Dossier zur Nutzenbewertung gemäß § 35a SGB V

Concizumab (Alhemo®)

Novo Nordisk Pharma GmbH

Anhang 4-H

Routineprophylaxe von Blutungen bei Patienten ab einem Alter von 12 Jahren mit mittelschwerer / schwerer Hämophilie B (Faktor IX ≤ 2 %) ohne Faktor-IX-Hemmkörper

Analysen für das Nutzendossier

Stand: 01.10.2025

Inhaltsverzeichnis

Studie Explorer8

* Die Gesamtmortalität wurde in der Studie Explorer8 über den Studienzeitraum im Rahmen der Sicherheitsanalysen erfasst.

Studie Explorer8

Analysesets

Analyseset[a]	Beschreibung
On-treatment without data before restart (OTexBR)	Das Analyseset umfasst die jeweils relevante Teilpopulation. Aufgrund der fehlenden Abbildung der zweckmäßigen Vergleichstherapie kann dieses Analyseset jedoch nicht zur Ableitung eines Zusatznutzens herangezogen werden. Umfasst den Beobachtungszeitraum nach dem Neustart, in dem die Patienten eine Bedarfsbehandlung (Studien-Arm 1) oder Routineprophylaxe mit Concizumab entsprechend der Fachinformation (Studien-Arm 2) erhalten haben (Zeitraum nach dem Neustart). Der Beobachtungszeitraum vor dem Neustart wird ausgeschlossen (Zeitraum vor dem Neustart).
On-treatment without ancillary therapy[b] excluding data before restart (OTwoATexBR)	Wird im Rahmen der vorliegenden Nutzenbewertung zusätzlich für alle Blutungsendpunkte als Sensitivitätsanalyse in Anhang 4-H dargestellt. Umfasst den Beobachtungszeitraum nach dem Neustart, in dem die Patienten eine Bedarfsbehandlung (Studien-Arm 1) oder Routineprophylaxe mit Concizumab entsprechend der Fachinformation (Studien-Arm 2) erhalten haben (Zeitraum nach dem Neustart). **Zusätzlich** wurden Zeiträume, in denen Patienten Faktorpräparate nicht im Zusammenhang mit der Behandlung einer Blutungsepisode erhalten haben, ausgeschlossen. Der Beobachtungszeitraum vor dem Neustart wird ausgeschlossen (Zeitraum vor dem Neustart).

a. Es wurden nur Analysesets dargestellt, die die in Anhang 4-H 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, außer bei diagnostischen Verfahren, intramuskulären Injektionen und kleineren chirurgischen Eingriffen.

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2.1.1 Demographics and baseline characteristics - summary - HB - OTexBR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of patients	12	24	36
Age group (years)			
Adolescents (12-17 years)	3 (25.0)	6 (25.0)	9 (25.0)
Adults (18-64 years)	8 (66.7)	18 (75.0)	26 (72.2)
Elderly/very elderly (65-84 years)	1 (8.3)	0	1 (2.8)
Ethnicity			
Hispanic or Latino	1 (8.3)	1 (4.2)	2 (5.6)
Not Hispanic or Latino	11 (91.7)	23 (95.8)	34 (94.4)
Not Reported	0	0	0
Race			
American Indian or Alaska Native	0	0	0
Asian	6 (50.0)	10 (41.7)	16 (44.4)
Black or African American	0	1 (4.2)	1 (2.8)
Native Hawaiian or Other Pacific Islander	0	0	0
White	6 (50.0)	12 (50.0)	18 (50.0)
Not Reported	0	0	0
Other	0	1 (4.2)	1 (2.8)
Country			
Algeria	1 (8.3)	0	1 (2.8)
Australia	1 (8.3)	1 (4.2)	2 (5.6)
Croatia	0	1 (4.2)	1 (2.8)
Hungary	0	1 (4.2)	1 (2.8)
India	5 (41.7)	9 (37.5)	14 (38.9)
Italy	1 (8.3)	0	1 (2.8)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
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.
Cut off date for data is 12th July 2022.

Demographics and baseline characteristics - summary - HB - OTexBR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Malaysia	1 (8.3)	1 (4.2)	2 (5.6)
Poland	0	2 (8.3)	2 (5.6)
Russian Federation	0	3 (12.5)	3 (8.3)
South Africa	0	1 (4.2)	1 (2.8)
Switzerland	0	1 (4.2)	1 (2.8)
Spain	1 (8.3)	1 (4.2)	2 (5.6)
Turkey	1 (8.3)	3 (12.5)	4 (11.1)
United States of America	1 (8.3)	0	1 (2.8)
OECD membership			
Non-OECD country	7 (58.3)	15 (62.5)	22 (61.1)
OECD country	5 (41.7)	9 (37.5)	14 (38.9)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
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.
Cut off date for data is 12th July 2022.

2.1.2 Demographics and baseline characteristics - descriptive statistics - HB - OTexBR - full analysis set

	No PPX	Concizumab PPX	Total
	Arm 1	Arm 2	
Number of patients	12	24	36
Age(years)			
N	12	24	36
Median	25.5	25.0	25.5
P25 ; P75	18.0 ; 40.0	17.5 ; 35.0	17.5 ; 35.0
Mean (SD)	30.4 (17.5)	28.0 (12.0)	28.8 (13.9)
Min ; Max	13.0 ; 72.0	12.0 ; 57.0	12.0 ; 72.0
Height (m)			
N	11	24	35
Median	1.7	1.7	1.7
P25 ; P75	1.6 ; 1.7	1.6 ; 1.8	1.6 ; 1.8
Mean (SD)	1.6 (0.1)	1.7 (0.1)	1.7 (0.1)
Min ; Max	1.5 ; 1.8	1.5 ; 1.9	1.5 ; 1.9
Body weight (kg)			
N	12	24	36
Median	64.0	64.3	64.3
P25 ; P75	49.5 ; 80.2	52.8 ; 76.8	50.9 ; 79.0
Mean (SD)	63.3 (16.3)	67.4 (18.7)	66.0 (17.8)
Min ; Max	37.2 ; 84.0	44.8 ; 107.0	37.2 ; 107.0
BMI, (kg/m^2)			
N	11	24	35
Median	22.2	22.7	22.4
P25 ; P75	20.5 ; 25.7	19.2 ; 25.6	19.8 ; 25.7
Mean (SD)	22.4 (4.2)	22.9 (5.4)	22.7 (5.0)
Min ; Max	15.1 ; 29.4	14.8 ; 34.5	14.8 ; 34.5

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, 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.
Cut off date for data is 12th July 2022.

2.1.3 Electrocardiography (ECG) at baseline - overall interpretation - summary - HB - OTexBR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of Patients	12	24	36
ECG			
N	12	24	36
Normal	11 (91.7)	23 (95.8)	34 (94.4)
Abnormal, NCS	0	1 (4.2)	1 (2.8)
Abnormal, CS	0	0	0
Missing	1 (8.3)	0	1 (2.8)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, ECG: electrocardiography, NCS: not clinically significant, CS: clinically significant.
Baseline is defined as the latest measurement before first dose with new regimen or before randomisation for arm 1.
Cut off date for data is 12th July 2022.

2.1.4 Haemophilia details - summary - HB - OTexBR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Number of patients	12	24	36
Classification of haemophilia type			
N	12 (100.0)	24 (100.0)	36 (100.0)
Haemophilia B	12 (100.0)	24 (100.0)	36 (100.0)
Factor IX level at diagnosis			
N	8 (100.0)	16 (100.0)	24 (100.0)
< 1%	5 (62.5)	13 (81.3)	18 (75.0)
1-2%	1 (12.5)	2 (12.5)	3 (12.5)
> 2%	2 (25.0)	1 (6.3)	3 (12.5)
Family history of haemophilia			
N	12 (100.0)	24 (100.0)	36 (100.0)
Yes	4 (33.3)	13 (54.2)	17 (47.2)
No	3 (25.0)	9 (37.5)	12 (33.3)
Unknown	5 (41.7)	2 (8.3)	7 (19.4)
Family history of prothrombotic disorders			
N	12 (100.0)	24 (100.0)	36 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	6 (50.0)	14 (58.3)	20 (55.6)
Unknown	6 (50.0)	10 (41.7)	16 (44.4)
Family history of thromboembolism			
N	12 (100.0)	24 (100.0)	36 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	6 (50.0)	14 (58.3)	20 (55.6)
Unknown	6 (50.0)	10 (41.7)	16 (44.4)
Family history of inhibitors			
N	12 (100.0)	24 (100.0)	36 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	6 (50.0)	20 (83.3)	26 (72.2)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
Cut off date for data is 12th July 2022.

Haemophilia details - summary - HB - OTexBR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Total N (%)
Unknown	6 (50.0)	4 (16.7)	10 (27.8)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
Cut off date for data is 12th July 2022.

