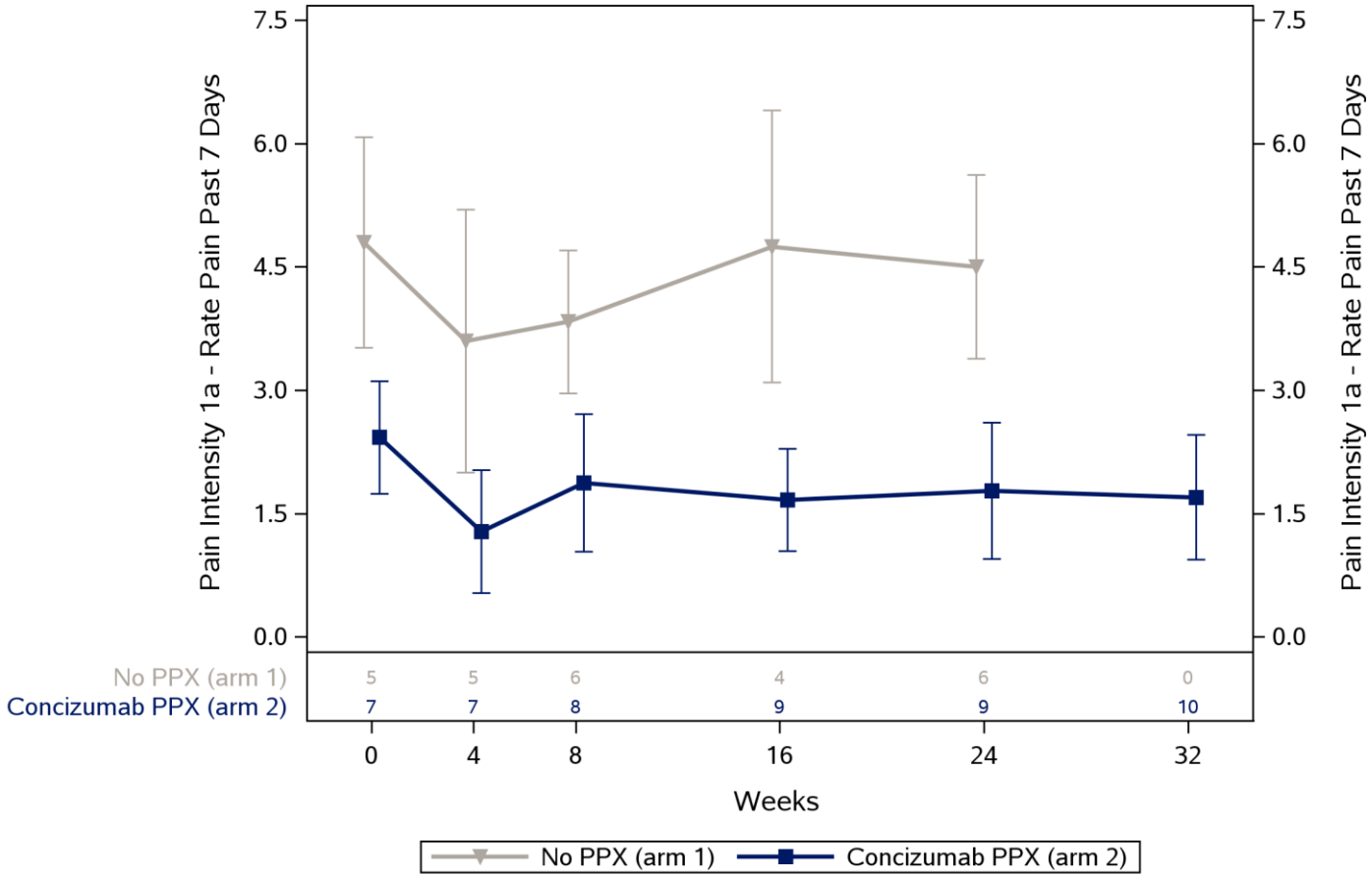
23: PROMIS Numeric Rating Scale v.1.0 – Pain Intensity 1a - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:23 - f-sf36mean.sas/f-prom_painfasHA.png

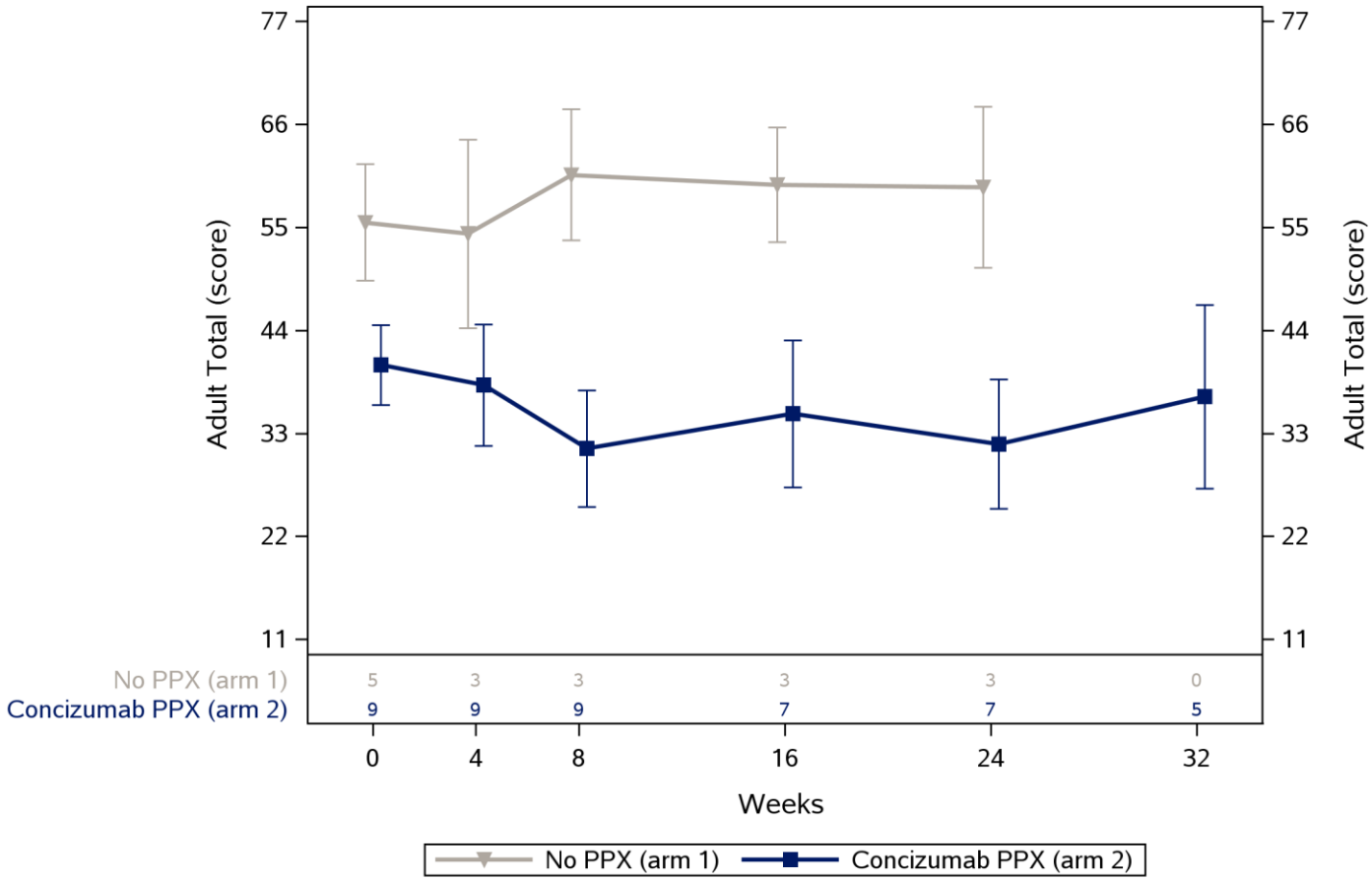
24: PROMIS Numeric Rating Scale v.1.0 – Pain Intensity 1a - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:24 - f-sf36mean.sas/f-prom_painfasHB.png

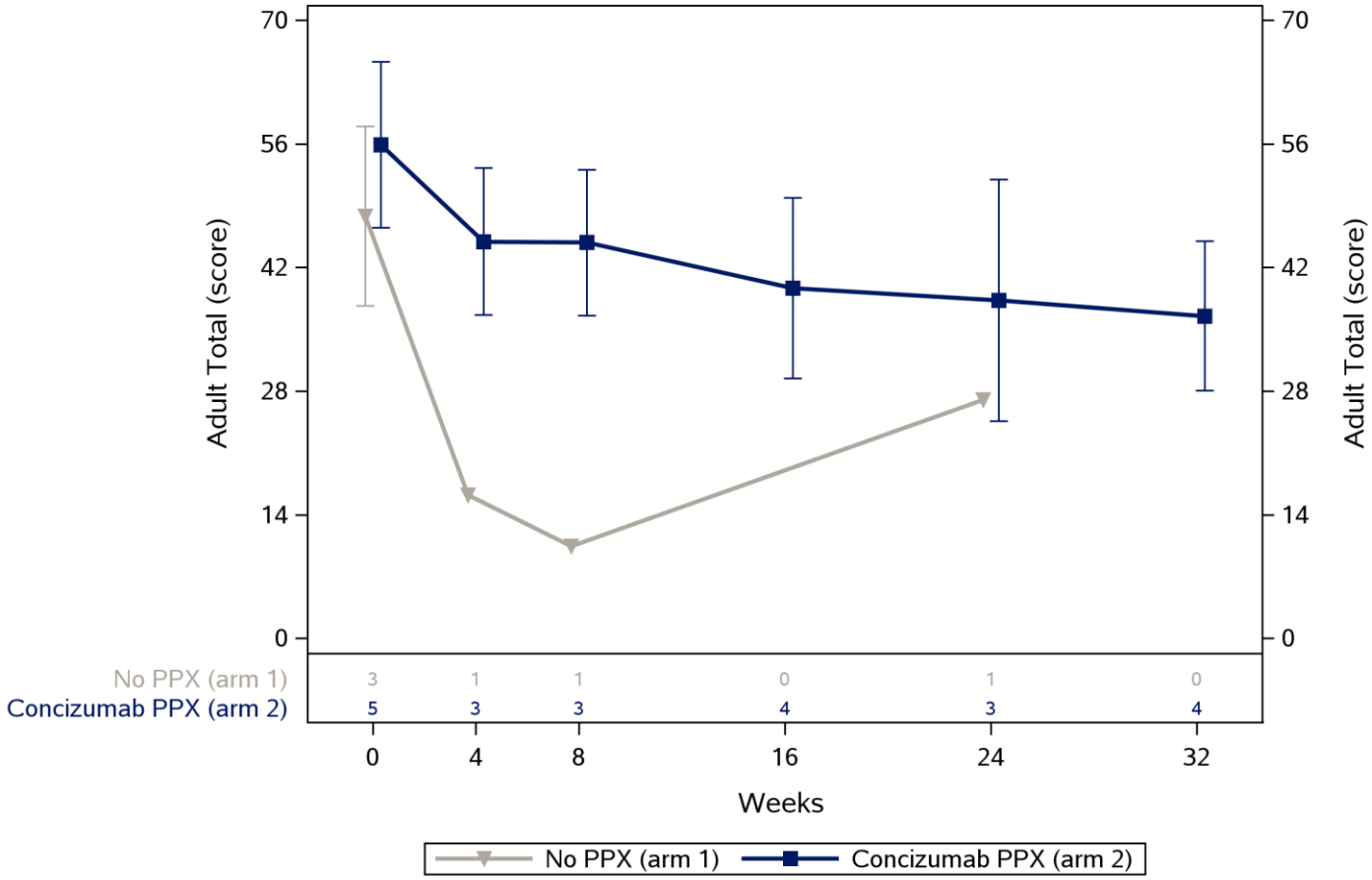
25: HAEM-A-QoL - Total score - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:26 - f-sf36mean.sas/f-HAQ_totfasHA.png

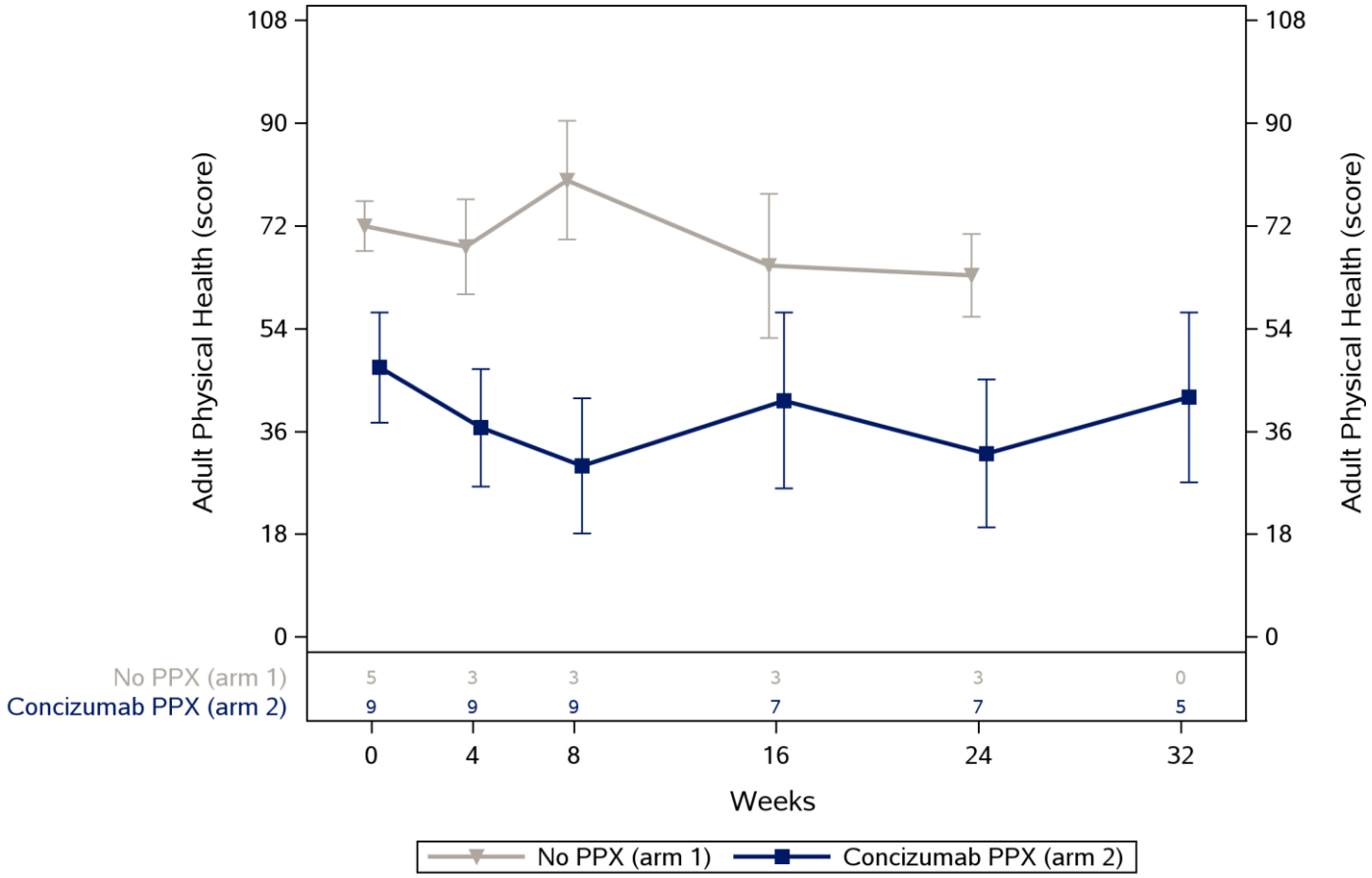
26: HAEM-A-QoL - Total score - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:27 - f-sf36mean.sas/f-HAQ_totfasHB.png

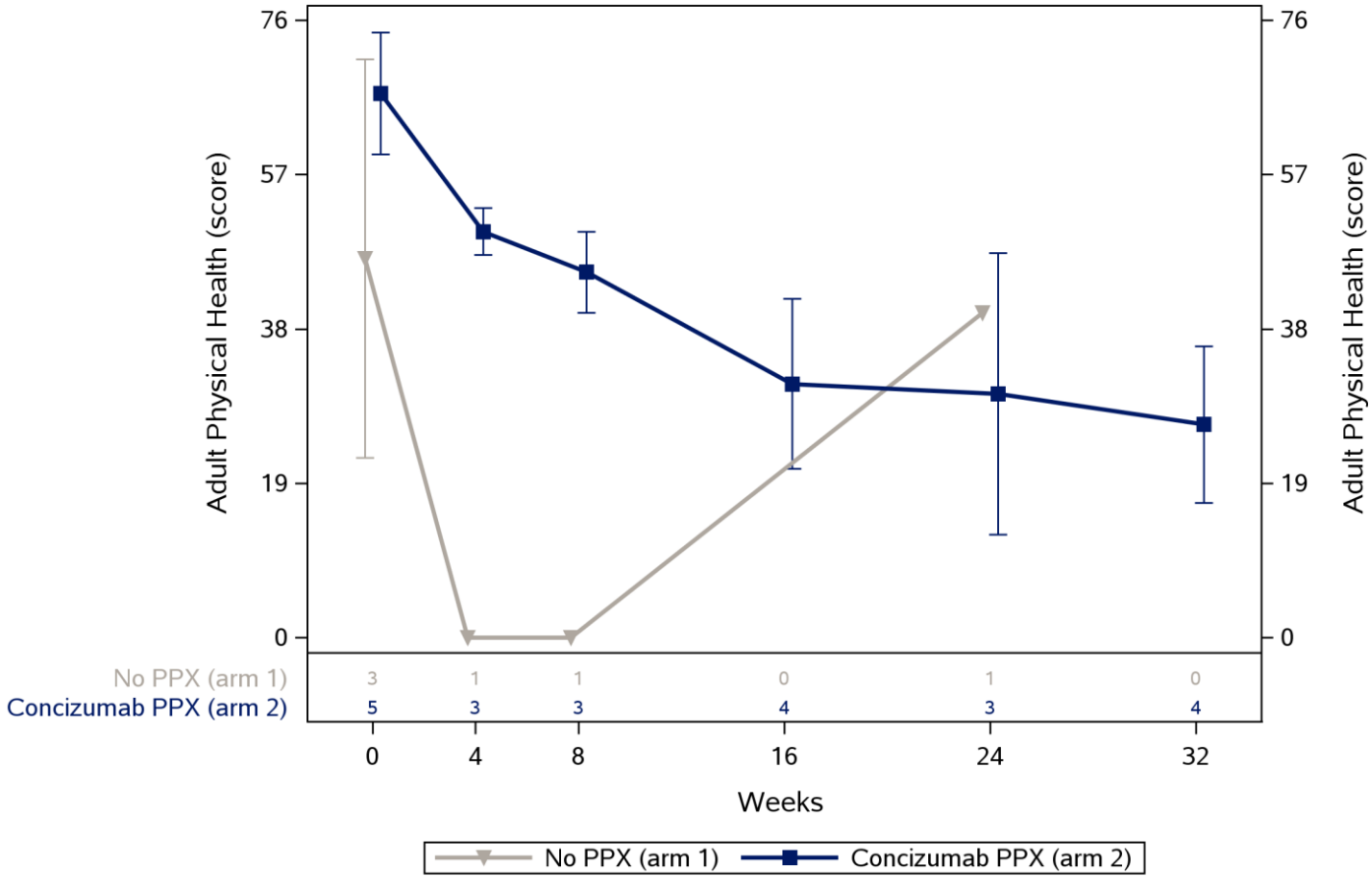
27: HAEM-A-QoL - Physical Health - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:29 - f-sf36mean.sas/f-HAQ_physfasHA.png