2.1.5 Haemophilia treatment and bleed history - summary - HB - OTexBR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Number of patients	12	24	36
Type of previous treatment, N (%)			
N	12 (100.0)	23 (100.0)	35 (100.0)
On demand	11 (91.7)	22 (95.7)	33 (94.3)
Prophylaxis	1 (8.3)	3 (13.0)	4 (11.4)
Time on prophylaxis, (months)			
N	0	3	3
Median		15.3	15.3
P25 ; P75		6.1 ; 168.2	6.1 ; 168.2
Mean (SD)		63.2 (91.1)	63.2 (91.1)
Min ; Max		6.1 ; 168.2	6.1 ; 168.2
Time on on demand, (months)			
N	9	20	29
Median	11.1	11.8	11.2
P25 ; P75	7.6 ; 11.8	6.8 ; 12.7	7.1 ; 12.3
Mean (SD)	28.6 (48.0)	33.8 (63.3)	32.2 (58.2)
Min ; Max	6.1 ; 153.8	1.2 ; 238.8	1.2 ; 238.8
Number of bleeding episodes during the prophylaxis treatment period			
N	1	3	4
Median	12.0	6.0	9.0
P25 ; P75	12.0 ; 12.0	2.0 ; 20.0	4.0 ; 16.0
Mean (SD)	12.0	9.3 (9.5)	10.0 (7.8)
Min ; Max	12 ; 12	2 ; 20	2 ; 20
ABR during the prophylaxis treatment period			
N	0	3	3
Median		11.8	11.8
P25 ; P75		0.1 ; 15.6	0.1 ; 15.6
Mean (SD)		9.2 (8.1)	9.2 (8.1)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, P25/P75 is the 25th/75th percentile, PPX: Prophylaxis, Min: minimum, Max: maximum, ABR: annualised bleeding rate
Patients can report both on-demand and prophylaxis prior to screening so therefore the Ns do not necessarily add up.
Cut off date for data is 12th July 2022.

Haemophilia treatment and bleed history - summary - HB - OTexBR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Min ; Max		0.1 ; 15.6	0.1 ; 15.6
Number of spontaneous bleeding episodes during the prophylaxis treatment period			
N	1	2	3
Median	12.0	6.0	10.0
P25 ; P75	12.0 ; 12.0	2.0 ; 10.0	2.0 ; 12.0
Mean (SD)	12.0	6.0 (5.7)	8.0 (5.3)
Min ; Max	12 ; 12	2 ; 10	2 ; 12
Type of factor product during the prophylaxis treatment period, N (%)			
N	1 (100.0)	3 (100.0)	4 (100.0)
BENEFIX	1 (100.0)	1 (33.3)	2 (50.0)
NONACOG ALPHA	0	1 (33.3)	1 (25.0)
RECOMBINANT FACTOR CONCENTRATE	0	1 (33.3)	1 (25.0)
Approximate number of doses to treat a bleed, during the prophylaxis treatment period			
N	1	3	4
Median	3.0	2.0	2.0
P25 ; P75	3.0 ; 3.0	1.0 ; 2.0	1.5 ; 2.5
Mean (SD)	3.0	1.7 (0.6)	2.0 (0.8)
Min ; Max	3 ; 3	1 ; 2	1 ; 3
Number of bleeding episodes during the on demand treatment period			
N	11	22	33
Median	17.0	15.0	15.0
P25 ; P75	8.0 ; 24.0	8.0 ; 23.0	8.0 ; 23.0
Mean (SD)	15.6 (9.6)	22.0 (20.7)	19.8 (17.9)
Min ; Max	2 ; 30	5 ; 90	2 ; 90
ABR during the on demand treatment period			
N	9	20	29
Median	18.4	17.3	17.6
P25 ; P75	10.7 ; 31.3	12.9 ; 37.5	12.9 ; 31.5

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, P25/P75 is the 25th/75th percentile, PPX: Prophylaxis, Min: minimum, Max: maximum, ABR: annualised bleeding rate
Patients can report both on-demand and prophylaxis prior to screening so therefore the Ns do not necessarily add up.
Cut off date for data is 12th July 2022.

Haemophilia treatment and bleed history - summary - HB - OTexBR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
Mean (SD)	19.4 (12.8)	26.0 (22.6)	23.9 (20.1)
Min ; Max	0.2 ; 33.2	0.3 ; 82.0	0.2 ; 82.0
Number of spontaneous bleeding episodes during the on demand treatment period			
N	11	21	32
Median	17.0	15.0	15.0
P25 ; P75	6.0 ; 22.0	8.0 ; 23.0	7.0 ; 22.5
Mean (SD)	14.9 (9.9)	19.2 (16.0)	17.8 (14.2)
Min ; Max	2 ; 30	2 ; 54	2 ; 54
Type of factor product during the on demand treatment period, N (%)			
N	11 (100.0)	22 (100.0)	33 (100.0)
ALPHANINE	1 (9.1)	1 (4.5)	2 (6.1)
ALPROLIX	0	3 (13.6)	3 (9.1)
ALPROLIX, BENEFIX	1 (9.1)	0	1 (3.0)
BENEFIX	3 (27.3)	1 (4.5)	4 (12.1)
FREQUENT CHANGE OF MEDICATIONS, IMMUNIN, OCTANATE	0	1 (4.5)	1 (3.0)
HAEMOSOLVEX	0	1 (4.5)	1 (3.0)
IMMUNIN	0	1 (4.5)	1 (3.0)
IMMUNINE	1 (9.1)	2 (9.1)	3 (9.1)
IMMUNINE 1200 IU/10 ML	0	1 (4.5)	1 (3.0)
IMMUNINE PLUS STIM	0	1 (4.5)	1 (3.0)
IMMUNINE, OCTANINE	0	1 (4.5)	1 (3.0)
NONACOG ALPHA	0	1 (4.5)	1 (3.0)
NOVOSEVEN	1 (9.1)	0	1 (3.0)
OCTANINE 1000 IU	0	1 (4.5)	1 (3.0)
OCTANINE F	0	1 (4.5)	1 (3.0)
PLASMA DERIVED	0	1 (4.5)	1 (3.0)
RECOMBINANT FACTOR CONCENTRATE	4 (36.4)	7 (31.8)	11 (33.3)
SEVENFACT	1 (9.1)	0	1 (3.0)
Approximate number of doses to treat a bleed, during the on demand treatment period			

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, P25/P75 is the 25th/75th percentile, PPX: Prophylaxis, Min: minimum, Max: maximum, ABR: annualised bleeding rate
Patients can report both on-demand and prophylaxis prior to screening so therefore the Ns do not necessarily add up.
Cut off date for data is 12th July 2022.

Haemophilia treatment and bleed history - summary - HB - OTexBR - full analysis set

	No PPX (arm 1)	Concizumab PPX (arm 2)	Total
N	11	22	33
Median	3.0	1.0	2.0
P25 ; P75	2.0 ; 3.0	1.0 ; 2.0	1.0 ; 3.0
Mean (SD)	4.5 (5.7)	1.6 (1.1)	2.6 (3.6)
Min ; Max	1 ; 20	1 ; 5	1 ; 20

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, P25/P75 is the 25th/75th percentile, PPX: Prophylaxis, Min: minimum, Max: maximum, ABR: annualised bleeding rate
Patients can report both on-demand and prophylaxis prior to screening so therefore the Ns do not necessarily add up.
Cut off date for data is 12th July 2022.

2.1.6 Target joints at baseline - summary - HB - OTexBR - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
Number of patients	12		24		36	
Number of patients having at least one target joint, N (%)	10 (83.3)		21 (87.5)		31 (86.1)	
Target joint location, N (%) E						
Ankle	1 (8.3)	1	9 (37.5)	10	10 (27.8)	11
Elbow	5 (41.7)	7	7 (29.2)	7	12 (33.3)	14
Hip	0		2 (8.3)	2	2 (5.6)	2
Knee	8 (66.7)	10	9 (37.5)	13	17 (47.2)	23
Body position of joint, N (%) E						
Left	8 (66.7)	10	11 (45.8)	12	19 (52.8)	22
Right	6 (50.0)	8	16 (66.7)	20	22 (61.1)	28
Number of bleeds in specified joint within 12 months						
E	18		32		50	
Median	5.0		6.0		5.5	
P25 ; P75	3.0 ; 7.0		4.0 ; 9.5		3.0 ; 9.0	
Mean (SD)	7.0 (6.9)		7.7 (5.7)		7.5 (6.1)	
Min ; Max	2.0 ; 30.0		3.0 ; 29.0		2.0 ; 30.0	
Number of bleeds in specified joint within 12 months, categorised, N (%) E						
2	1 (8.3)	2	0		1 (2.8)	2
3	4 (33.3)	5	4 (16.7)	7	8 (22.2)	12
4	1 (8.3)	1	4 (16.7)	5	5 (13.9)	6
5	2 (16.7)	2	3 (12.5)	3	5 (13.9)	5
6	2 (16.7)	2	4 (16.7)	4	6 (16.7)	6
7	2 (16.7)	2	0		2 (5.6)	2
8	0		2 (8.3)	2	2 (5.6)	2
9	1 (8.3)	1	3 (12.5)	3	4 (11.1)	4

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, E: number of target joints, P25/P75 is the 25th/75th percentile, SD: standard deviation, 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.
Cut off date for data is 12th July 2022.