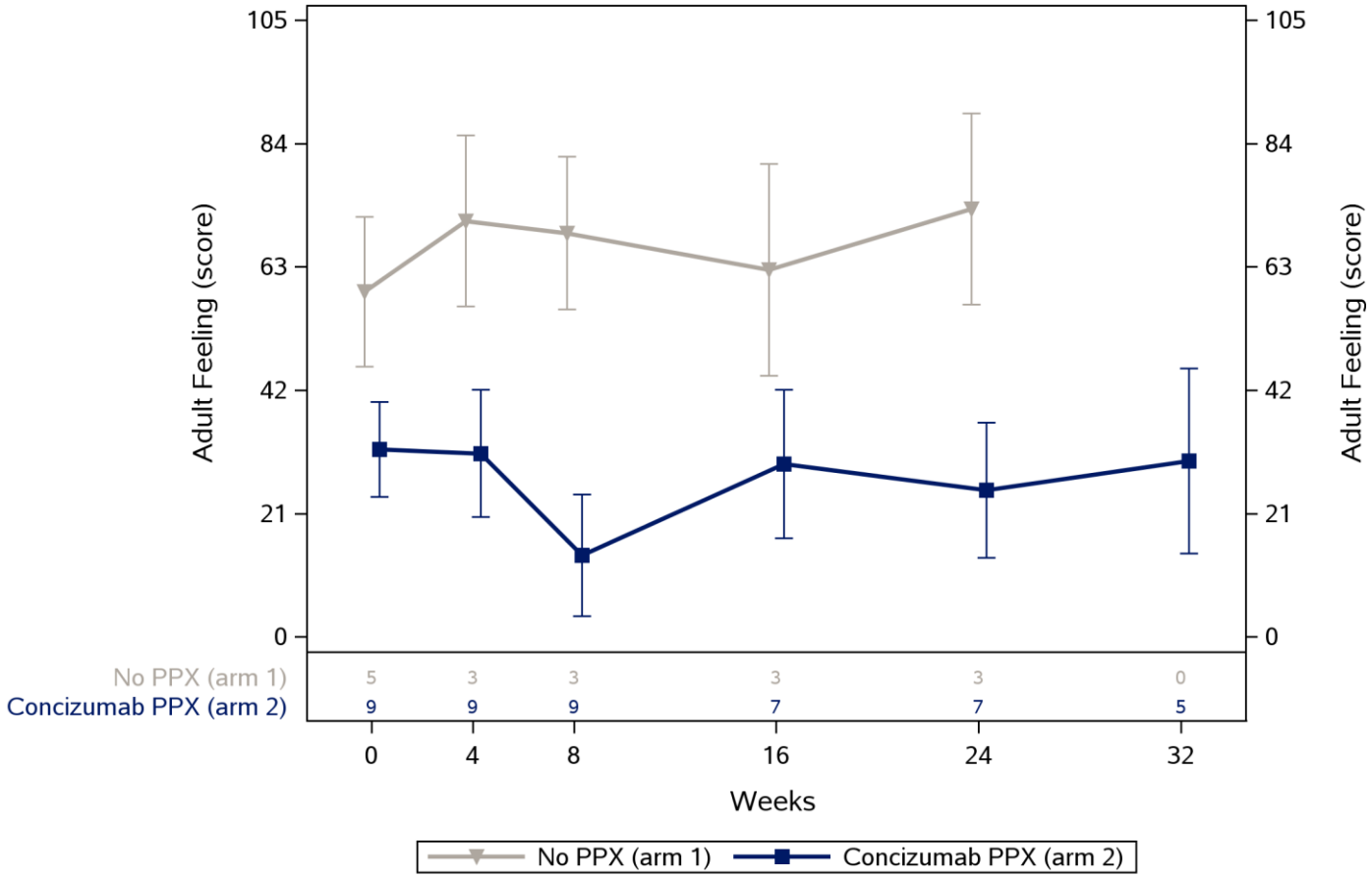
28: HAEM-A-QoL - Physical Health - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:30 - f-sf36mean.sas/f-HAQ_physfasHB.png

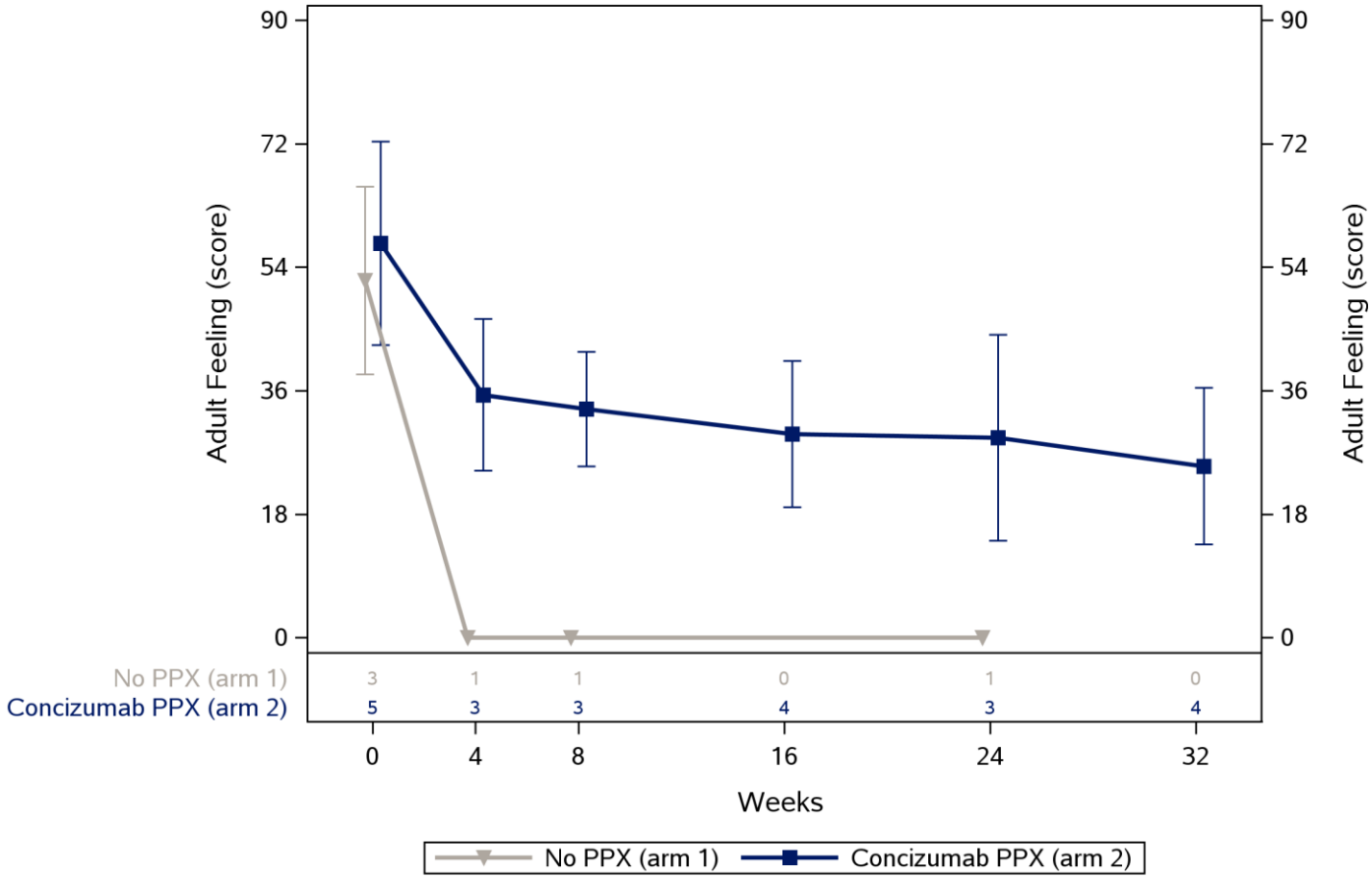
29: HAEM-A-QoL - Feeling - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:31 - f-sf36mean.sas/f-HAQ_feelfasHA.png

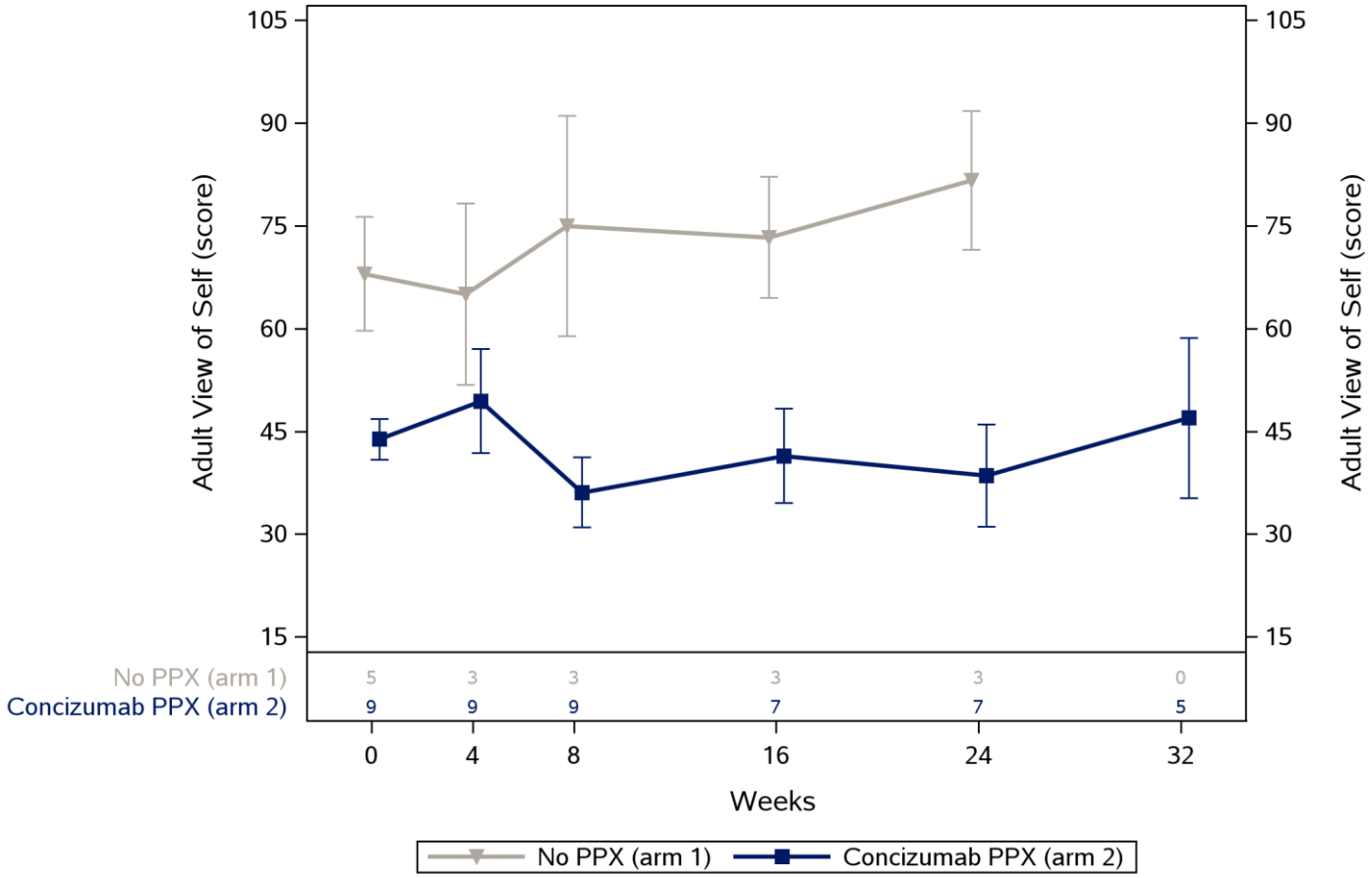
30: HAEM-A-QoL - Feeling - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:33 - f-sf36mean.sas/f-HAQ_feelfasHB.png

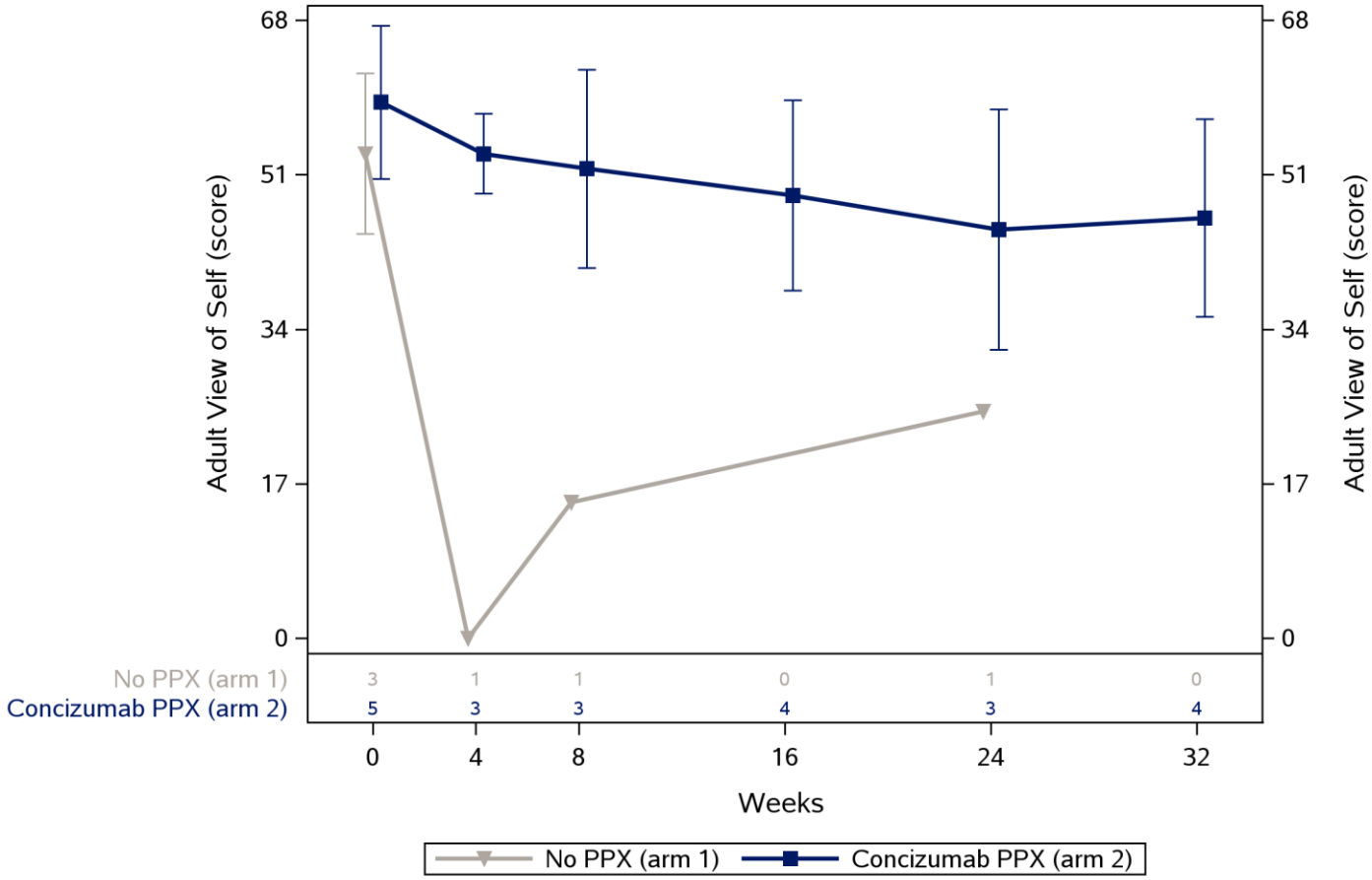
31: HAEM-A-QoL - view of yourself - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:34 - f-sf36mean.sas/f-HAQ_viewfasHA.png

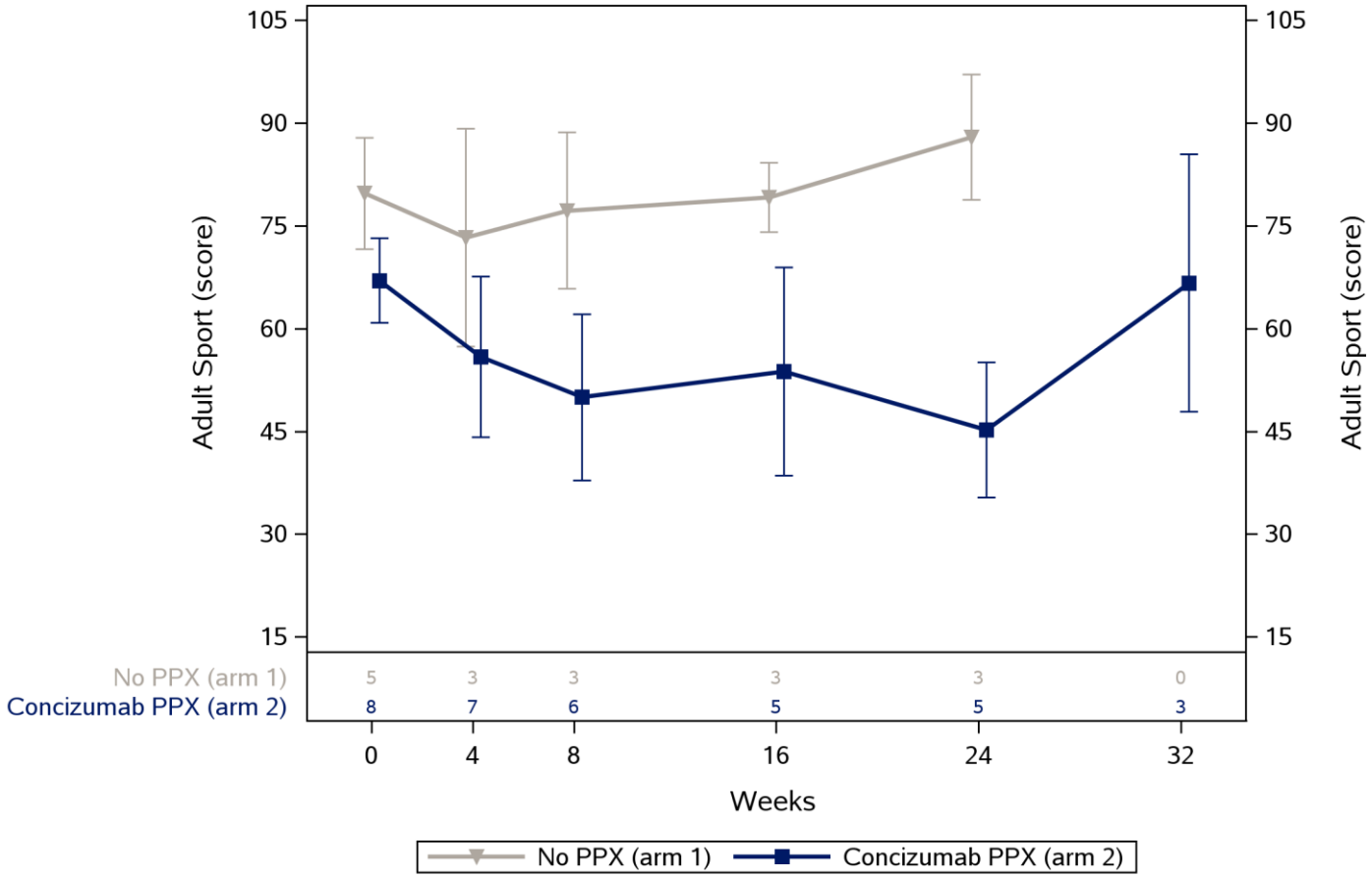
32: HAEM-A-QoL - view of yourself - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:37 - f-sf36mean.sas/f-HAQ_viewfasHB.png