Target joints at baseline - summary - HB - OTexBR - full analysis set

	No PPX (arm 1)		Concizumab PPX (arm 2)		Total	
10	0		2 (8.3)	2	2 (5.6)	2
11	1 (8.3)	1	1 (4.2)	1	2 (5.6)	2
13	0		1 (4.2)	1	1 (2.8)	1
17	1 (8.3)	1	1 (4.2)	3	2 (5.6)	4
29	0		1 (4.2)	1	1 (2.8)	1
30	1 (8.3)	1	0		1 (2.8)	1

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients, E: number of target joints, P25/P75 is the 25th/75th percentile, SD: standard deviation, 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.
Cut off date for data is 12th July 2022.

2.1.7 Target joints at baseline and bleeding in the last 24 weeks before study entry - HB - OTexBR - full analysis set

	No PPX (arm 1) N (%)	Concizumab PPX (arm 2) N (%)	Totals N (%)
Number of patients	12	24	36
Target joints at baseline			
Patients with zero target joints, N (%)	2 (16.7)	3 (12.5)	5 (13.9)
Patients with one target joint, N (%)	6 (50.0)	15 (62.5)	21 (58.3)
Patients with > 1 target joints, N (%)	4 (33.3)	6 (25.0)	10 (27.8)
Bleeding episodes in the last 24 weeks before study entry			
< 9 bleeding episodes, N (%)	5 (41.7)	10 (41.7)	15 (41.7)
>= 9 bleeding episodes, N (%)	7 (58.3)	14 (58.3)	21 (58.3)

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
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.
Cut off date for data is 12th July 2022.

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

	No PPX	Concizumab PPX
	Arm 1 N (%)	Arm 2 N (%)
Number of patients	12	24
1. Overall, which treatment do you prefer?		
Current treatment	4 (33.3)	17 (70.8)
Previous treatment	0	0
No preference	4 (33.3)	0
Missing	4 (33.3)	7 (29.2)
For patients preferring current treatment:		
N preferring current treatment	4 (100)	17 (100)
2. How strong is this treatment preference (indicated in question 1)?		
Very strong	2 (50.0)	8 (47.1)
Fairly strong	1 (25.0)	9 (52.9)
Not very strong	1 (25.0)	0
3. What are the TWO main reasons for this treatment preference?		
Easier to remember to inject	3 (75.0)	7 (41.2)
Feels less emotionally distressing	2 (50.0)	4 (23.5)
Less painful to inject	3 (75.0)	6 (35.3)
How often do you have to inject	0	0
Fewer bleeds	1 (25.0)	6 (35.3)
Require less time	2 (50.0)	9 (52.9)
Other reason	0	1 (5.9)
For patients preferring previous treatment:		
N preferring previous treatment	0	0
2. How strong is this treatment preference (indicated in question 1)?		

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
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.
Cut off date for data is 12th July 2022.

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

	No PPX	Concizumab PPX
	Arm 1 N (%)	Arm 2 N (%)
Very strong	0	0
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	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

HB: haemophilia B, OTexBR: On-treatment without data before restart.
PPX: Prophylaxis, N: number of patients, %: percentage of patients.
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.
Cut off date for data is 12th July 2022.

2.1.9 Observation time in weeks - descriptive statistics - HB - safety analysis set

	Arm 1 - No PPX	Arm 2 - Concizumab PPX
Patient weeks of observation / exposure		
ADS: On-treatment excluding data before restart (OTexBR)		
For safety endpoints/assessments relating to events [a][b]		
N	12	24
Median	24.1	32.3
P25 ; P75	24.0 ; 25.5	32.0 ; 44.4
Mean (SD)	26.3 (5.8)	39.7 (16.7)
Min ; Max	23.6 ; 44.1	3.9 ; 80.3
For all other endpoint/assessments [c]		
N	12	24
Median	24.1	32.3
P25 ; P75	24.0 ; 25.5	32.0 ; 44.4
Mean (SD)	26.3 (5.8)	39.7 (16.8)
Min ; Max	23.6 ; 44.1	2.6 ; 80.3

HB: haemophilia B.
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 observation time in main phase (no PPX).
[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.

Cut off date for data is 12th July 2022.

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2.2.1 Treated spontaneous and traumatic bleeding episodes - Explorer 8 - HB - OTwoATexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	3.10 [1.91 , 5.04]	12	12	14.78 [8.14 , 26.86]	0.21 [0.10 , 0.45]	0.0001	
							NA [NA , Inf]		
Age									
< 18 years	6	6	2.30 [0.87 , 6.10]	3	3	25.05 [8.02 , 78.25]	0.09 [0.02 , 0.43]	0.0023	0.4374
							NA [NA , Inf]		
>= 18 years	18	18	3.30 [1.93 , 5.66]	9	9	11.09 [5.43 , 22.67]	0.30 [0.12 , 0.72]	0.0074	
							NA [NA , Inf]		
Region									
Non-OECD country	15	15	4.18 [2.38 , 7.36]	7	7	12.22 [5.81 , 25.73]	0.34 [0.14 , 0.84]	0.0193	0.1124
							NA [NA , Inf]		
OECD country	9	9	1.44 [0.60 , 3.46]	5	5	19.29 [8.45 , 44.02]	0.07 [0.02 , 0.25]	< 0.0001	
							NA [NA , Inf]		

ABR: Annualized bleeding rate, HB: Haemophilia B, OTwoATexBR = On-treatment without ancillary therapy excluding data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.2 Treated spontaneous bleeding episodes - Explorer 8 - HB - OTwoATexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	1.76 [1.02 , 3.03]	12	12	10.45 [5.66 , 19.27]	0.17 [0.08 , 0.37] NA [NA , Inf]	< 0.0001	
Age									
< 18 years	6	6	1.26 [0.42 , 3.77]	3	3	15.32 [4.63 , 50.62]	0.08 [0.02 , 0.43] NA [NA , Inf]	0.0032	0.6242
>= 18 years	18	18	1.88 [1.03 , 3.43]	9	9	8.79 [4.29 , 17.99]	0.21 [0.09 , 0.52] NA [NA , Inf]	0.0008	
Region									
Non-OECD country	15	15	2.52 [1.37 , 4.60]	7	7	9.95 [4.81 , 20.60]	0.25 [0.10 , 0.63] NA [NA , Inf]	0.0030	0.0841
OECD country	9	9	0.63 [0.21 , 1.85]	5	5	11.90 [5.15 , 27.52]	0.05 [0.01 , 0.21] NA [NA , Inf]	< 0.0001	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTwoATexBR = On-treatment without ancillary therapy excluding data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.3 Treated spontaneous and traumatic joint bleeds - Explorer 8 - HB - OTwoATexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	2.61 [1.50 , 4.55]	12	12	12.55 [6.29 , 25.04]	0.21 [0.09 , 0.50] NA [NA , Inf]	0.0004	
Age									
< 18 years	6	6	1.13 [0.34 , 3.75]	3	3	22.85 [6.24 , 83.68]	0.05 [0.01 , 0.31] NA [NA , Inf]	0.0013	0.2167
>= 18 years	18	18	3.04 [1.68 , 5.52]	9	9	8.89 [3.96 , 19.95]	0.34 [0.13 , 0.93] NA [NA , Inf]	0.0350	
Region									
Non-OECD country	15	15	3.55 [1.84 , 6.86]	7	7	11.05 [4.62 , 26.48]	0.32 [0.11 , 0.92] NA [NA , Inf]	0.0342	0.2010
OECD country	9	9	1.18 [0.43 , 3.24]	5	5	15.39 [5.78 , 41.03]	0.08 [0.02 , 0.31] NA [NA , Inf]	0.0004	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTwoATexBR = On-treatment without ancillary therapy excluding data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.4 Treated spontaneous and traumatic target joint bleeds - Explorer 8 - HB - OTwoATexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	1.44 [0.70 , 2.92]	12	12	3.91 [1.52 , 10.05]	0.37 [0.12 , 1.16]	0.0882	
							NA [NA , Inf]		
Age									
< 18 years	6	6	0.21 [0.03 , 1.31]	3	3	2.29 [0.40 , 12.95]	0.09 [0.01 , 1.08]	0.0575	0.0779
							NA [NA , Inf]		
>= 18 years	18	18	1.90 [0.92 , 3.92]	9	9	4.08 [1.57 , 10.62]	0.46 [0.14 , 1.53]	0.2079	
							NA [NA , Inf]		
Region									
Non-OECD country	15	15	2.03 [0.92 , 4.50]	7	7	3.76 [1.25 , 11.30]	0.54 [0.14 , 2.02]	0.3597	0.2091
							NA [NA , Inf]		
OECD country	9	9	0.44 [0.10 , 1.92]	5	5	4.78 [1.31 , 17.39]	0.09 [0.01 , 0.66]	0.0173	
							NA [NA , Inf]		