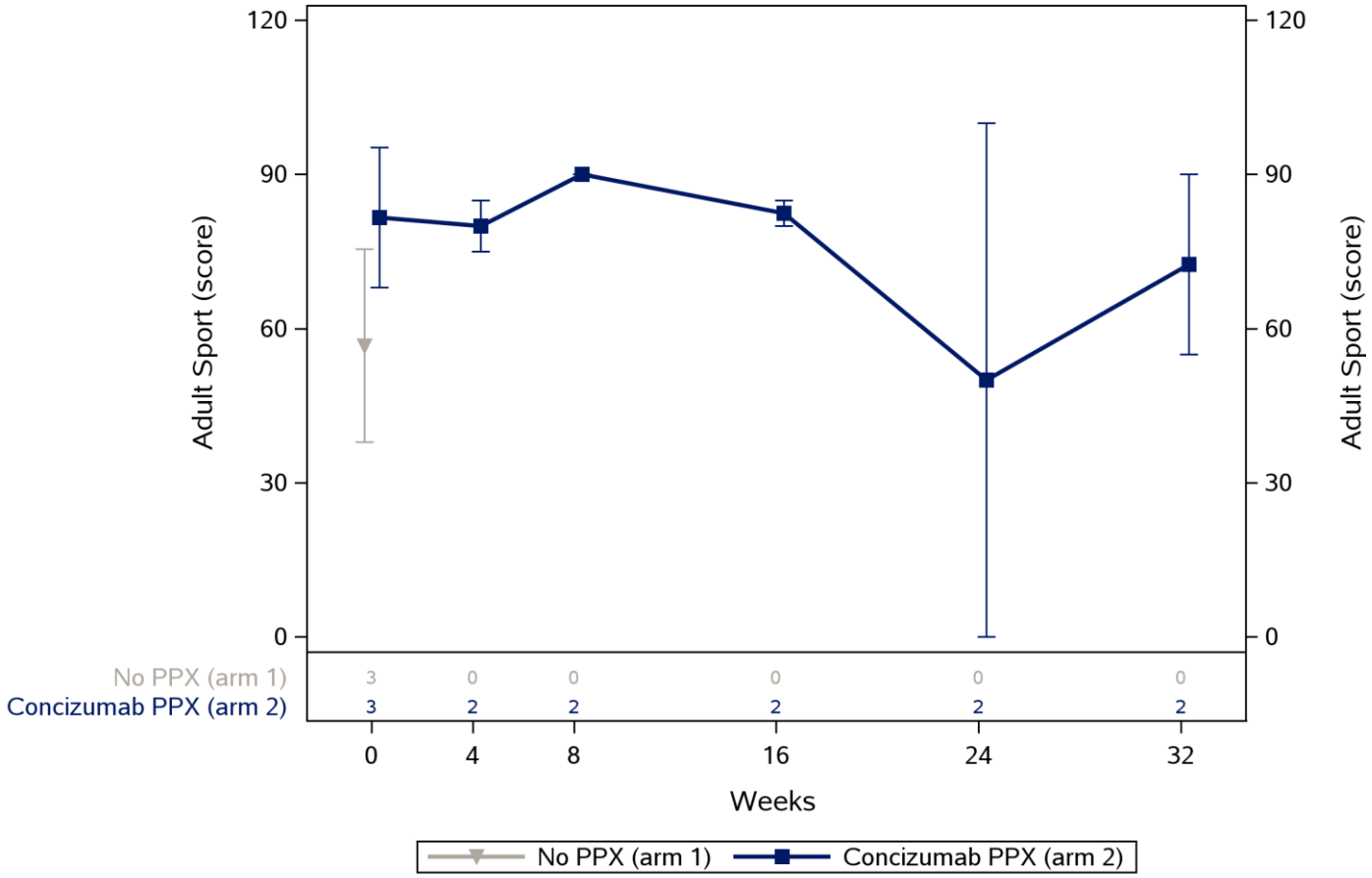
33: HAEM-A-QoL - sport and leisure - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:39 - f-sf36mean.sas/f-HAQ_sportfasHA.png

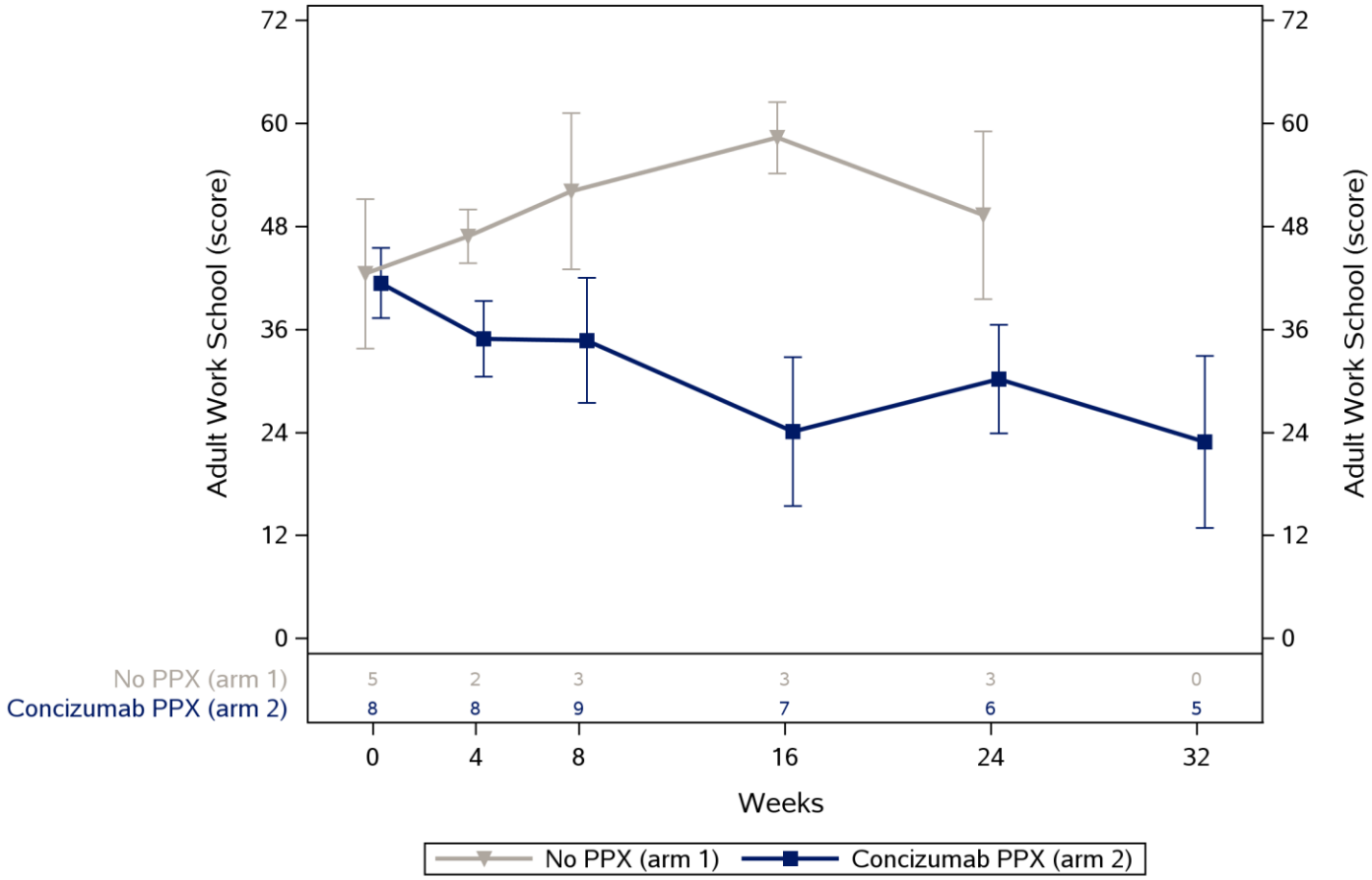
34: HAEM-A-QoL - sport and leisure - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:40 - f-sf36mean.sas/f-HAQ_sportfasHB.png

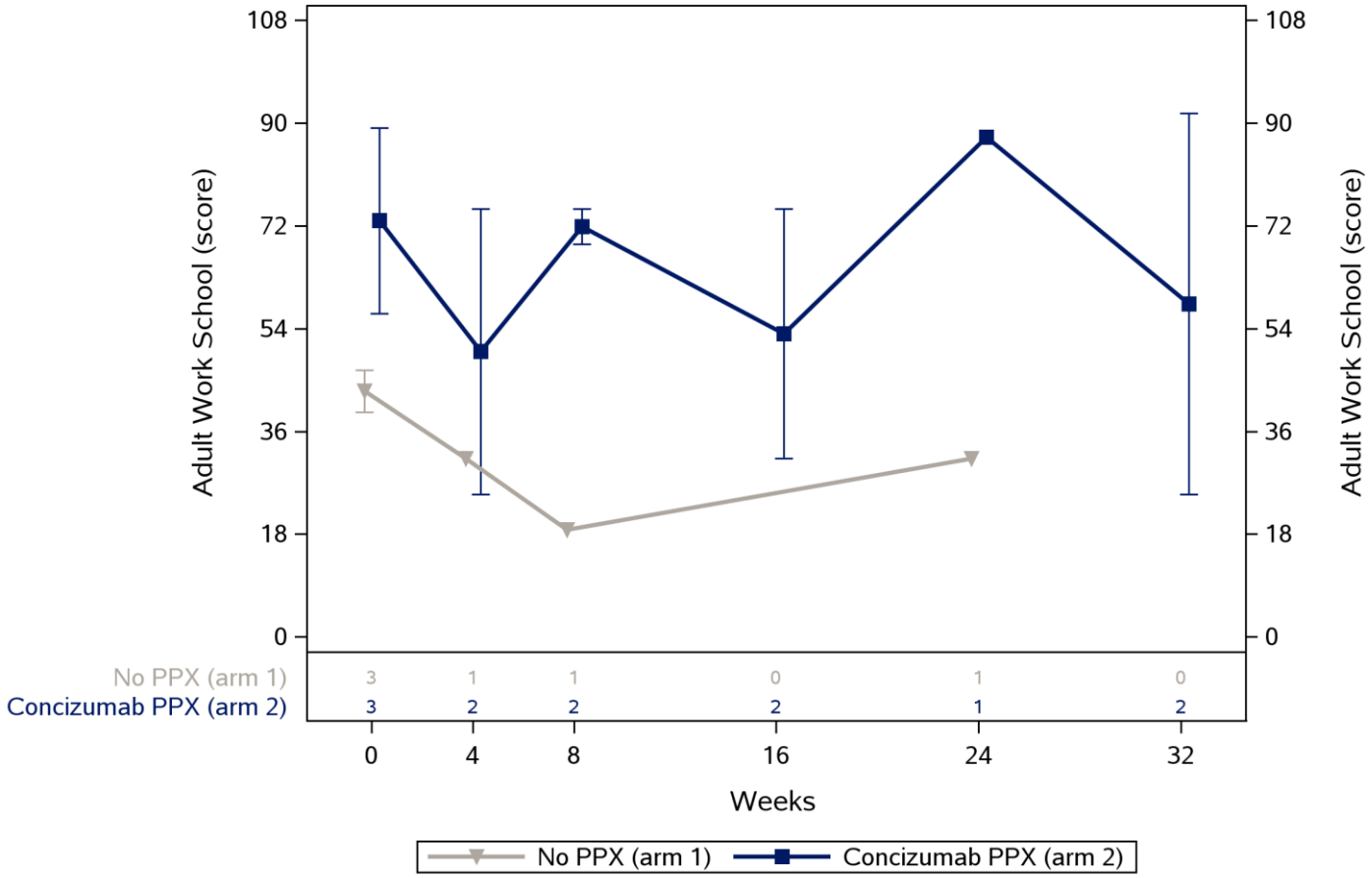
35: HAEM-A-QoL - work and studies - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:41 - f-sf36mean.sas/f-HAQ_workfasHA.png

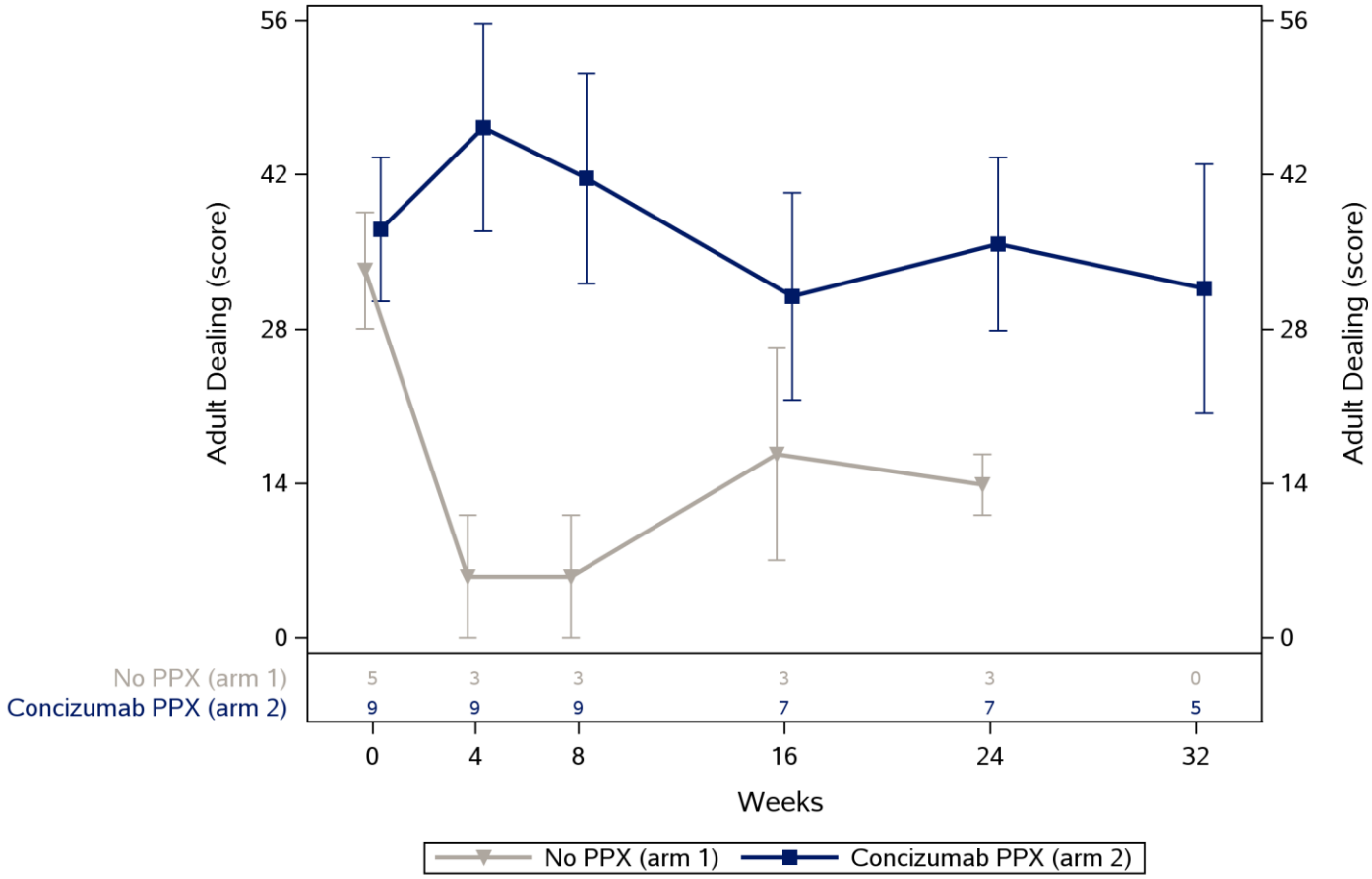
36: HAEM-A-QoL - work and studies - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:43 - f-sf36mean.sas/f-HAQ_workfasHB.png

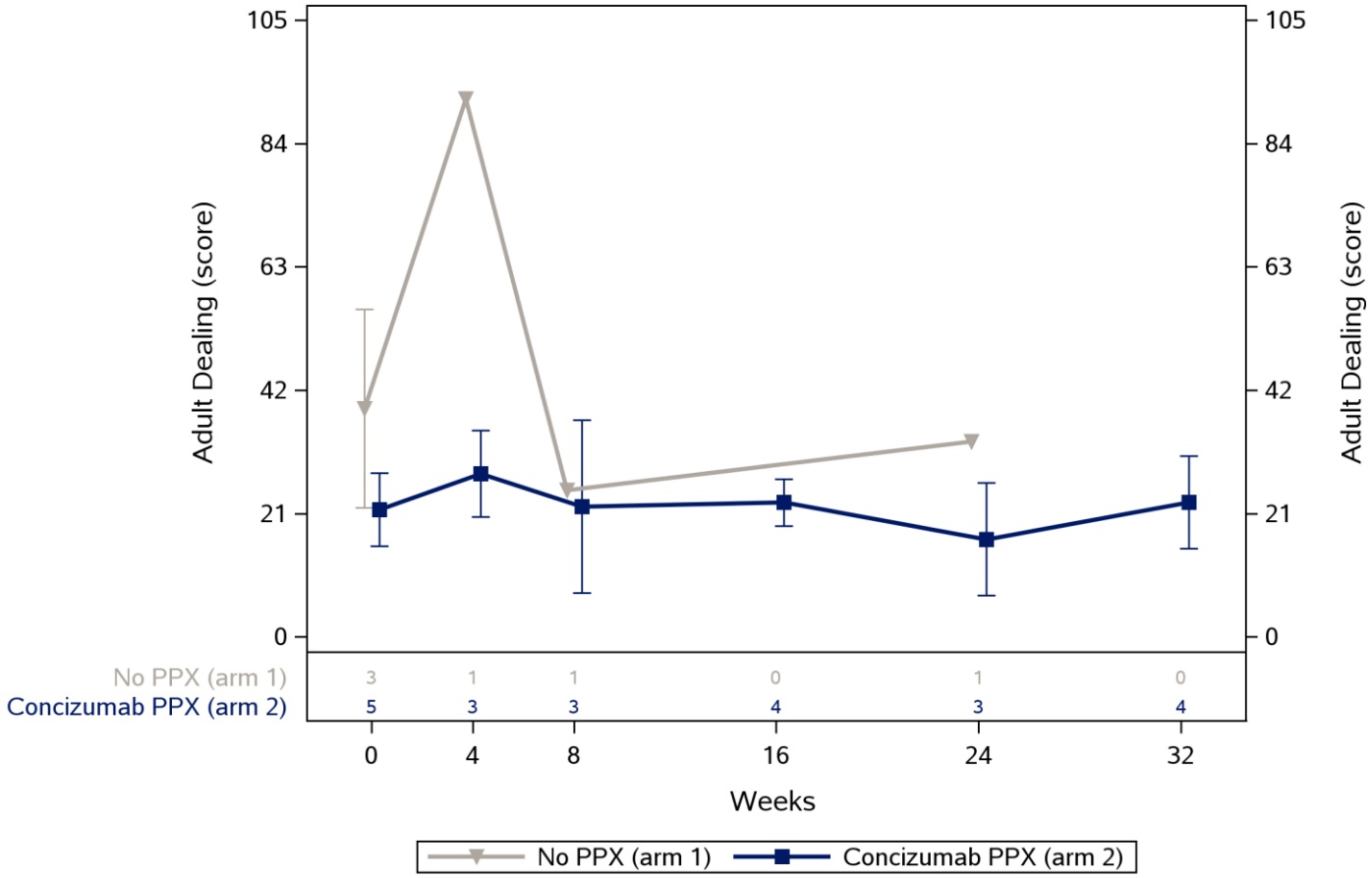
37: HAEM-A-QoL - dealing with haemophilia - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:44 - f-sf36mean.sas/f-HAQ_dealfasHA.png