ABR: Annualized bleeding rate, HB: Haemophilia B, OTwoATexBR = On-treatment without ancillary therapy excluding data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.5 Treated spontaneous and traumatic bleeding episodes - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	3.10 [1.91 , 5.03]	12	12	14.78 [8.14 , 26.86]	0.21 [0.10 , 0.45] NA [NA , Inf]	0.0001	
Age									
< 18 years	6	6	2.30 [0.87 , 6.10]	3	3	25.05 [8.02 , 78.26]	0.09 [0.02 , 0.43] NA [NA , Inf]	0.0023	0.4374
>= 18 years	18	18	3.30 [1.93 , 5.65]	9	9	11.09 [5.43 , 22.67]	0.30 [0.12 , 0.72] NA [NA , Inf]	0.0074	
Region									
Non-OECD country	15	15	4.18 [2.38 , 7.36]	7	7	12.22 [5.81 , 25.73]	0.34 [0.14 , 0.84] NA [NA , Inf]	0.0193	0.1122
OECD country	9	9	1.44 [0.60 , 3.46]	5	5	19.29 [8.45 , 44.02]	0.07 [0.02 , 0.25] NA [NA , Inf]	< 0.0001	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTexBR = On-treatment without data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.6 Treated spontaneous bleeding episodes - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	1.76 [1.02 , 3.03]	12	12	10.45 [5.66 , 19.27]	0.17 [0.08 , 0.37] NA [NA , Inf]	< 0.0001	
Age									
< 18 years	6	6	1.26 [0.42 , 3.77]	3	3	15.32 [4.63 , 50.62]	0.08 [0.02 , 0.43] NA [NA , Inf]	0.0032	0.6241
>= 18 years	18	18	1.88 [1.03 , 3.43]	9	9	8.78 [4.29 , 17.99]	0.21 [0.09 , 0.52] NA [NA , Inf]	0.0008	
Region									
Non-OECD country	15	15	2.52 [1.37 , 4.60]	7	7	9.95 [4.81 , 20.60]	0.25 [0.10 , 0.63] NA [NA , Inf]	0.0030	0.0838
OECD country	9	9	0.62 [0.21 , 1.84]	5	5	11.90 [5.15 , 27.52]	0.05 [0.01 , 0.21] NA [NA , Inf]	< 0.0001	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTexBR = On-treatment without data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.7 Treated spontaneous and traumatic joint bleeds - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	2.61 [1.50 , 4.55]	12	12	12.55 [6.29 , 25.04]	0.21 [0.09 , 0.50] NA [NA , Inf]	0.0004	
Age									
< 18 years	6	6	1.13 [0.34 , 3.75]	3	3	22.85 [6.24 , 83.70]	0.05 [0.01 , 0.31] NA [NA , Inf]	0.0013	0.2167
>= 18 years	18	18	3.04 [1.68 , 5.52]	9	9	8.89 [3.96 , 19.95]	0.34 [0.13 , 0.93] NA [NA , Inf]	0.0350	
Region									
Non-OECD country	15	15	3.55 [1.84 , 6.86]	7	7	11.05 [4.62 , 26.48]	0.32 [0.11 , 0.92] NA [NA , Inf]	0.0342	0.2009
OECD country	9	9	1.18 [0.43 , 3.24]	5	5	15.39 [5.78 , 41.03]	0.08 [0.02 , 0.31] NA [NA , Inf]	0.0004	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTexBR = On-treatment without data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.8 Treated spontaneous and traumatic target joint bleeds - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	1.44 [0.70 , 2.92]	12	12	3.91 [1.52 , 10.05]	0.37 [0.12 , 1.16] NA [NA , Inf]	0.0883	
Age									
< 18 years	6	6	0.21 [0.03 , 1.31]	3	3	2.29 [0.40 , 12.95]	0.09 [0.01 , 1.08] NA [NA , Inf]	0.0575	0.0779
>= 18 years	18	18	1.90 [0.92 , 3.92]	9	9	4.08 [1.57 , 10.62]	0.46 [0.14 , 1.53] NA [NA , Inf]	0.2079	
Region									
Non-OECD country	15	15	2.03 [0.92 , 4.50]	7	7	3.76 [1.25 , 11.30]	0.54 [0.14 , 2.02] NA [NA , Inf]	0.3597	0.2090
OECD country	9	9	0.44 [0.10 , 1.92]	5	5	4.78 [1.31 , 17.39]	0.09 [0.01 , 0.66] NA [NA , Inf]	0.0173	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTexBR = On-treatment without data before restart, PPX: Prophylaxis, 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. Cut off date for data is 12th July 2022.

2.2.9 All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 8 - HB - OTwoATexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	3.98 [2.58 , 6.13]	12	12	19.32 [11.31 , 32.99]	0.21 [0.10 , 0.41] NA [NA , Inf]	< 0.0001	
Age									
< 18 years	6	6	2.73 [1.17 , 6.38]	3	3	35.62 [13.90 , 91.28]	0.08 [0.02 , 0.27] NA [NA , Inf]	0.0001	0.1643
>= 18 years	18	18	4.35 [2.74 , 6.90]	9	9	13.53 [7.48 , 24.47]	0.32 [0.15 , 0.68] NA [NA , Inf]	0.0029	
Region									
Non-OECD country	15	15	4.98 [3.05 , 8.12]	7	7	12.13 [6.31 , 23.30]	0.41 [0.19 , 0.91] NA [NA , Inf]	0.0274	0.0547
OECD country	9	9	2.34 [1.14 , 4.79]	5	5	29.89 [14.78 , 60.43]	0.08 [0.03 , 0.21] NA [NA , Inf]	< 0.0001	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTwoATexBR = On-treatment without ancillary therapy excluding data before restart, PPX: Prophylaxis, 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.

2.2.10 All treated and untreated spontaneous and traumatic bleeding episodes - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab 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.
All subjects	24	24	3.98 [2.58 , 6.13]	12	12	19.32 [11.31 , 32.99]	0.21 [0.10 , 0.41] NA [NA , Inf]	< 0.0001	
Age									
< 18 years	6	6	2.73 [1.17 , 6.38]	3	3	35.62 [13.90 , 91.29]	0.08 [0.02 , 0.27] NA [NA , Inf]	0.0001	0.1644
>= 18 years	18	18	4.35 [2.74 , 6.90]	9	9	13.53 [7.48 , 24.47]	0.32 [0.15 , 0.68] NA [NA , Inf]	0.0029	
Region									
Non-OECD country	15	15	4.98 [3.05 , 8.12]	7	7	12.13 [6.31 , 23.30]	0.41 [0.19 , 0.91] NA [NA , Inf]	0.0274	0.0546
OECD country	9	9	2.33 [1.14 , 4.78]	5	5	29.89 [14.78 , 60.43]	0.08 [0.03 , 0.21] NA [NA , Inf]	< 0.0001	

ABR: Annualized bleeding rate, HB: Haemophilia B, OTexBR = On-treatment without data before restart, PPX: Prophylaxis, 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.

2.2.11 Zero treated spontaneous and traumatic bleeding episodes - Explorer 8 - HB - OTwoATexBR - Full analysis set

	Concizumab 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.
All subjects	24	10	0.69 [0.30 , 1.58]	12	1	0.09 [0.01 , 0.69]	7.94 [0.87 , 72.14]	0.0658	NA
Age									
< 18 years	6	3		3	0		NA [NA , NA]		NA
>= 18 years	18	7		9	1		NA [NA , NA]		NA
Region									
Non-OECD country	15	5		7	1		NA [NA , NA]		NA
OECD country	9	5		5	0		NA [NA , NA]		NA

HB: Haemophilia B, PPX: Prophylaxis,, 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). Cut off date for data is 12th July 2022.

2.2.12 Zero treated spontaneous and traumatic bleeding episodes - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab 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.
All subjects	24	10	0.69 [0.30 , 1.58]	12	1	0.09 [0.01 , 0.69]	7.94 [0.87 , 72.14]	0.0658	NA
Age									
< 18 years	6	3		3	0		NA [NA , NA]		NA
>= 18 years	18	7		9	1		NA [NA , NA]		NA
Region									
Non-OECD country	15	5		7	1		NA [NA , NA]		NA
OECD country	9	5		5	0		NA [NA , NA]		NA

HB: Haemophilia B, PPX: Prophylaxis,, 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). Cut off date for data is 12th July 2022.

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2.3.2.1 Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	37.50 (8.33)	24	11	33.33 (25.55)
Week 4	12	2	20.83 (29.46)	23	10	30.83 (24.86)
Week 8	12	2	33.33 (11.79)	23	10	18.33 (15.61)
Week 16	12	3	22.22 (25.46)	23	9	17.59 (18.84)
Week 24	12	3	44.44 (29.27)	23	7	20.24 (12.60)
Week 32				23	6	34.72 (22.62)
Age						
< 18 years						
Baseline				6	1	16.67 (NA)
Week 4				6	1	25.00 (NA)
Week 8				6	1	25.00 (NA)
Week 16				6	1	25.00 (NA)
Week 24				6	1	25.00 (NA)
Week 32				6	1	50.00 (NA)
>= 18 years						
Baseline	9	4	37.50 (8.33)	18	10	35.00 (26.29)
Week 4	9	2	20.83 (29.46)	17	9	31.48 (26.28)
Week 8	9	2	33.33 (11.79)	17	9	17.59 (16.37)
Week 16	9	3	22.22 (25.46)	17	8	16.67 (19.92)
Week 24	9	3	44.44 (29.27)	17	6	19.44 (13.61)
Week 32				17	5	31.67 (23.86)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	33.33 (NA)	15	5	48.33 (33.02)
Week 4	7	1	0.00 (NA)	14	5	45.00 (28.63)
Week 8	7	1	25.00 (NA)	14	4	27.08 (7.98)
Week 16	7	1	0.00 (NA)	14	4	33.33 (13.61)
Week 24	7	1	75.00 (NA)	14	4	27.08 (7.98)
Week 32				14	4	39.58 (18.48)
OECD country						
Baseline	5	3	38.89 (9.62)	9	6	20.83 (4.56)
Week 4	5	1	41.67 (NA)	9	5	16.67 (8.33)
Week 8	5	1	41.67 (NA)	9	6	12.50 (17.28)
Week 16	5	2	33.33 (23.57)	9	5	5.00 (11.18)
Week 24	5	2	29.17 (17.68)	9	3	11.11 (12.73)
Week 32				9	2	25.00 (35.36)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.2 Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	28.12 (28.18)	24	11	24.43 (22.96)
Week 4	12	2	9.38 (13.26)	23	10	20.00 (18.82)
Week 8	12	2	9.38 (13.26)	23	10	11.25 (12.43)
Week 16	12	3	29.17 (35.54)	23	9	16.67 (19.76)
Week 24	12	3	29.17 (40.18)	23	7	16.07 (14.37)
Week 32				23	6	21.88 (25.85)
Age						
< 18 years						
Baseline				6	1	25.00 (NA)
Week 4				6	1	25.00 (NA)
Week 8				6	1	18.75 (NA)
Week 16				6	1	25.00 (NA)
Week 24				6	1	31.25 (NA)
Week 32				6	1	12.50 (NA)
>= 18 years						
Baseline	9	4	28.12 (28.18)	18	10	24.38 (24.20)
Week 4	9	2	9.38 (13.26)	17	9	19.44 (19.87)
Week 8	9	2	9.38 (13.26)	17	9	10.42 (12.88)
Week 16	9	3	29.17 (35.54)	17	8	15.62 (20.86)
Week 24	9	3	29.17 (40.18)	17	6	13.54 (13.93)
Week 32				17	5	23.75 (28.44)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	6.25 (NA)	15	5	36.25 (24.37)
Week 4	7	1	0.00 (NA)	14	5	27.50 (23.63)
Week 8	7	1	0.00 (NA)	14	4	18.75 (15.31)
Week 16	7	1	0.00 (NA)	14	4	28.12 (24.21)
Week 24	7	1	0.00 (NA)	14	4	17.19 (15.62)
Week 32				14	4	29.69 (29.04)
OECD country						
Baseline	5	3	35.42 (29.54)	9	6	14.58 (17.97)
Week 4	5	1	18.75 (NA)	9	5	12.50 (9.88)
Week 8	5	1	18.75 (NA)	9	6	6.25 (7.91)
Week 16	5	2	43.75 (35.36)	9	5	7.50 (10.27)
Week 24	5	2	43.75 (44.19)	9	3	14.58 (15.73)
Week 32				9	2	6.25 (8.84)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.3 Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	27.50 (35.00)	24	11	37.73 (22.51)
Week 4	12	2	7.50 (10.61)	23	10	30.00 (20.55)
Week 8	12	2	15.00 (0.00)	23	10	23.50 (12.92)
Week 16	12	3	35.00 (35.00)	23	9	31.67 (17.68)
Week 24	12	3	40.00 (43.30)	23	7	28.57 (21.16)
Week 32				23	6	25.00 (22.80)
Age						
< 18 years						
Baseline				6	1	20.00 (NA)
Week 4				6	1	15.00 (NA)
Week 8				6	1	15.00 (NA)
Week 16				6	1	25.00 (NA)
Week 24				6	1	15.00 (NA)
Week 32				6	1	15.00 (NA)
>= 18 years						
Baseline	9	4	27.50 (35.00)	18	10	39.50 (22.91)
Week 4	9	2	7.50 (10.61)	17	9	31.67 (21.07)
Week 8	9	2	15.00 (0.00)	17	9	24.44 (13.33)
Week 16	9	3	35.00 (35.00)	17	8	32.50 (18.71)
Week 24	9	3	40.00 (43.30)	17	6	30.83 (22.23)
Week 32				17	5	27.00 (24.90)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	10.00 (NA)	15	5	44.00 (21.62)
Week 4	7	1	0.00 (NA)	14	5	39.00 (23.56)
Week 8	7	1	15.00 (NA)	14	4	31.25 (11.81)
Week 16	7	1	10.00 (NA)	14	4	45.00 (16.83)
Week 24	7	1	15.00 (NA)	14	4	37.50 (24.66)
Week 32				14	4	32.50 (25.00)
OECD country						
Baseline	5	3	33.33 (40.41)	9	6	32.50 (23.82)
Week 4	5	1	15.00 (NA)	9	5	21.00 (13.87)
Week 8	5	1	15.00 (NA)	9	6	18.33 (11.69)
Week 16	5	2	47.50 (38.89)	9	5	21.00 (9.62)
Week 24	5	2	52.50 (53.03)	9	3	16.67 (7.64)
Week 32				9	2	10.00 (7.07)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.4 Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	2.08 (4.17)	24	11	18.94 (33.35)
Week 4	12	2	0.00 (0.00)	23	10	25.83 (40.15)
Week 8	12	2	0.00 (0.00)	23	10	16.67 (31.67)
Week 16	12	3	11.11 (19.25)	23	9	9.26 (12.80)
Week 24	12	3	22.22 (38.49)	23	7	13.10 (19.16)
Week 32				23	6	8.33 (10.54)
Age						
< 18 years						
Baseline				6	1	0.00 (NA)
Week 4				6	1	0.00 (NA)
Week 8				6	1	0.00 (NA)
Week 16				6	1	0.00 (NA)
Week 24				6	1	0.00 (NA)
Week 32				6	1	0.00 (NA)
>= 18 years						
Baseline	9	4	2.08 (4.17)	18	10	20.83 (34.53)
Week 4	9	2	0.00 (0.00)	17	9	28.70 (41.48)
Week 8	9	2	0.00 (0.00)	17	9	18.52 (33.01)
Week 16	9	3	11.11 (19.25)	17	8	10.42 (13.18)
Week 24	9	3	22.22 (38.49)	17	6	15.28 (20.01)
Week 32				17	5	10.00 (10.87)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	0.00 (NA)	15	5	41.67 (39.97)
Week 4	7	1	0.00 (NA)	14	5	48.33 (48.02)
Week 8	7	1	0.00 (NA)	14	4	39.58 (42.70)
Week 16	7	1	0.00 (NA)	14	4	18.75 (14.23)
Week 24	7	1	0.00 (NA)	14	4	22.92 (20.83)
Week 32				14	4	12.50 (10.76)
OECD country						