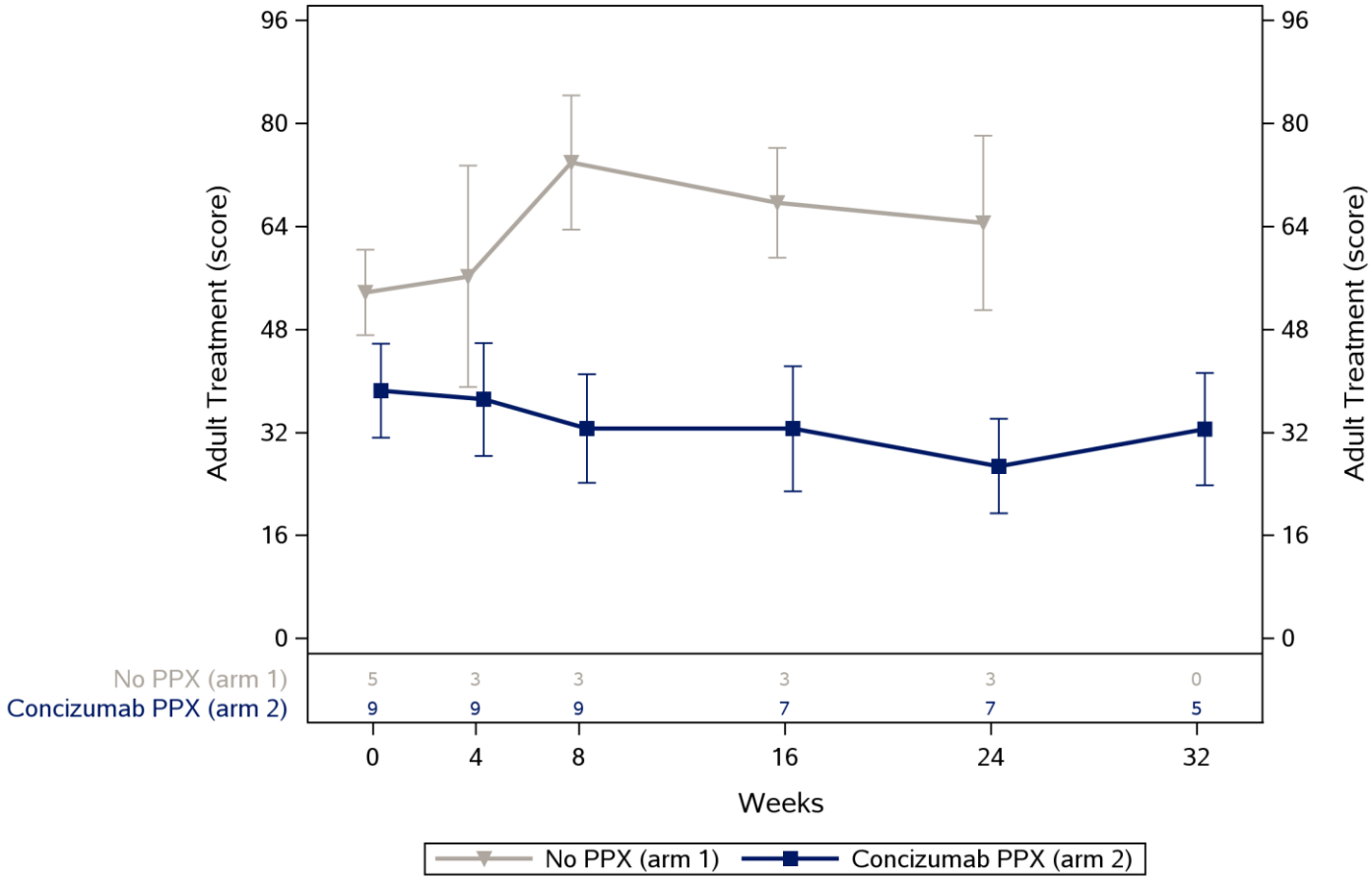
38: HAEM-A-QoL - dealing with haemophilia - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:45 - f-sf36mean.sas/f-HAQ_dealfasHB.png

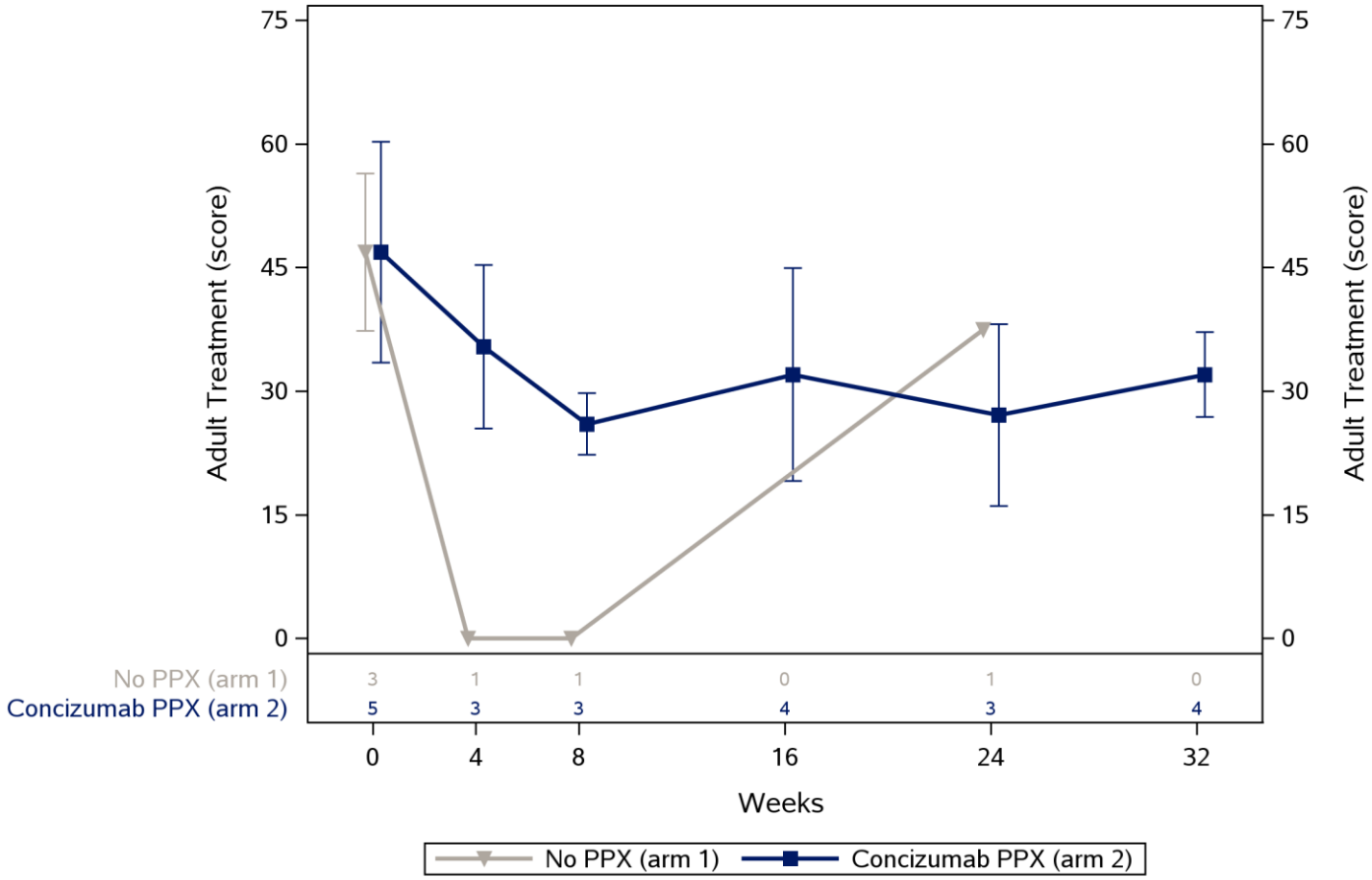
39: HAEM-A-QoL - treatment - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:47 - f-sf36mean.sas/f-HAQ_treatfasHA.png

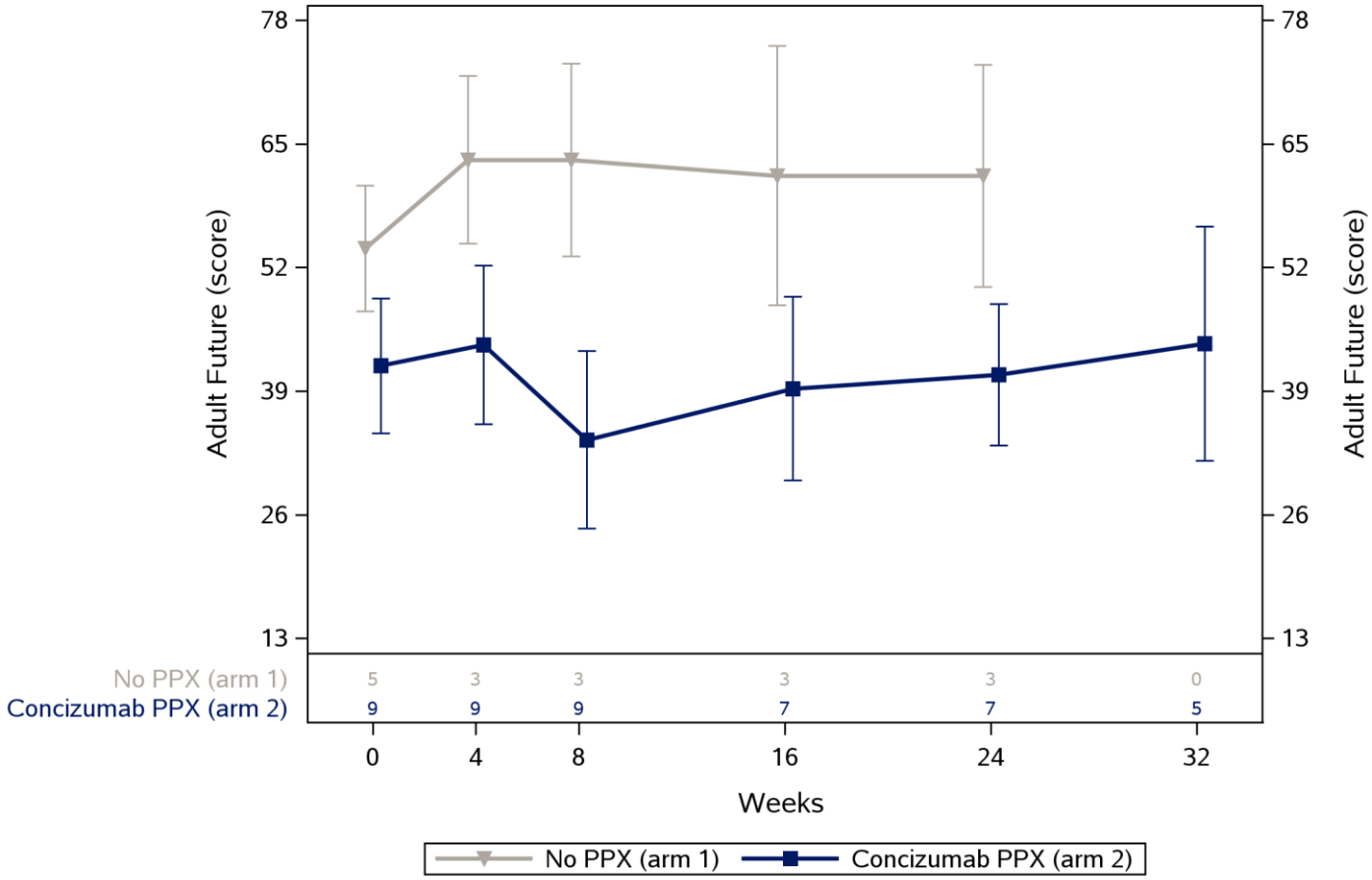
40: HAEM-A-QoL - treatment - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:48 - f-sf36mean.sas/f-HAQ_treatfasHB.png

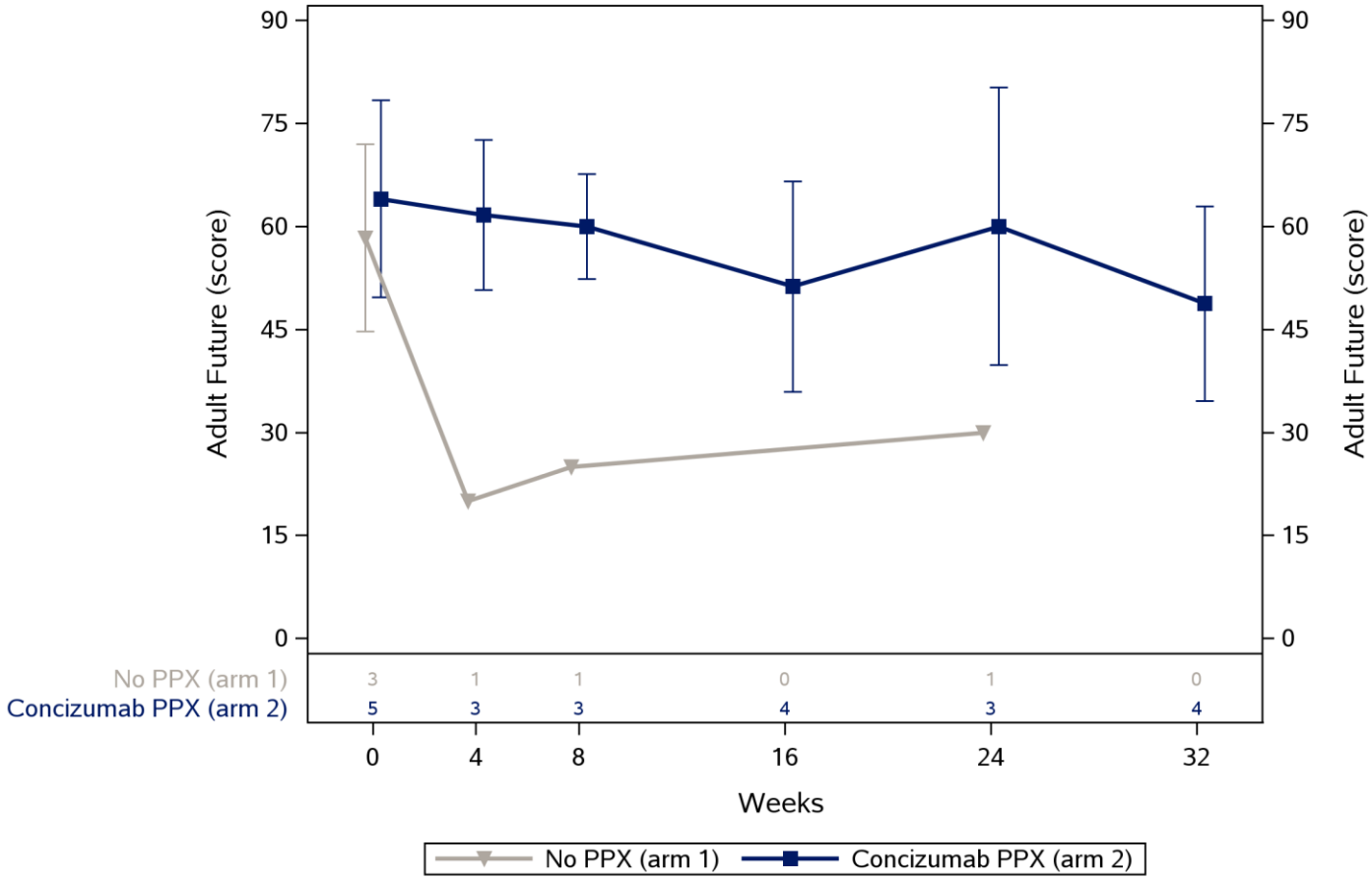
41: HAEM-A-QoL - future - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:49 - f-sf36mean.sas/f-HAQ_futurefasHA.png

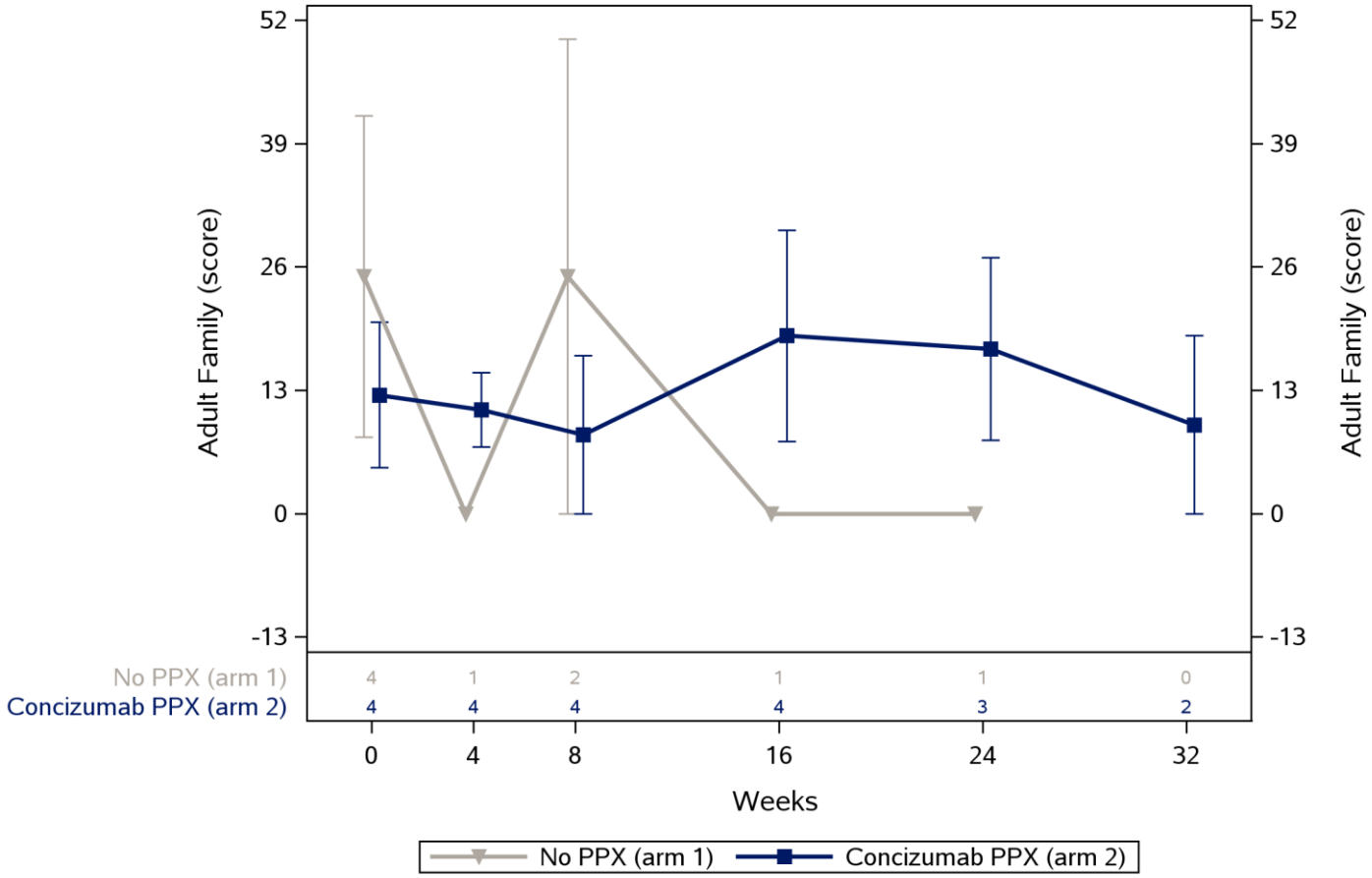
42: HAEM-A-QoL - future - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:51 - f-sf36mean.sas/f-HAQ_futurefasHB.png