Baseline	5	3	2.78 (4.81)	9	6	0.00 (0.00)
Week 4	5	1	0.00 (NA)	9	5	3.33 (7.45)
Week 8	5	1	0.00 (NA)	9	6	1.39 (3.40)
Week 16	5	2	16.67 (23.57)	9	5	1.67 (3.73)
Week 24	5	2	33.33 (47.14)	9	3	0.00 (0.00)
Week 32				9	2	0.00 (0.00)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.5 Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	45.00 (33.17)	24	11	57.73 (25.14)
Week 4	12	2	20.00 (21.21)	23	10	35.00 (34.40)
Week 8	12	2	17.50 (24.75)	23	10	28.00 (26.06)
Week 16	12	3	33.33 (38.19)	23	9	31.11 (27.47)
Week 24	12	3	45.00 (47.70)	23	7	32.86 (28.41)
Week 32				23	6	33.33 (22.51)
Age						
< 18 years						
Baseline				6	1	90.00 (NA)
Week 4				6	1	90.00 (NA)
Week 8				6	1	90.00 (NA)
Week 16				6	1	95.00 (NA)
Week 24				6	1	85.00 (NA)
Week 32				6	1	55.00 (NA)
>= 18 years						
Baseline	9	4	45.00 (33.17)	18	10	54.50 (23.97)
Week 4	9	2	20.00 (21.21)	17	9	28.89 (30.18)
Week 8	9	2	17.50 (24.75)	17	9	21.11 (15.16)
Week 16	9	3	33.33 (38.19)	17	8	23.12 (14.38)
Week 24	9	3	45.00 (47.70)	17	6	24.17 (18.28)
Week 32				17	5	29.00 (22.19)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	20.00 (NA)	15	5	67.00 (21.68)
Week 4	7	1	5.00 (NA)	14	5	40.00 (37.25)
Week 8	7	1	0.00 (NA)	14	4	28.75 (18.43)
Week 16	7	1	0.00 (NA)	14	4	32.50 (15.55)
Week 24	7	1	0.00 (NA)	14	4	26.25 (22.87)
Week 32				14	4	33.75 (22.50)
OECD country						
Baseline	5	3	53.33 (35.12)	9	6	50.00 (27.02)
Week 4	5	1	35.00 (NA)	9	5	30.00 (34.82)
Week 8	5	1	35.00 (NA)	9	6	27.50 (31.90)
Week 16	5	2	50.00 (35.36)	9	5	30.00 (36.40)
Week 24	5	2	67.50 (38.89)	9	3	41.67 (37.86)
Week 32				9	2	32.50 (31.82)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.6 Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	3	40.00 (39.05)	24	9	58.33 (21.21)
Week 4	12	2	15.00 (7.07)	23	7	46.07 (28.79)
Week 8	12	2	17.50 (10.61)	23	8	47.08 (28.27)
Week 16	12	3	43.33 (28.43)	23	8	42.03 (29.64)
Week 24	12	3	54.58 (37.09)	23	6	52.50 (31.10)
Week 32				23	6	56.11 (24.51)
Age						
< 18 years						
Week 32				6	1	60.00 (NA)
>= 18 years						
Baseline	9	3	40.00 (39.05)	18	9	58.33 (21.21)
Week 4	9	2	15.00 (7.07)	17	7	46.07 (28.79)
Week 8	9	2	17.50 (10.61)	17	8	47.08 (28.27)
Week 16	9	3	43.33 (28.43)	17	8	42.03 (29.64)
Week 24	9	3	54.58 (37.09)	17	6	52.50 (31.10)
Week 32				17	5	55.33 (27.32)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	20.00 (NA)	15	4	71.25 (17.02)
Week 4	7	1	20.00 (NA)	14	3	65.83 (24.02)
Week 8	7	1	25.00 (NA)	14	4	66.25 (21.36)
Week 16	7	1	20.00 (NA)	14	4	66.25 (17.97)
Week 24	7	1	20.00 (NA)	14	4	67.50 (25.98)
Week 32				14	4	65.42 (17.81)
OECD country						
Baseline	5	2	50.00 (49.50)	9	5	48.00 (19.56)
Week 4	5	1	10.00 (NA)	9	4	31.25 (24.28)
Week 8	5	1	10.00 (NA)	9	4	27.92 (20.70)
Week 16	5	2	55.00 (28.28)	9	4	17.81 (12.76)
Week 24	5	2	71.88 (30.94)	9	2	22.50 (10.61)
Week 32				9	2	37.50 (31.82)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.7 Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	32.15 (22.51)	24	11	37.02 (18.27)
Week 4	12	2	14.50 (7.93)	23	10	30.31 (18.68)
Week 8	12	2	13.86 (8.84)	23	10	23.39 (12.31)
Week 16	12	3	29.19 (24.68)	23	9	25.27 (15.34)
Week 24	12	3	36.91 (31.23)	23	7	28.22 (14.02)
Week 32				23	6	29.20 (16.83)
Age						
< 18 years						
Baseline				6	1	36.59 (NA)
Week 4				6	1	32.56 (NA)
Week 8				6	1	32.93 (NA)
Week 16				6	1	33.93 (NA)
Week 24				6	1	30.81 (NA)
Week 32				6	1	29.35 (NA)
>= 18 years						
Baseline	9	4	32.15 (22.51)	18	10	37.07 (19.26)
Week 4	9	2	14.50 (7.93)	17	9	30.07 (19.79)
Week 8	9	2	13.86 (8.84)	17	9	22.33 (12.56)
Week 16	9	3	29.19 (24.68)	17	8	24.19 (16.03)
Week 24	9	3	36.91 (31.23)	17	6	27.79 (15.30)
Week 32				17	5	29.17 (18.82)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	13.33 (NA)	15	5	48.85 (18.87)
Week 4	7	1	8.89 (NA)	14	5	40.53 (20.86)
Week 8	7	1	7.61 (NA)	14	4	34.26 (3.52)
Week 16	7	1	8.70 (NA)	14	4	37.77 (9.46)
Week 24	7	1	9.78 (NA)	14	4	34.61 (14.02)
Week 32				14	4	33.88 (18.01)
OECD country						
Baseline	5	3	38.43 (22.89)	9	6	27.17 (11.24)
Week 4	5	1	20.11 (NA)	9	5	20.10 (9.44)
Week 8	5	1	20.11 (NA)	9	6	16.14 (10.38)
Week 16	5	2	39.43 (24.25)	9	5	15.27 (11.06)
Week 24	5	2	50.47 (29.11)	9	3	19.69 (10.17)
Week 32				9	2	19.84 (13.45)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.8 Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	28.91 (14.52)	24	11	40.06 (21.78)
Week 4	12	2	23.44 (19.89)	23	10	32.81 (16.35)
Week 8	12	2	18.75 (26.52)	23	10	25.62 (17.23)
Week 16	12	3	27.08 (14.09)	23	9	28.82 (22.03)
Week 24	12	3	32.29 (28.36)	23	7	32.14 (17.93)
Week 32				23	6	31.77 (22.74)
Age						
< 18 years						
Baseline				6	1	43.75 (NA)
Week 4				6	1	31.25 (NA)
Week 8				6	1	28.12 (NA)
Week 16				6	1	28.12 (NA)
Week 24				6	1	28.12 (NA)
Week 32				6	1	31.25 (NA)
>= 18 years						
Baseline	9	4	28.91 (14.52)	18	10	39.69 (22.92)
Week 4	9	2	23.44 (19.89)	17	9	32.99 (17.34)
Week 8	9	2	18.75 (26.52)	17	9	25.35 (18.25)
Week 16	9	3	27.08 (14.09)	17	8	28.91 (23.55)
Week 24	9	3	32.29 (28.36)	17	6	32.81 (19.54)
Week 32				17	5	31.88 (25.43)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	15.62 (NA)	15	5	53.75 (21.13)
Week 4	7	1	9.38 (NA)	14	5	38.12 (16.89)
Week 8	7	1	0.00 (NA)	14	4	39.06 (13.86)
Week 16	7	1	12.50 (NA)	14	4	45.31 (18.49)
Week 24	7	1	0.00 (NA)	14	4	35.16 (24.26)
Week 32				14	4	33.59 (29.02)
OECD country						
Baseline	5	3	33.33 (14.09)	9	6	28.65 (15.74)
Week 4	5	1	37.50 (NA)	9	5	27.50 (15.69)
Week 8	5	1	37.50 (NA)	9	6	16.67 (13.36)
Week 16	5	2	34.38 (8.84)	9	5	15.62 (14.99)
Week 24	5	2	48.44 (6.63)	9	3	28.12 (6.25)
Week 32				9	2	28.12 (4.42)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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 32.1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.9 Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	4	44.69 (22.74)	24	11	40.91 (20.10)
Week 4	12	2	32.50 (10.61)	23	10	34.50 (19.92)
Week 8	12	2	20.00 (7.07)	23	10	30.50 (18.92)
Week 16	12	3	43.33 (23.09)	23	9	32.22 (17.87)
Week 24	12	3	41.67 (32.53)	23	7	35.71 (19.24)
Week 32				23	6	34.17 (12.42)
Age						
< 18 years						
Baseline				6	1	55.00 (NA)
Week 4				6	1	30.00 (NA)
Week 8				6	1	45.00 (NA)
Week 16				6	1	35.00 (NA)
Week 24				6	1	30.00 (NA)
Week 32				6	1	30.00 (NA)
>= 18 years						
Baseline	9	4	44.69 (22.74)	18	10	39.50 (20.61)
Week 4	9	2	32.50 (10.61)	17	9	35.00 (21.07)
Week 8	9	2	20.00 (7.07)	17	9	28.89 (19.33)
Week 16	9	3	43.33 (23.09)	17	8	31.88 (19.07)
Week 24	9	3	41.67 (32.53)	17	6	36.67 (20.90)
Week 32				17	5	35.00 (13.69)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	20.00 (NA)	15	5	52.00 (20.19)
Week 4	7	1	40.00 (NA)	14	5	49.00 (14.75)
Week 8	7	1	15.00 (NA)	14	4	40.00 (16.83)
Week 16	7	1	30.00 (NA)	14	4	45.00 (17.80)
Week 24	7	1	10.00 (NA)	14	4	47.50 (15.55)
Week 32				14	4	38.75 (12.50)
OECD country						
Baseline	5	3	52.92 (19.22)	9	6	31.67 (16.02)
Week 4	5	1	25.00 (NA)	9	5	20.00 (12.25)
Week 8	5	1	25.00 (NA)	9	6	24.17 (18.82)
Week 16	5	2	50.00 (28.28)	9	5	22.00 (10.37)
Week 24	5	2	57.50 (24.75)	9	3	20.00 (10.00)
Week 32				9	2	25.00 (7.07)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.10 Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	3	18.75 (27.24)	24	10	20.62 (21.66)
Week 4	12	2	0.00 (0.00)	23	8	17.97 (20.98)
Week 8	12	2	0.00 (0.00)	23	10	17.50 (17.87)
Week 16	12	2	3.12 (4.42)	23	9	13.19 (20.60)
Week 24	12	2	15.62 (22.10)	23	7	21.43 (19.72)
Week 32				23	6	25.00 (22.01)
Age						
< 18 years						
Baseline				6	1	43.75 (NA)
Week 4				6	1	56.25 (NA)
Week 8				6	1	56.25 (NA)
Week 16				6	1	56.25 (NA)
Week 24				6	1	50.00 (NA)
Week 32				6	1	25.00 (NA)
>= 18 years						
Baseline	9	3	18.75 (27.24)	18	9	18.06 (21.30)
Week 4	9	2	0.00 (0.00)	17	7	12.50 (15.31)
Week 8	9	2	0.00 (0.00)	17	9	13.19 (12.28)
Week 16	9	2	3.12 (4.42)	17	8	7.81 (13.67)
Week 24	9	2	15.62 (22.10)	17	6	16.67 (16.61)
Week 32				17	5	25.00 (24.61)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	0.00 (NA)	15	4	21.88 (27.24)
Week 4	7	1	0.00 (NA)	14	3	20.83 (21.95)
Week 8	7	1	0.00 (NA)	14	4	21.88 (10.83)
Week 16	7	1	0.00 (NA)	14	4	14.06 (17.95)
Week 24	7	1	0.00 (NA)	14	4	23.44 (16.44)
Week 32				14	4	29.69 (25.71)
OECD country						
Baseline	5	2	28.12 (30.94)	9	6	19.79 (19.93)
Week 4	5	1	0.00 (NA)	9	5	16.25 (22.79)
Week 8	5	1	0.00 (NA)	9	6	14.58 (21.89)
Week 16	5	1	6.25 (NA)	9	5	12.50 (24.61)
Week 24	5	1	31.25 (NA)	9	3	18.75 (27.24)
Week 32				9	2	15.62 (13.26)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.11 Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	2	0.00 (0.00)	24	9	6.94 (8.53)
Week 4	12	2	0.00 (0.00)	23	7	8.04 (12.35)
Week 8	12	2	0.00 (0.00)	23	8	6.25 (11.57)
Week 16	12	2	0.00 (0.00)	23	7	10.71 (15.19)
Week 24	12	2	0.00 (0.00)	23	5	12.50 (17.68)
Week 32				23	5	13.75 (19.96)
Age						
< 18 years						
Baseline				6	1	0.00 (NA)
Week 4				6	1	0.00 (NA)
Week 8				6	1	0.00 (NA)
Week 16				6	1	0.00 (NA)
Week 24				6	1	0.00 (NA)
Week 32				6	1	0.00 (NA)
>= 18 years						
Baseline	9	2	0.00 (0.00)	18	8	7.81 (8.68)
Week 4	9	2	0.00 (0.00)	17	6	9.38 (12.96)
Week 8	9	2	0.00 (0.00)	17	7	7.14 (12.20)
Week 16	9	2	0.00 (0.00)	17	6	12.50 (15.81)
Week 24	9	2	0.00 (0.00)	17	4	15.62 (18.75)
Week 32				17	4	17.19 (21.27)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	1	0.00 (NA)	15	4	10.94 (10.67)
Week 4	7	1	0.00 (NA)	14	3	16.67 (15.73)
Week 8	7	1	0.00 (NA)	14	3	16.67 (14.43)
Week 16	7	1	0.00 (NA)	14	3	25.00 (12.50)
Week 24	7	1	0.00 (NA)	14	2	31.25 (8.84)
Week 32				14	3	22.92 (21.95)
OECD country						
Baseline	5	1	0.00 (NA)	9	5	3.75 (5.59)
Week 4	5	1	0.00 (NA)	9	4	1.56 (3.12)
Week 8	5	1	0.00 (NA)	9	5	0.00 (0.00)
Week 16	5	1	0.00 (NA)	9	4	0.00 (0.00)
Week 24	5	1	0.00 (NA)	9	3	0.00 (0.00)
Week 32				9	2	0.00 (0.00)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.2.12 Hemo-TEM Total Score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	24.88 (13.56)	24	15	23.08 (14.59)
Week 24	12	8	12.78 (14.43)	23	17	5.92 (5.52)
Week 32				23	16	9.54 (10.16)
Age						
< 18 years						
Baseline	3	1	30.12 (NA)	6	3	23.28 (23.83)
Week 24	3	2	15.77 (22.31)	6	5	6.36 (6.46)
Week 32				6	4	8.14 (2.74)
>= 18 years						
Baseline	9	7	24.13 (14.47)	18	12	23.04 (12.95)
Week 24	9	6	11.78 (13.68)	17	12	5.74 (5.40)
Week 32				17	12	10.01 (11.74)
Region						
Non-OECD country						
Baseline	7	5	28.48 (11.97)	15	9	26.95 (16.49)
Week 24	7	4	10.62 (14.12)	14	11	7.46 (5.83)
Week 32				14	10	12.06 (11.50)
OECD country						
Baseline	5	3	18.89 (16.46)	9	6	17.28 (9.69)
Week 24	5	4	14.94 (16.55)	9	6	3.10 (3.85)
Week 32				9	6	5.35 (6.16)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.13 Hemo-TEM ease of use by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	31.25 (24.70)	24	15	20.56 (23.33)
Week 24	12	8	5.21 (9.90)	23	17	3.92 (8.90)
Week 32				23	16	5.21 (8.54)
Age						
< 18 years						
Baseline	3	1	25.00 (NA)	6	3	22.22 (25.46)
Week 24	3	2	12.50 (17.68)	6	5	0.00 (0.00)
Week 32				6	4	10.42 (12.50)
>= 18 years						
Baseline	9	7	32.14 (26.54)	18	12	20.14 (23.96)
Week 24	9	6	2.78 (6.80)	17	12	5.56 (10.26)
Week 32				17	12	3.47 (6.61)
Region						
Non-OECD country						
Baseline	7	5	31.67 (22.36)	15	9	28.70 (26.39)
Week 24	7	4	4.17 (8.33)	14	11	3.03 (5.62)
Week 32				14	10	8.33 (9.62)
OECD country						
Baseline	5	3	30.56 (33.68)	9	6	8.33 (10.54)
Week 24	5	4	6.25 (12.50)	9	6	5.56 (13.61)
Week 32				9	6	0.00 (0.00)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.14 Hemo-TEM emotional impact by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	30.73 (15.90)	24	15	26.89 (22.45)
Week 24	12	8	16.77 (18.95)	23	17	9.95 (10.77)
Week 32				23	16	14.32 (14.75)
Age						
< 18 years						
Baseline	3	1	37.50 (NA)	6	3	23.33 (25.17)