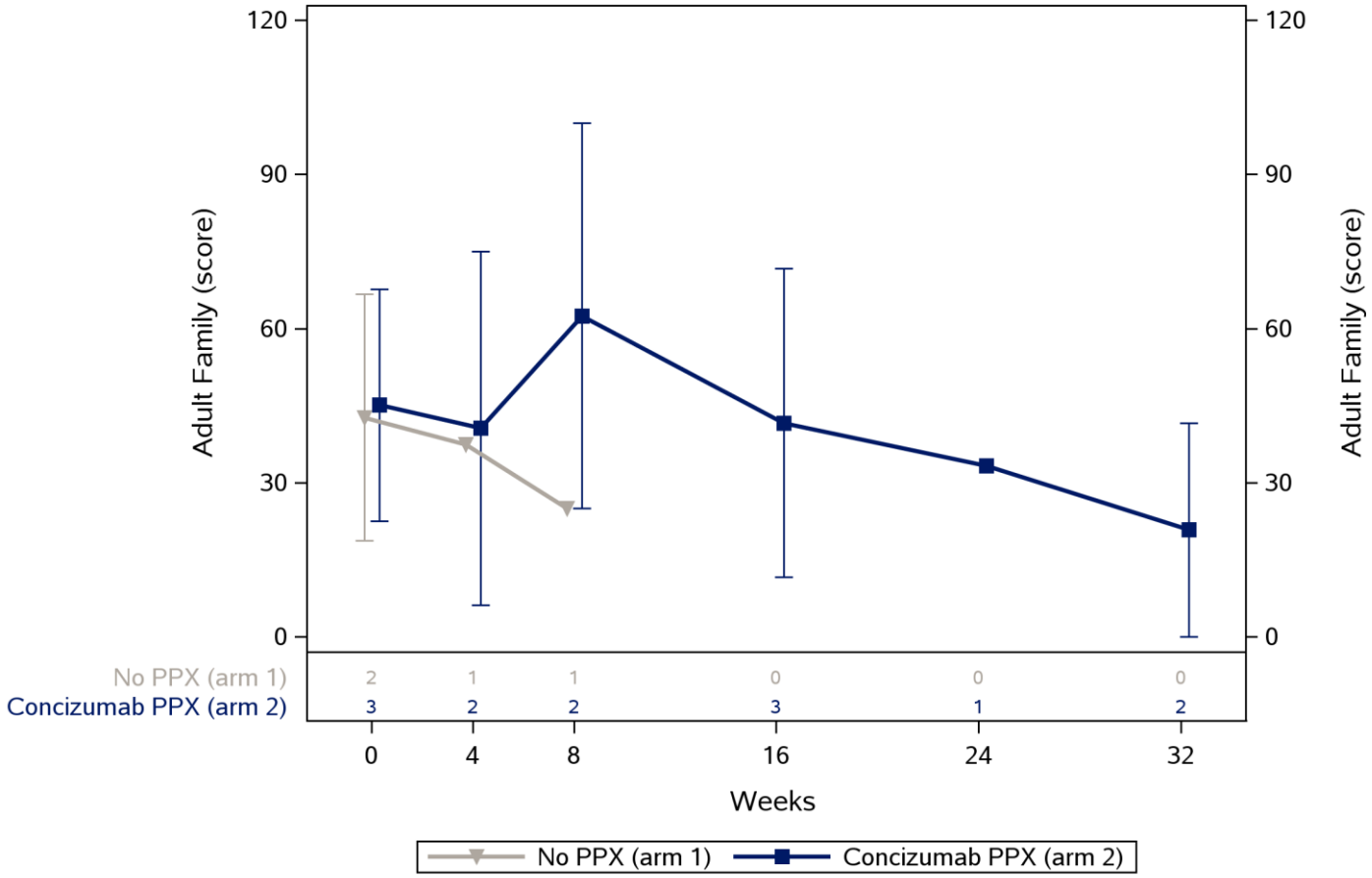
43: HAEM-A-QoL - family planning - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:52 - f-sf36mean.sas/f-HAQ_famfasHA.png

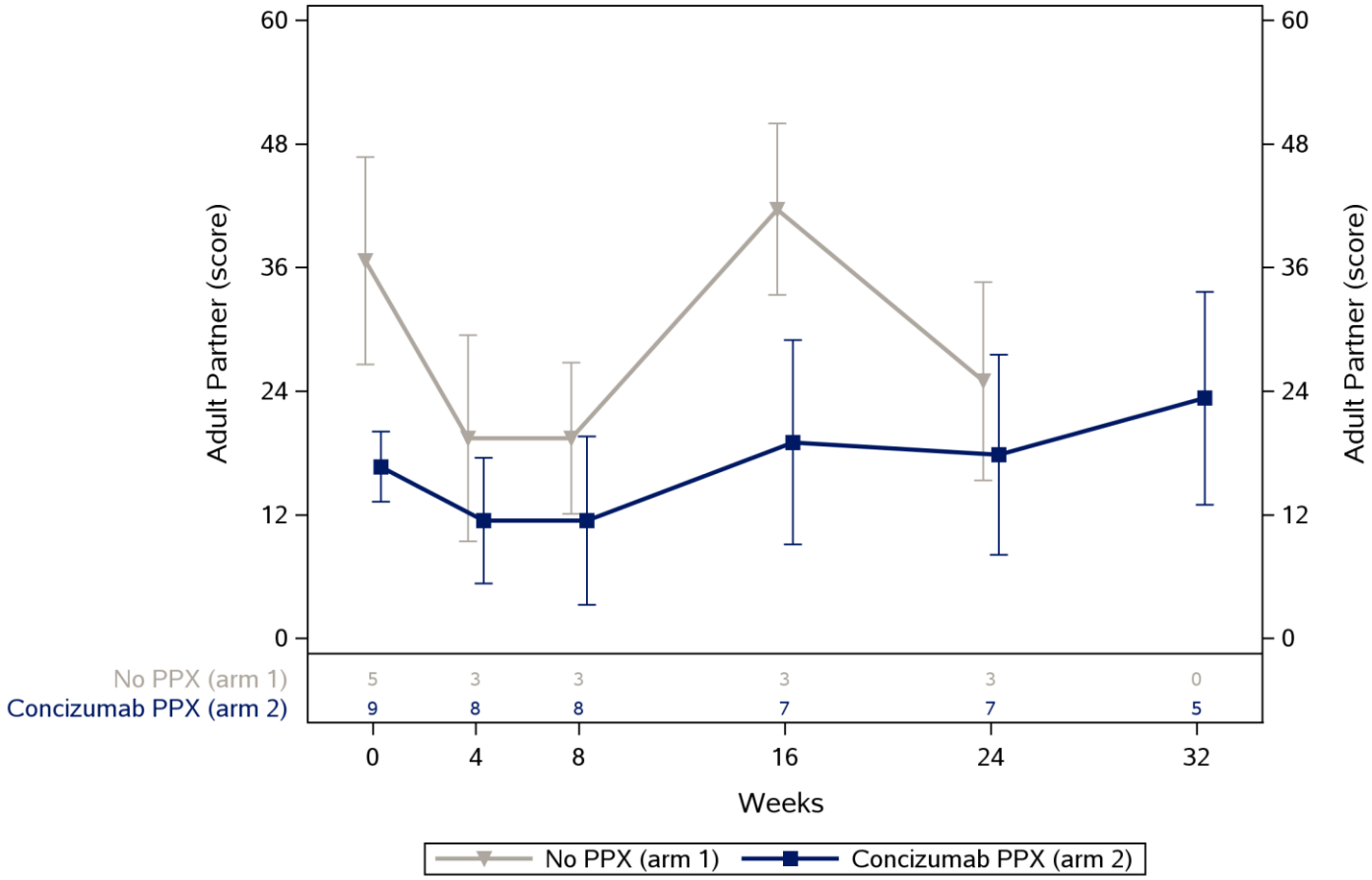
44: HAEM-A-QoL - family planning - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:55 - f-sf36mean.sas/f-HAQ_famfasHB.png

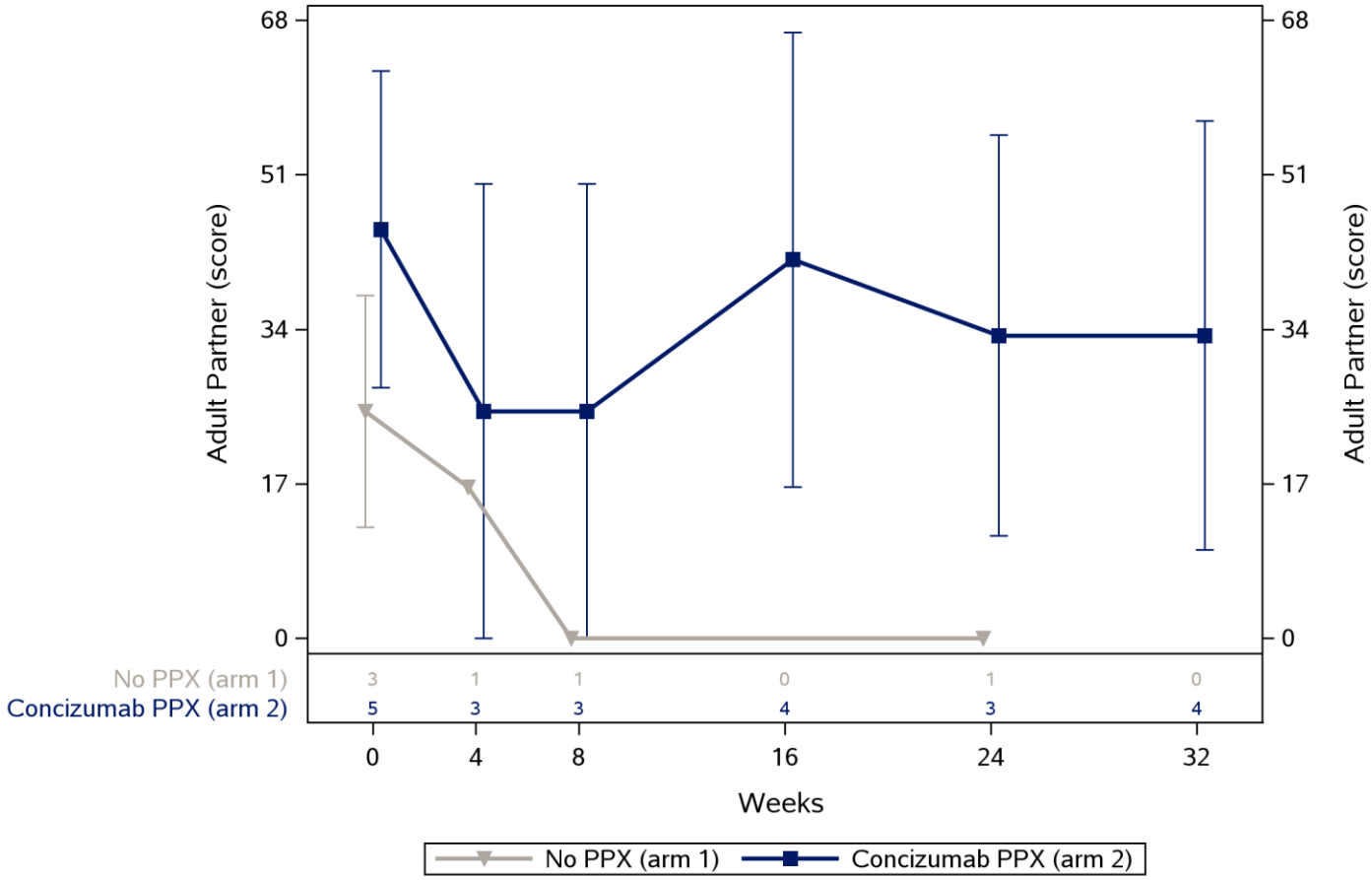
45: HAEM-A-QoL - partnership and sexuality - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:57 - f-sf36mean.sas/f-HAQ_partfasHA.png

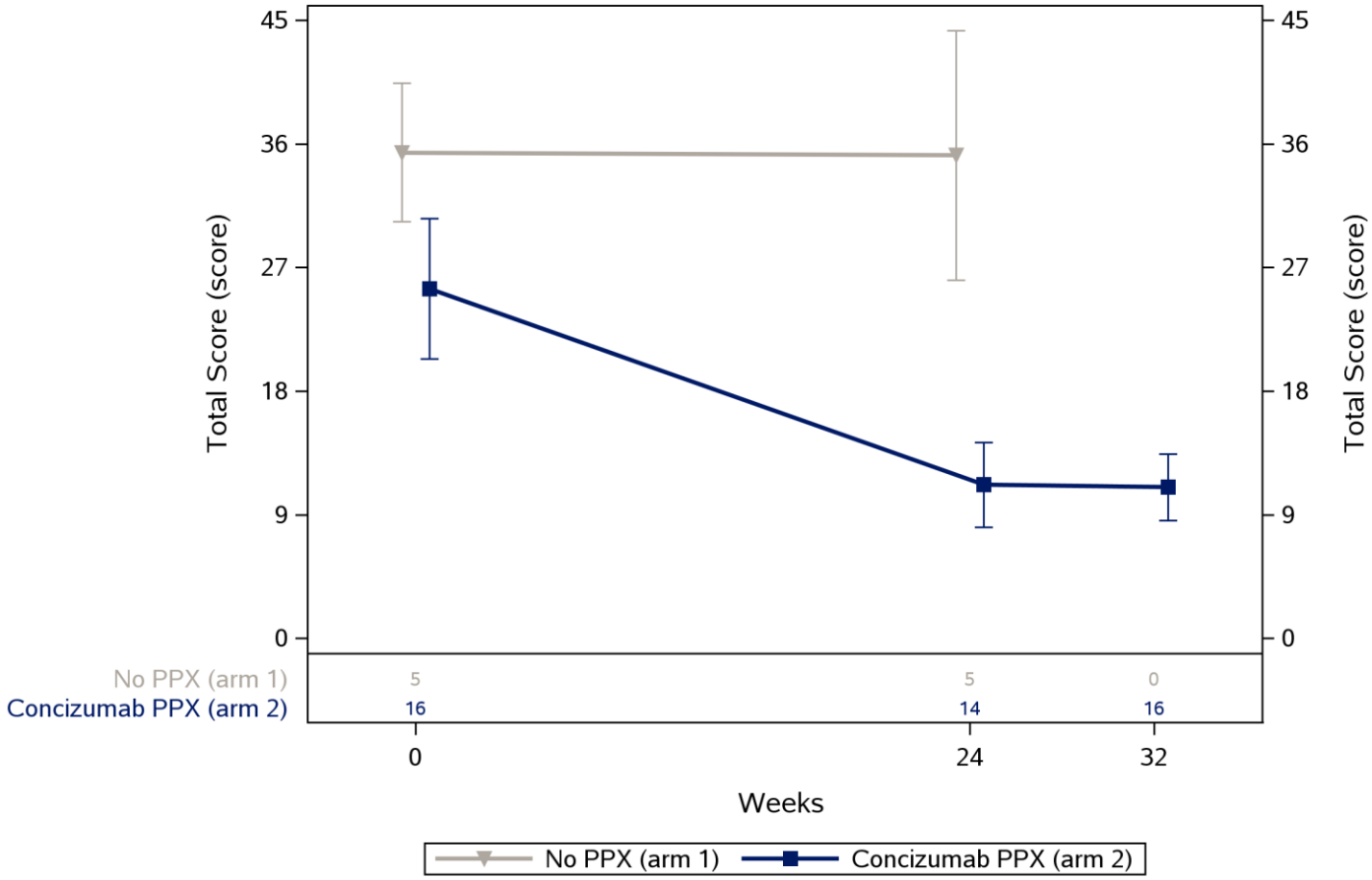
46: HAEM-A-QoL - partnership and sexuality - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:58 - f-sf36mean.sas/f-HAQ_partfasHB.png

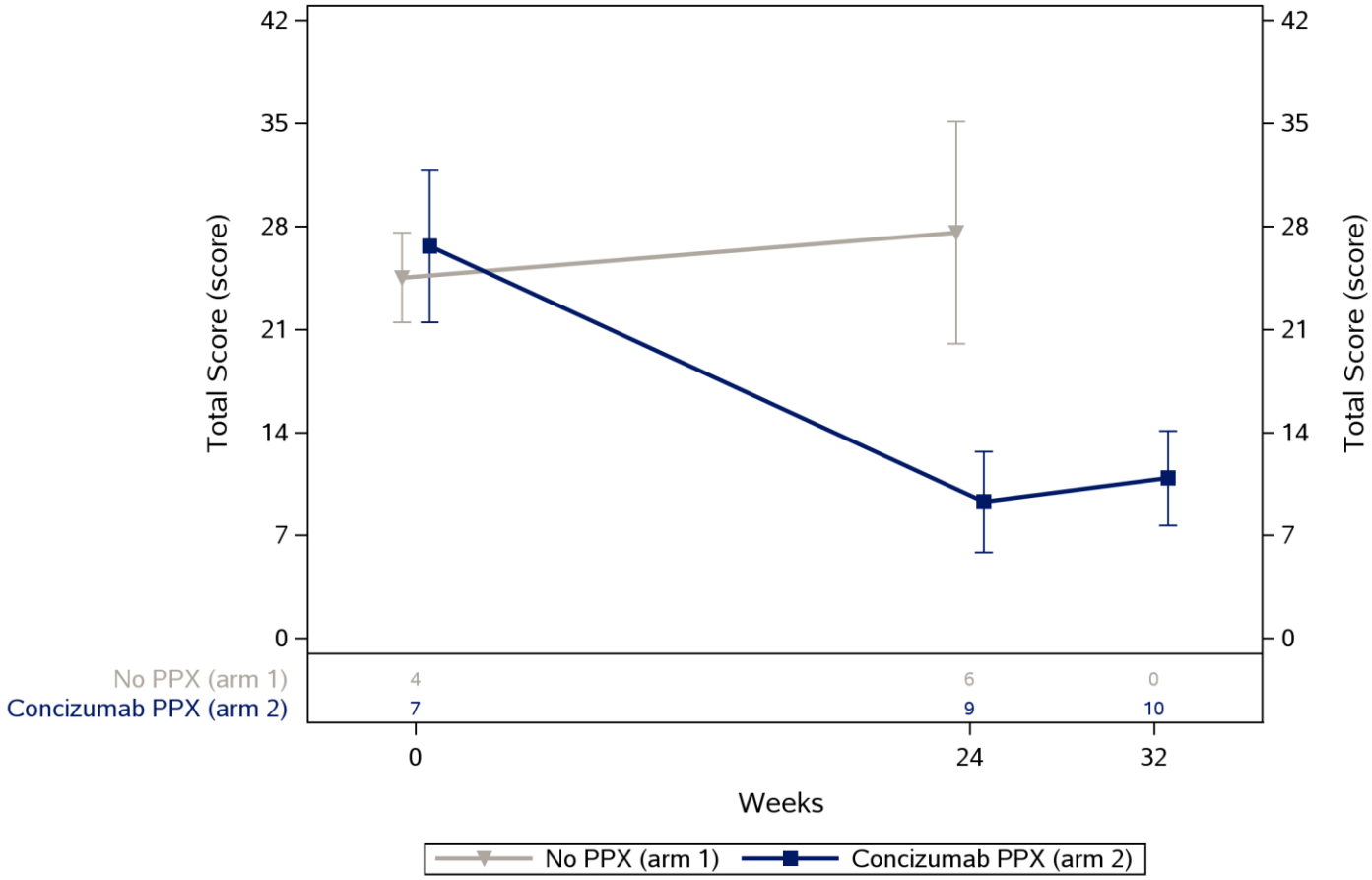
47: Hemo-TEM - Total score - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:38:59 - f-sf36mean.sas/f-HTEM_totalfasHA.png

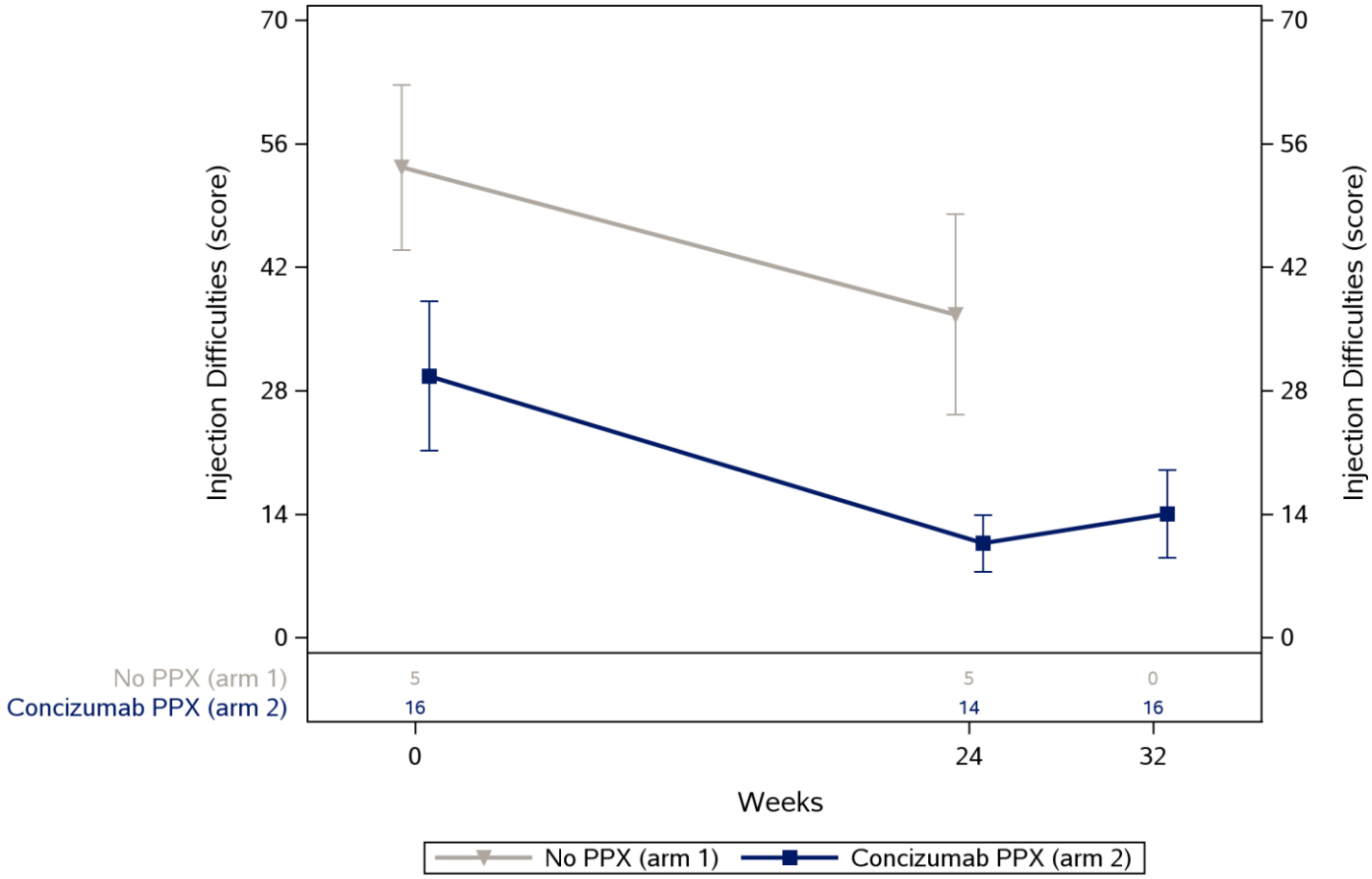
48: Hemo-TEM - Total score - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:00 - f-sf36mean.sas/f-HTEM_totalfasHB.png

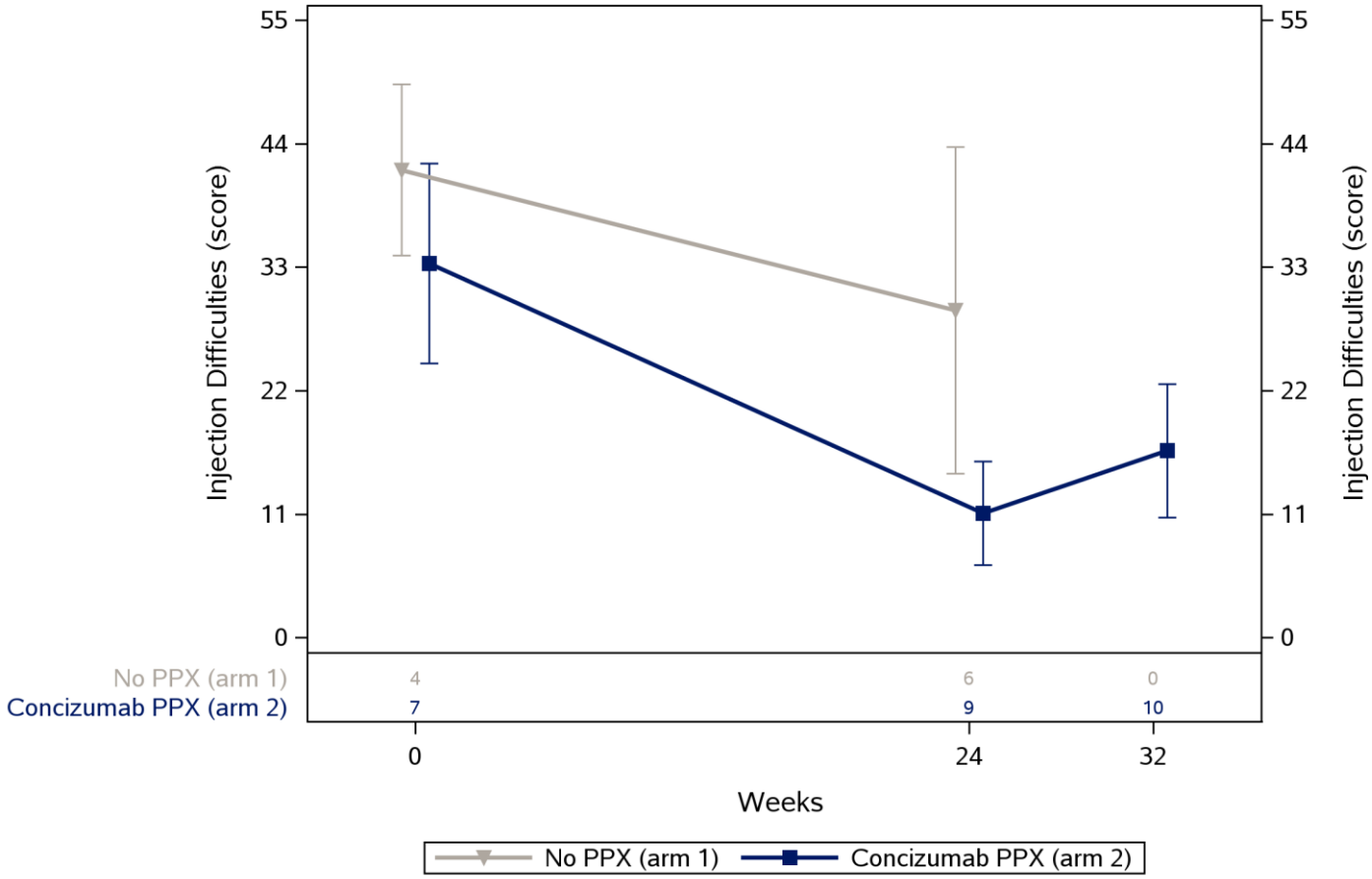
49: Hemo-TEM - Ease of use - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:04 - f-sf36mean.sas/f-HTEM_easefasHA.png

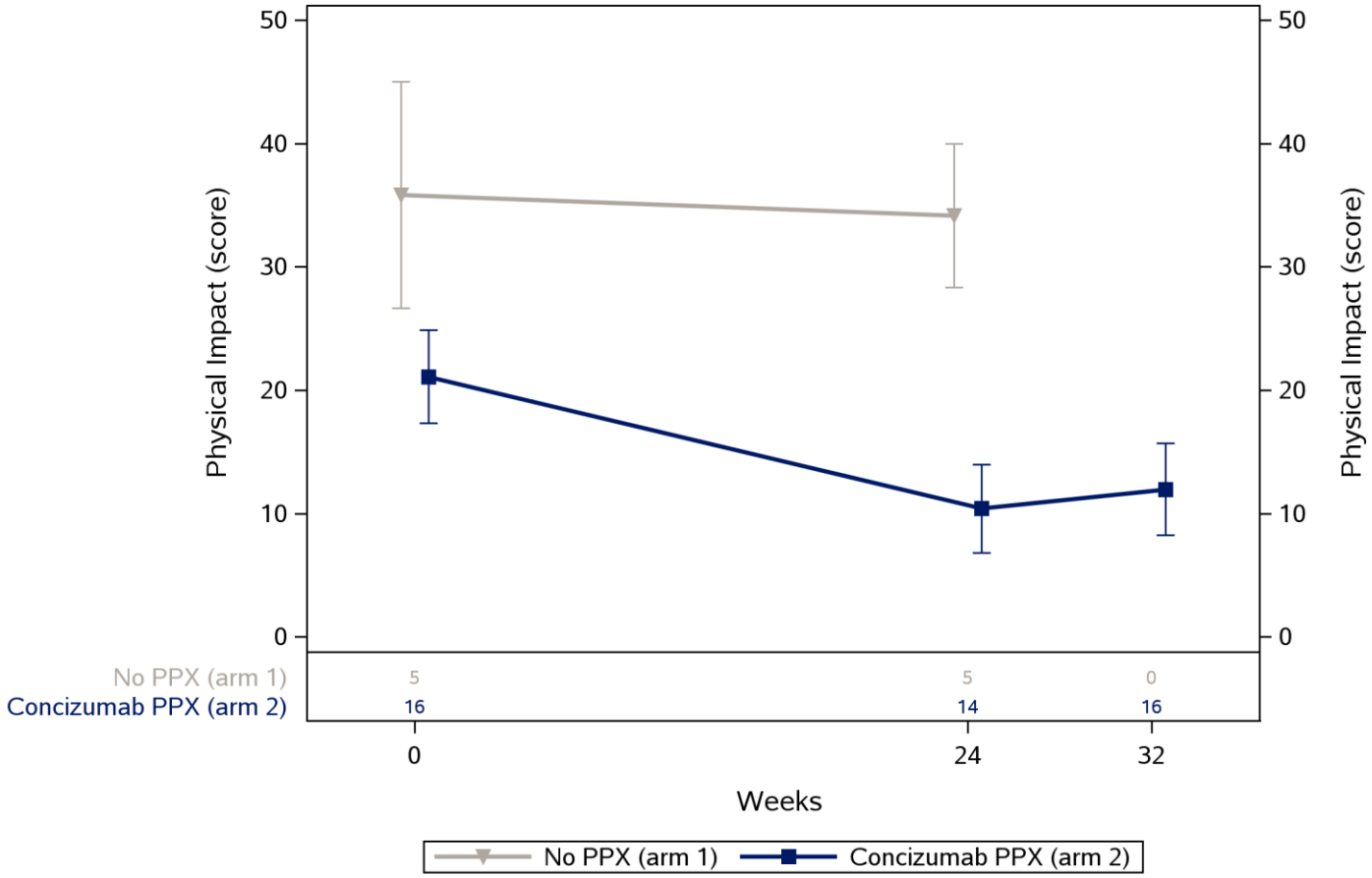
50: Hemo-TEM - Ease of use - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:05 - f-sf36mean.sas/f-HTEM_easefasHB.png

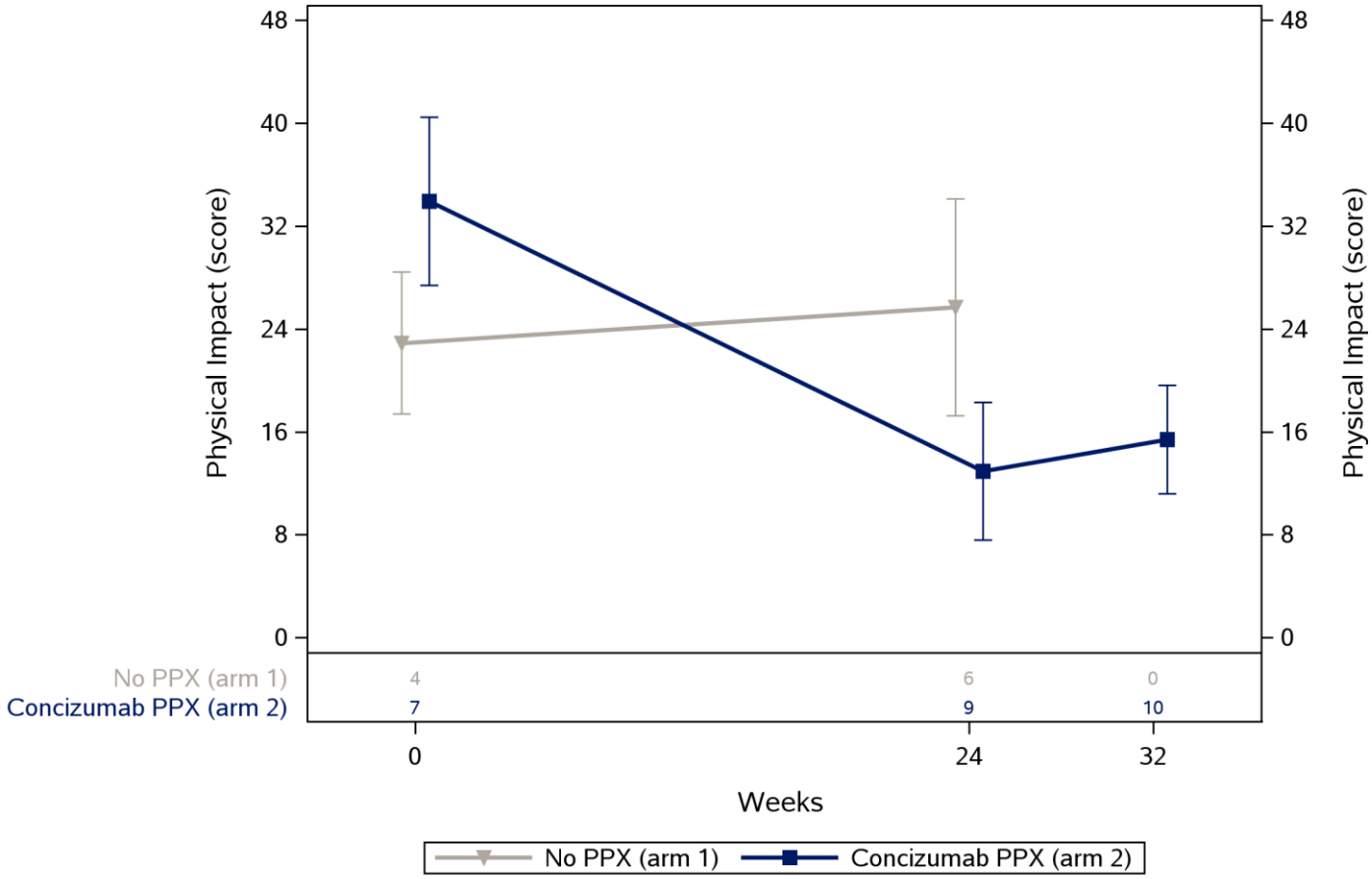
51: Hemo-TEM - Physical impact - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:06 - f-sf36mean.sas/f-HTEM_impactfasHA.png

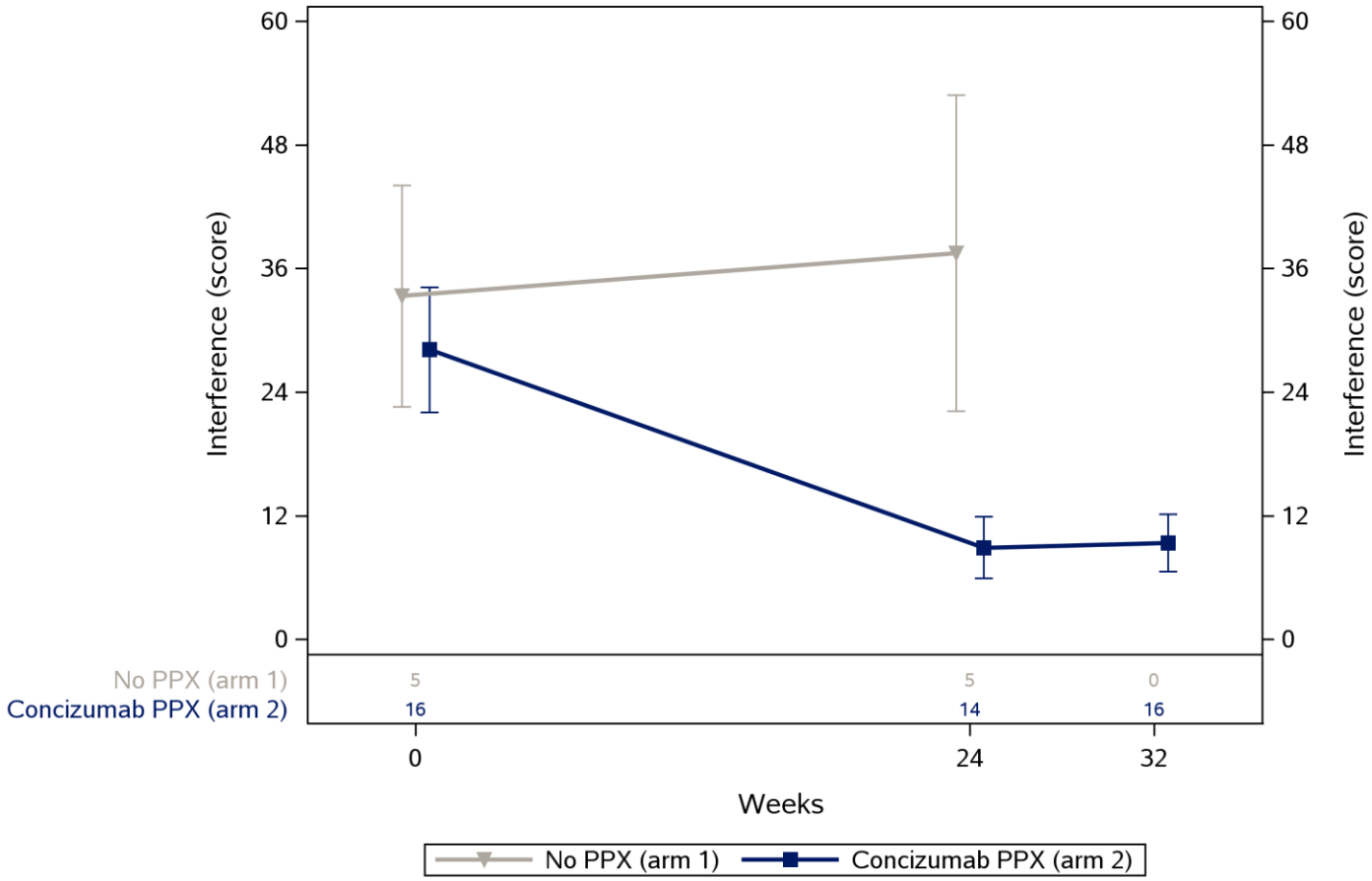
52: Hemo-TEM - Physical impact - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:08 - f-sf36mean.sas/f-HTEM_impactfasHB.png

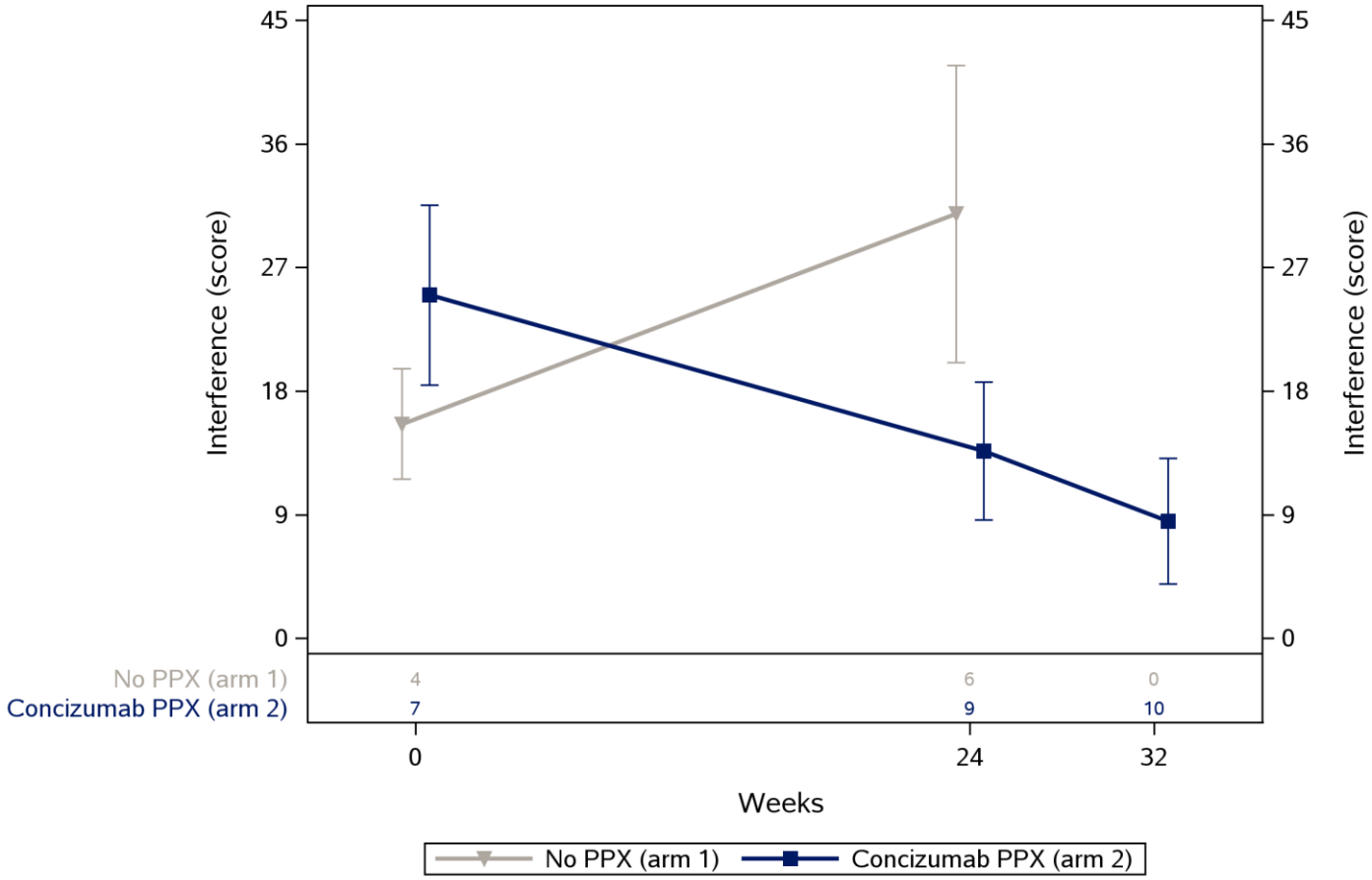
53: Hemo-TEM - Interference - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:09 - f-sf36mean.sas/f-HTEM_interfasHA.png

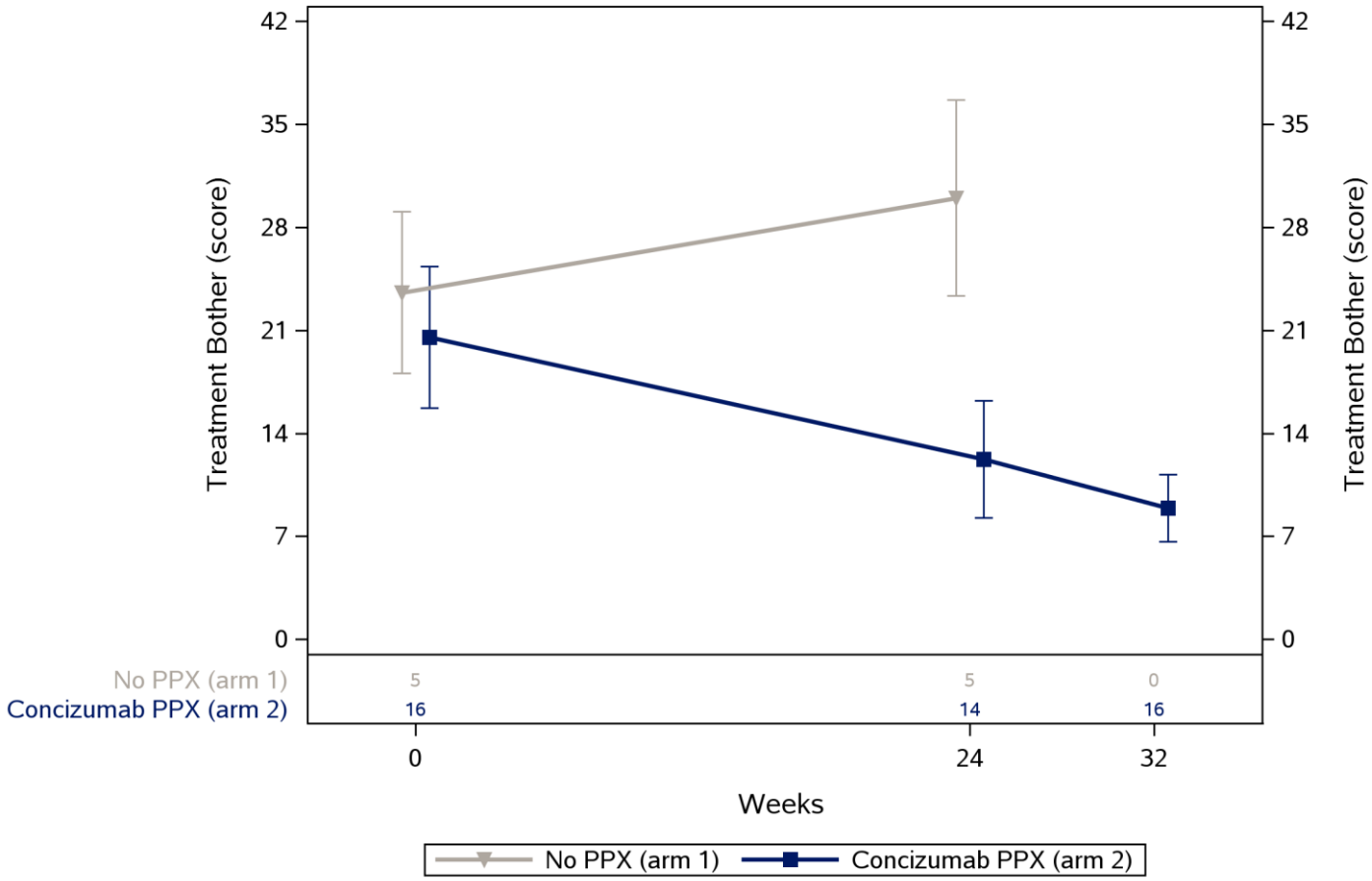
54: Hemo-TEM - Interference - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:10 - f-sf36mean.sas/f-HTEM_interfasHB.png

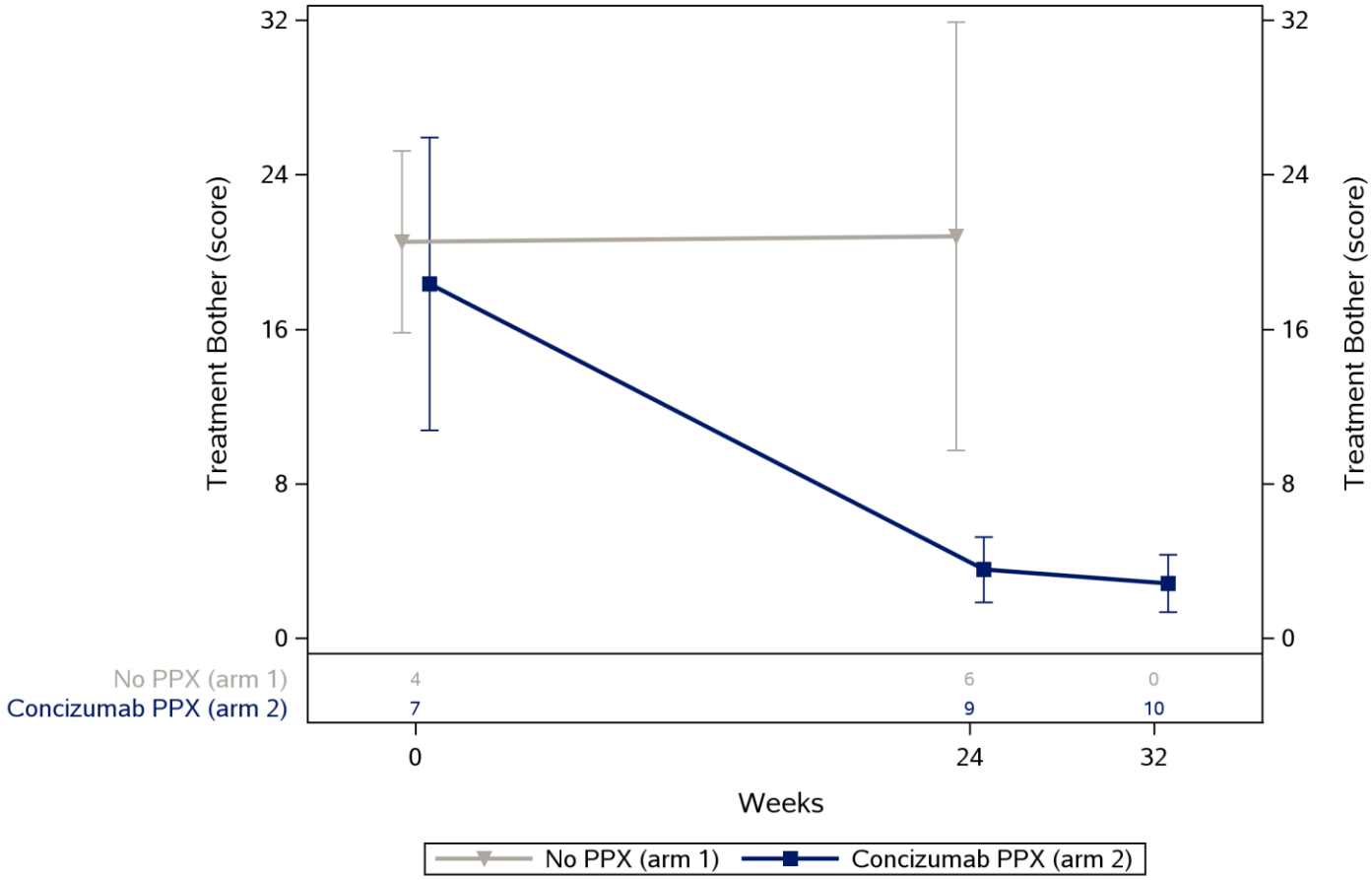
55: Hemo-TEM - Treatment burden - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:11 - f-sf36mean.sas/f-HTEM_burdenfasHA.png

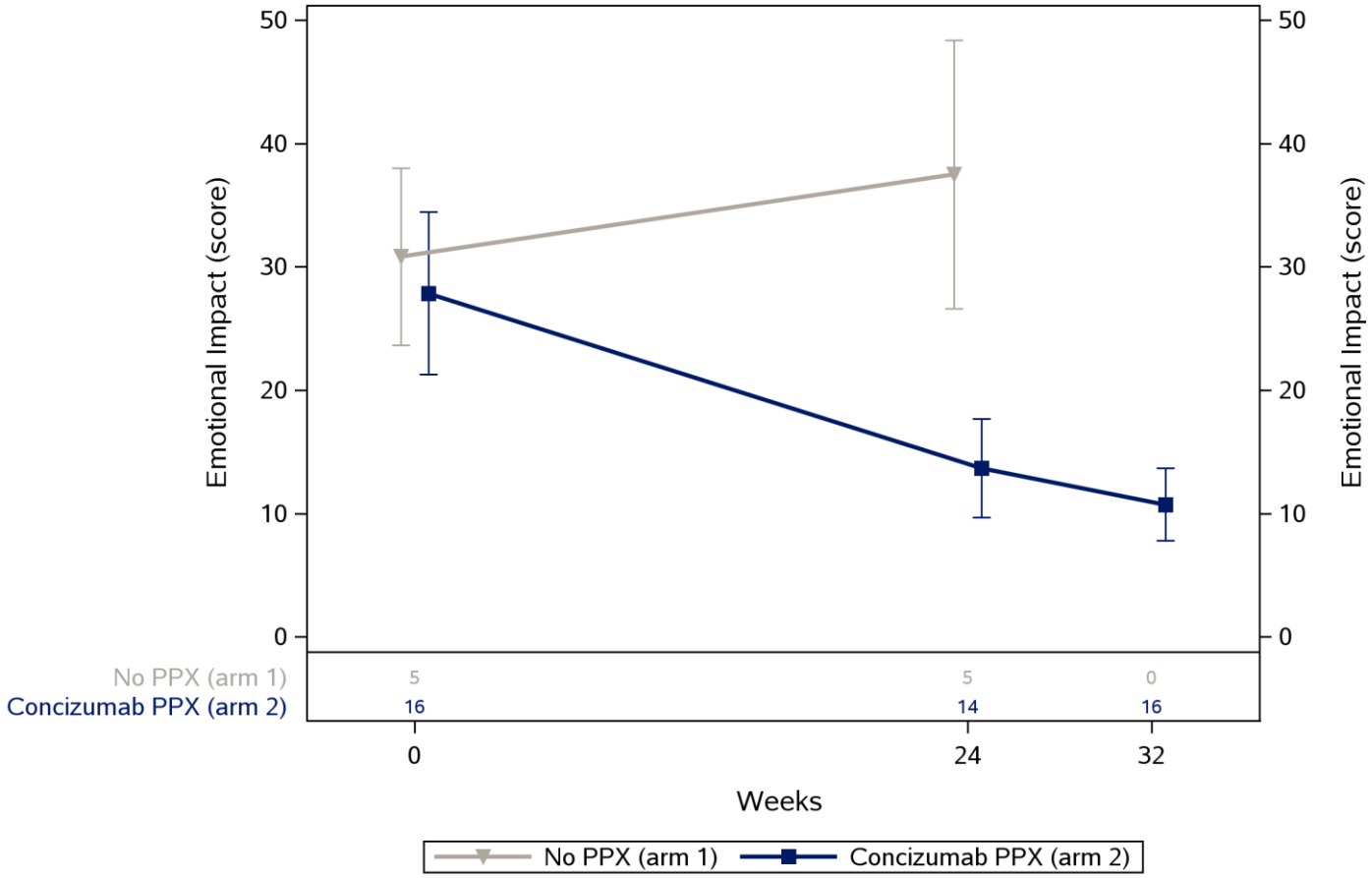
56: Hemo-TEM - Treatment burden - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:13 - f-sf36mean.sas/f-HTEM_burdenfasHB.png

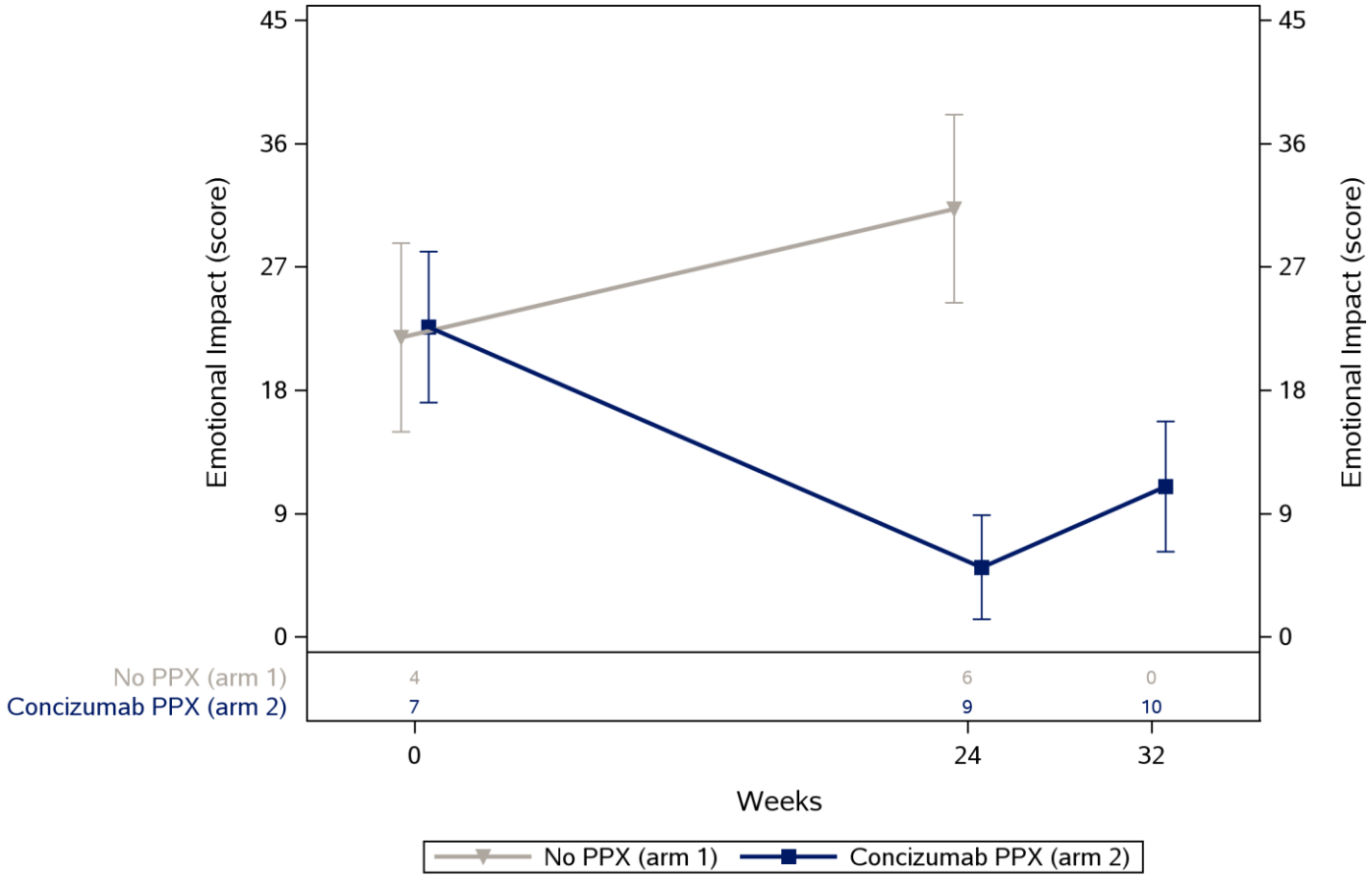
57: Hemo-TEM - Emotional impact - mean plot - HAwI - OTexIR - full analysis set



HAwI: haemophilia A with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:14 - f-sf36mean.sas/f-HTEM_emoimpfasHA.png

58: Hemo-TEM - Emotional impact - mean plot - HBwI - OTexIR - full analysis set



HBwI: haemophilia B with inhibitors, OTexIR: On-treatment without data on initial regimen.
PPX: Prophylaxis.
Week 0 is defined as the baseline value in this plot (Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:39:15 - f-sf36mean.sas/f-HTEM_emoimpfasHB.png

Table of contents

Page

1: Any adverse events - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)				
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value	p-value int.
All subjects (total)	17	9 (52.9)	9	5 (55.6)	0.90 (0.18, 4.56)	0.95 (0.46, 1.99)	-2.61 (-42.82, 37.60)	0.9664*	
Age									0.5289
< 18 years	10	4 (40.0)	1	0 (0.0)	2.08 (0.07, 63.42)	1.64 (0.13, 20.00)	40.00 (9.64, 70.36)	0.8281*	
>= 18 years	7	5 (71.4)	8	5 (62.5)	1.50 (0.17, 13.23)	1.14 (0.56, 2.33)	8.93 (-38.46, 56.31)	0.7496*	
Disease severity									0.1979
high titer	5	2 (40.0)	6	2 (33.3)	1.33 (0.11, 15.70)	1.20 (0.25, 5.71)	6.67 (-50.49, 63.82)	0.9149*	
low titer	12	7 (58.3)	3	3 (100.0)	0.19 (0.01, 4.60)	0.66 (0.36, 1.20)	-41.67 (-69.56, -13.77)	0.2565*	

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

2: Any adverse events - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	6 (50.0)	10	3 (30.0)	2.33 (0.40, 13.61)	1.67 (0.55, 5.02)	20.00 (-20.09, 60.09)	0.3572*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

3: Any adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Acarodermatitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Arthritis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Nasopharyngitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Pneumonitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Rhinitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Any adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Thermal burn								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Upper respiratory tract infection								
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

4: Any adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Back pain								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Blood alkaline phosphatase increased								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Blood pressure increased								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Conjunctival hyperaemia								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Constipation								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Any adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
COVID-19								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Erythema								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Fibroma								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Haematoma								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Haematuria								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Any adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Lower limb fracture								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Pruritus								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Pyrexia								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Respiratory tract infection viral								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Road traffic accident								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Any adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Skin abrasion								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Subcutaneous abscess								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Tibia fracture								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

5: Any adverse events by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Gastrointestinal disorders								
All subjects (total)	17	2 (11.8)	9	0 (0.0)	3.06 (0.13, 70.94)	2.78 (0.15, 52.35)	11.76 (-3.55, 27.08)	0.3923*
Infections and infestations								
All subjects (total)	17	2 (11.8)	9	4 (44.4)	0.17 (0.02, 1.20)	0.26 (0.06, 1.18)	-32.68 (-68.57, 3.22)	0.0647*
Injury, poisoning and procedural complications								
All subjects (total)	17	2 (11.8)	9	1 (11.1)	1.07 (0.08, 13.65)	1.06 (0.11, 10.15)	0.65 (-24.96, 26.27)	1.0000*
Musculoskeletal and connective tissue disorders								
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*
Respiratory, thoracic and mediastinal disorders								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

6: Any adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Eye disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Gastrointestinal disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
General disorders and administration site conditions								
All subjects (total)	12	3 (25.0)	10	1 (10.0)	3.00 (0.26, 34.57)	2.50 (0.31, 20.45)	15.00 (-15.76, 45.76)	0.5260*
Infections and infestations								
All subjects (total)	12	3 (25.0)	10	2 (20.0)	1.33 (0.18, 10.12)	1.25 (0.26, 6.07)	5.00 (-29.85, 39.85)	0.8228*
Injury, poisoning and procedural complications								
All subjects (total)	12	2 (16.7)	10	3 (30.0)	0.47 (0.06, 3.56)	0.56 (0.11, 2.70)	-13.33 (-48.71, 22.04)	0.5947*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Any adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Investigations								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Musculoskeletal and connective tissue disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Nervous system disorders								
All subjects (total)	12	2 (16.7)	10	0 (0.0)	5.00 (0.21, 117.21)	4.23 (0.23, 79.10)	16.67 (-4.42, 37.75)	0.2074*
Renal and urinary disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Any adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Skin and subcutaneous tissue disorders								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Vascular disorders								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:13 - t-socpt-baker.R/AnyAESOC_HBwI_saf_4311.txt

7: Severe adverse events - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:06 - t-safety-baker.R/SevAE_HAwI_saf_4311.txt

8: Severe adverse events - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	2 (16.7)	10	2 (20.0)	0.80 (0.09, 7.00)	0.83 (0.14, 4.90)	-3.33 (-35.88, 29.21)	0.9113*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

9: Severe adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Haematemesis								
All subjects (total)	17	1 (5.9)	9	0 (0.0)	1.73 (0.06, 46.77)	1.67 (0.07, 37.21)	5.88 (-5.30, 17.07)	0.5720*
Melaena								
All subjects (total)	17	1 (5.9)	9	0 (0.0)	1.73 (0.06, 46.77)	1.67 (0.07, 37.21)	5.88 (-5.30, 17.07)	0.5720*
Pneumonitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

10: Severe adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
COVID-19								
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*
Femur fracture								
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*
Humerus fracture								
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*
Lower limb fracture								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Road traffic accident								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Severe adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Tibia fracture								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

11: Severe adverse events by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Gastrointestinal disorders								
All subjects (total)	17	1 (5.9)	9	0 (0.0)	1.73 (0.06, 46.77)	1.67 (0.07, 37.21)	5.88 (-5.30, 17.07)	0.5720*
Respiratory, thoracic and mediastinal disorders								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

12: Severe adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*
Injury, poisoning and procedural complications								
All subjects (total)	12	1 (8.3)	10	2 (20.0)	0.36 (0.03, 4.74)	0.42 (0.04, 3.95)	-11.67 (-40.98, 17.64)	0.5828*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

13: Moderate adverse events - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	17	2 (11.8)	9	0 (0.0)	3.06 (0.13, 70.94)	2.78 (0.15, 52.35)	11.76 (-3.55, 27.08)	0.3923*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:09 - t-safety-baker.R/ModAE_HAwI_saf_4311.txt

14: Moderate adverse events - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	1 (8.3)	10	2 (20.0)	0.36 (0.03, 4.74)	0.42 (0.04, 3.95)	-11.67 (-40.98, 17.64)	0.5828*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:10 - t-safety-baker.R/ModAE_HBwI_saf_4311.txt

15: Moderate adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

16: Moderate adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Blood alkaline phosphatase increased								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Blood pressure increased								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
COVID-19								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Haematoma								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Respiratory tract infection viral								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

17: Moderate adverse events by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

18: Moderate adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	12	0 (0.0)	10	2 (20.0)	0.14 (0.01, 3.20)	0.17 (0.01, 3.16)	-20.00 (-44.79, 4.79)	0.1470*
Investigations								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Vascular disorders								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

19: Mild adverse events - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	17	7 (41.2)	9	4 (44.4)	0.88 (0.17, 4.47)	0.93 (0.37, 2.34)	-3.27 (-43.28, 36.75)	0.8823*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:11 - t-safety-baker.R/MilAE_HAwI_saf_4311.txt

20: Mild adverse events - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	4 (33.3)	10	2 (20.0)	2.00 (0.28, 14.20)	1.67 (0.38, 7.29)	13.33 (-23.08, 49.75)	0.6007*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:12 - t-safety-baker.R/MilAE_HBwI_saf_4311.txt

21: Mild adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Acarodermatitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Arthritis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Nasopharyngitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Rhinitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*
Thermal burn								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Mild adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Upper respiratory tract infection								
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

22: Mild adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Back pain								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Conjunctival hyperaemia								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Constipation								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Erythema								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Fibroma								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Mild adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Haematuria								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Pruritus								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Pyrexia								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Skin abrasion								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Subcutaneous abscess								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

23: Mild adverse events by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	17	2 (11.8)	9	4 (44.4)	0.17 (0.02, 1.20)	0.26 (0.06, 1.18)	-32.68 (-68.57, 3.22)	0.0647*
Injury, poisoning and procedural complications								
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*
Musculoskeletal and connective tissue disorders								
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

24: Mild adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Eye disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Gastrointestinal disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
General disorders and administration site conditions								
All subjects (total)	12	3 (25.0)	10	1 (10.0)	3.00 (0.26, 34.57)	2.50 (0.31, 20.45)	15.00 (-15.76, 45.76)	0.5260*
Infections and infestations								
All subjects (total)	12	2 (16.7)	10	1 (10.0)	1.80 (0.14, 23.37)	1.67 (0.18, 15.80)	6.67 (-21.45, 34.78)	0.7053*
Injury, poisoning and procedural complications								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Mild adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Musculoskeletal and connective tissue disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Renal and urinary disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Skin and subcutaneous tissue disorders								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

25: Serious adverse events - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	17	1 (5.9)	9	1 (11.1)	0.50 (0.03, 9.08)	0.53 (0.04, 7.50)	-5.23 (-28.61, 18.15)	0.7343*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:13 - t-safety-baker.R/SerAE_HAwI_saf_4311.txt

26: Serious adverse events - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	2 (16.7)	10	2 (20.0)	0.80 (0.09, 7.00)	0.83 (0.14, 4.90)	-3.33 (-35.88, 29.21)	0.9113*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:14 - t-safety-baker.R/SerAE_HBwI_saf_4311.txt

27: Serious adverse events by preferred term - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Haematemesis								
All subjects (total)	17	1 (5.9)	9	0 (0.0)	1.73 (0.06, 46.77)	1.67 (0.07, 37.21)	5.88 (-5.30, 17.07)	0.5720*
Melaena								
All subjects (total)	17	1 (5.9)	9	0 (0.0)	1.73 (0.06, 46.77)	1.67 (0.07, 37.21)	5.88 (-5.30, 17.07)	0.5720*
Pneumonitis								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

28: Serious adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
COVID-19								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Femur fracture								
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*
Haematoma								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*
Humerus fracture								
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*
Lower limb fracture								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

Serious adverse events by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Road traffic accident								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

29: Serious adverse events by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Gastrointestinal disorders								
All subjects (total)	17	1 (5.9)	9	0 (0.0)	1.73 (0.06, 46.77)	1.67 (0.07, 37.21)	5.88 (-5.30, 17.07)	0.5720*
Respiratory, thoracic and mediastinal disorders								
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

30: Serious adverse events by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Injury, poisoning and procedural complications								
All subjects (total)	12	1 (8.3)	10	1 (10.0)	0.82 (0.04, 15.00)	0.83 (0.06, 11.70)	-1.67 (-25.96, 22.63)	0.9877*
Vascular disorders								
All subjects (total)	12	0 (0.0)	10	1 (10.0)	0.25 (0.01, 6.94)	0.28 (0.01, 6.25)	-10.00 (-28.59, 8.59)	0.3424*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:28 - t-socpt-baker.R/SerAESOC_HBwI_saf_4311.txt

31: Adverse events leading to premature treatment discontinuation - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:15 - t-safety-baker.R/DisAE_HAwI_saf_4311.txt

32: Adverse events leading to premature treatment discontinuation - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	1 (8.3)	10	0 (0.0)	2.74 (0.10, 74.87)	2.54 (0.11, 56.25)	8.33 (-7.30, 23.97)	0.5124*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test). P-value (two-sided) for the interaction of subgroups is calculated using the Breslow-Day test for homogeneity across 2x2xk contingency tables for k levels of each subgroup.

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:15 - t-safety-baker.R/DisAE_HBwI_saf_4311.txt

33: Adverse events leading to premature treatment discontinuation by preferred term- Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:30 - t-socpt-baker.R/DisAEPT_HAwI_saf_4311.txt

34: Adverse events leading to premature treatment discontinuation by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:31 - t-socpt-baker.R/DisAEPT_HBwI_saf_4311.txt

35: Adverse events leading to premature treatment discontinuation by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:32 - t-socpt-baker.R/DisAESOC_HAwI_saf_4311.txt

36: Adverse events leading to premature treatment discontinuation by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:33 - t-socpt-baker.R/DisAESOC_HBwI_saf_4311.txt

37: Any adverse events of special interest - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:16 - t-safety-baker.R/AnyAESI_HAwI_saf_4311.txt

38: Any adverse events of special interest - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:17 - t-safety-baker.R/AnyAESI_HBwI_saf_4311.txt

39: Any adverse events of special interest by preferred term- Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:34 - t-socpt-baker.R/AnyAESIPT_HAwI_saf_4311.txt

40: Any adverse events of special interest by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:34 - t-socpt-baker.R/AnyAESIPT_HBwI_saf_4311.txt

41: Any adverse events of special interest by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:35 - t-socpt-baker.R/AnyAESISOC_HAwI_saf_4311.txt

42: Any adverse events of special interest by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:36 - t-socpt-baker.R/AnyAESISOC_HBwI_saf_4311.txt

43: Severe adverse events of special interest - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:18 - t-safety-baker.R/SevAESI_HAwI_saf_4311.txt

44: Severe adverse events of special interest - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:18 - t-safety-baker.R/SevAESI_HBwI_saf_4311.txt

45: Severe adverse events of special interest by preferred term- Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:36 - t-socpt-baker.R/SevAESIPT_HAwI_saf_4311.txt

46: Severe adverse events of special interest by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:37 - t-socpt-baker.R/SevAESIPT_HBwI_saf_4311.txt

47: Severe adverse events of special interest by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:38 - t-socpt-baker.R/SevAESISOC_HAwI_saf_4311.txt

48: Severe adverse events of special interest by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:39 - t-socpt-baker.R/SevAESISOC_HBwI_saf_4311.txt

49: Moderate adverse events of special interest - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:19 - t-safety-baker.R/ModAESI_HAwI_saf_4311.txt

50: Moderate adverse events of special interest - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:20 - t-safety-baker.R/ModAESI_HBwI_saf_4311.txt

51: Moderate adverse events of special interest by preferred term- Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:44 - t-socpt-baker.R/ModAESIPT_HAwI_saf_4311.txt

52: Moderate adverse events of special interest by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:45 - t-socpt-baker.R/ModAESIPT_HBwI_saf_4311.txt

53: Moderate adverse events of special interest by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:46 - t-socpt-baker.R/ModAESISOC_HAwI_saf_4311.txt

54: Moderate adverse events of special interest by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:47 - t-socpt-baker.R/ModAESISOC_HBwI_saf_4311.txt

55: Mild adverse events of special interest - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:21 - t-safety-baker.R/MilAESI_HAwI_saf_4311.txt

56: Mild adverse events of special interest - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:21 - t-safety-baker.R/MilAESI_HBwI_saf_4311.txt

57: Mild adverse events of special interest by preferred term- Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:47 - t-socpt-baker.R/MilAESIPT_HAwI_saf_4311.txt

58: Mild adverse events of special interest by preferred term - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:48 - t-socpt-baker.R/MilAESIPT_HBwI_saf_4311.txt

59: Mild adverse events of special interest by system organ class - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:49 - t-socpt-baker.R/MilAESISOC_HAwI_saf_4311.txt

60: Mild adverse events of special interest by system organ class - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:50 - t-socpt-baker.R/MilAESISOC_HBwI_saf_4311.txt

61: Overall Mortality - Explorer 7 - HAwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	17	0 (0.0)	9	1 (11.1)	0.16 (0.01, 4.41)	0.19 (0.01, 4.13)	-11.11 (-31.64, 9.42)	0.1733*

HAwI: Haemophilia A with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test).

nn7415/nn7415-summary/amnog_20241206_er
23JAN2025:14:43:22 - t-safety-baker.R/MORT_HAwI_saf_4311.txt

62: Overall Mortality - Explorer 7 - HBwI - on-treatment excluding initial regimen - safety analysis set

	Concizumab PPX (arm 2)		No PPX (arm 1)		Concizumab PPX (arm 2) vs. No PPX (arm 1)			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	12	2 (16.7)	10	0 (0.0)	5.00 (0.21, 117.21)	4.23 (0.23, 79.10)	16.67 (-4.42, 37.75)	0.2074*

HBwI: Haemophilia B with inhibitors, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, Low titer: Baseline inhibitor test result < 5 BU, High titer: Baseline inhibitor test results >= 5 BU, OR: Odds Ratio, RR: Relative Risk, RD: Risk Difference, CI: Confidence Interval. The relative risk, odds ratio, risk difference estimates and confidence limits were derived based on a non-parametric analysis (2x2 contingency tables) of the binary response (had an event in the in-trial observation period or not). To calculate odds ratios and relative risks in the event of zero cells, the correction value of 0.5 was added to each cell frequency of the corresponding fourfold table. P-values (two-sided) are based on Barnard's unconditional exact test if the minimum of the four cell counts in the 2x2 contingency table is <= 5 or the sum of the four cell counts is <= 200. Otherwise, Fisher's exact test is applied (*: Barnard's unconditional exact test, **: Fisher's exact test).