Week 24	3	2	20.83 (29.46)	6	5	8.33 (10.62)
Week 32				6	4	16.67 (5.89)
>= 18 years						
Baseline	9	7	29.76 (16.91)	18	12	27.78 (22.84)
Week 24	9	6	15.42 (17.90)	17	12	10.62 (11.23)
Week 32				17	12	13.54 (16.87)
Region						
Non-OECD country						
Baseline	7	5	36.67 (11.93)	15	9	30.93 (27.92)
Week 24	7	4	14.79 (18.64)	14	11	14.24 (10.74)
Week 32				14	10	20.83 (14.57)
OECD country						
Baseline	5	3	20.83 (19.09)	9	6	20.83 (9.50)
Week 24	5	4	18.75 (21.92)	9	6	2.08 (5.10)
Week 32				9	6	3.47 (6.68)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.15 Hemo-TEM interference by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	23.44 (17.28)	24	15	23.33 (19.83)
Week 24	12	8	17.97 (19.89)	23	17	1.84 (6.16)
Week 32				23	16	8.98 (17.97)
Age						
< 18 years						
Baseline	3	1	37.50 (NA)	6	3	25.00 (22.53)
Week 24	3	2	18.75 (26.52)	6	5	5.00 (11.18)
Week 32				6	4	1.56 (3.12)
>= 18 years						
Baseline	9	7	21.43 (17.62)	18	12	22.92 (20.18)
Week 24	9	6	17.71 (20.32)	17	12	0.52 (1.80)
Week 32				17	12	11.46 (20.27)
Region						
Non-OECD country						
Baseline	7	5	30.00 (12.02)	15	9	26.39 (22.49)
Week 24	7	4	17.19 (21.27)	14	11	2.84 (7.58)
Week 32				14	10	11.25 (21.61)
OECD country						
Baseline	5	3	12.50 (21.65)	9	6	18.75 (15.81)
Week 24	5	4	18.75 (21.65)	9	6	0.00 (0.00)
Week 32				9	6	5.21 (10.01)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.16 Hemo-TEM physical impact by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	22.92 (12.20)	24	15	20.83 (14.69)
Week 24	12	8	8.33 (10.68)	23	17	7.60 (7.69)
Week 32				23	16	9.38 (10.37)
Age						
< 18 years						
Baseline	3	1	29.17 (NA)	6	3	20.83 (25.34)
Week 24	3	2	12.50 (17.68)	6	5	9.17 (6.85)
Week 32				6	4	9.38 (11.97)
>= 18 years						
Baseline	9	7	22.02 (12.89)	18	12	20.83 (12.56)
Week 24	9	6	6.94 (9.38)	17	12	6.94 (8.21)
Week 32				17	12	9.38 (10.38)
Region						
Non-OECD country						
Baseline	7	5	23.33 (8.12)	15	9	24.54 (17.61)
Week 24	7	4	6.25 (9.92)	14	11	9.09 (8.70)
Week 32				14	10	11.67 (12.08)
OECD country						
Baseline	5	3	22.22 (19.69)	9	6	15.28 (6.80)
Week 24	5	4	10.42 (12.50)	9	6	4.86 (4.87)
Week 32				9	6	5.56 (5.69)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.17 Hemo-TEM treatment burden by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	16.07 (12.52)	24	15	23.81 (17.22)
Week 24	12	8	15.62 (17.59)	23	17	6.30 (7.09)
Week 32				23	16	9.82 (16.93)
Age						
< 18 years						
Baseline	3	1	21.43 (NA)	6	3	25.00 (21.72)
Week 24	3	2	14.29 (20.20)	6	5	9.29 (10.59)
Week 32				6	4	2.68 (1.79)
>= 18 years						
Baseline	9	7	15.31 (13.32)	18	12	23.51 (17.06)
Week 24	9	6	16.07 (18.73)	17	12	5.06 (5.15)
Week 32				17	12	12.20 (19.11)
Region						
Non-OECD country						
Baseline	7	5	20.71 (11.68)	15	9	24.21 (13.34)
Week 24	7	4	10.71 (14.58)	14	11	8.12 (7.67)
Week 32				14	10	8.21 (13.26)
OECD country						
Baseline	5	3	8.33 (11.48)	9	6	23.21 (23.34)
Week 24	5	4	20.54 (21.10)	9	6	2.98 (4.75)
Week 32				9	6	12.50 (23.01)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.18 PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	7	3.57 (2.15)	24	15	3.47 (2.00)
Week 4	12	7	3.00 (3.06)	23	17	2.12 (1.87)
Week 8	12	5	2.80 (1.79)	23	17	1.88 (2.15)
Week 16	12	7	3.86 (3.13)	23	18	2.39 (2.45)
Week 24	12	8	4.38 (2.20)	23	17	2.88 (3.08)
Week 32				23	16	2.50 (2.58)
Age						
< 18 years						
Baseline	3	1	4.00 (NA)	6	3	4.33 (2.52)
Week 4	3	2	2.50 (2.12)	6	5	1.80 (1.48)
Week 8	3	2	3.00 (2.83)	6	5	1.80 (1.79)
Week 16	3	2	4.50 (0.71)	6	5	2.00 (2.92)
Week 24	3	2	4.00 (1.41)	6	5	1.00 (1.73)
Week 32				6	4	1.25 (1.50)
>= 18 years						
Baseline	9	6	3.50 (2.35)	18	12	3.25 (1.91)
Week 4	9	5	3.20 (3.56)	17	12	2.25 (2.05)
Week 8	9	3	2.67 (1.53)	17	12	1.92 (2.35)
Week 16	9	5	3.60 (3.78)	17	13	2.54 (2.37)
Week 24	9	6	4.50 (2.51)	17	12	3.67 (3.23)
Week 32				17	12	2.92 (2.78)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	2.80 (1.79)	15	9	3.33 (2.45)
Week 4	7	4	2.00 (2.71)	14	10	2.00 (1.89)
Week 8	7	3	2.67 (1.53)	14	10	1.90 (2.47)
Week 16	7	4	2.25 (2.63)	14	11	2.27 (2.61)
Week 24	7	4	4.00 (2.83)	14	11	3.36 (3.67)
Week 32				14	10	2.60 (3.06)
OECD country						
Baseline	5	2	5.50 (2.12)	9	6	3.67 (1.21)
Week 4	5	3	4.33 (3.51)	9	7	2.29 (1.98)
Week 8	5	2	3.00 (2.83)	9	7	1.86 (1.77)
Week 16	5	3	6.00 (2.65)	9	7	2.57 (2.37)
Week 24	5	4	4.75 (1.71)	9	6	2.00 (1.41)
Week 32				9	6	2.33 (1.75)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.19 PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	7	37.44 (5.46)	24	13	41.79 (11.62)
Week 4	12	7	43.97 (14.56)	23	14	45.81 (10.01)
Week 8	12	5	41.55 (3.64)	23	15	46.53 (10.36)
Week 16	12	7	43.61 (9.61)	23	16	46.99 (10.37)
Week 24	12	8	45.15 (9.37)	23	16	47.41 (10.36)
Week 32				23	14	46.13 (12.05)
Age						
< 18 years						
Baseline	3	1	39.32 (NA)	6	3	40.05 (8.05)
Week 4	3	2	45.02 (7.24)	6	5	50.36 (6.63)
Week 8	3	2	42.45 (5.14)	6	5	49.89 (5.94)
Week 16	3	2	42.61 (4.91)	6	5	51.29 (6.31)
Week 24	3	2	42.34 (5.96)	6	5	52.83 (7.41)
Week 32				6	4	53.28 (9.82)
>= 18 years						
Baseline	9	6	37.12 (5.91)	18	10	42.31 (12.82)
Week 4	9	5	43.55 (17.44)	17	9	43.28 (10.98)
Week 8	9	3	40.94 (3.46)	17	10	44.85 (11.90)
Week 16	9	5	44.01 (11.48)	17	11	45.03 (11.48)
Week 24	9	6	46.08 (10.56)	17	11	44.94 (10.85)
Week 32				17	10	43.27 (12.08)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	38.74 (4.92)	15	9	36.04 (8.72)
Week 4	7	4	49.82 (12.00)	14	10	44.26 (11.16)
Week 8	7	3	40.94 (3.46)	14	10	43.57 (11.15)
Week 16	7	4	47.49 (9.74)	14	11	44.14 (11.13)
Week 24	7	4	46.61 (8.32)	14	11	45.12 (11.43)
Week 32				14	10	43.13 (12.83)
OECD country						
Baseline	5	2	34.19 (7.27)	9	4	54.71 (4.02)
Week 4	5	3	36.17 (16.15)	9	4	49.69 (5.67)
Week 8	5	2	42.45 (5.14)	9	5	52.45 (5.46)
Week 16	5	3	38.44 (8.03)	9	5	53.25 (4.71)
Week 24	5	4	43.68 (11.39)	9	5	52.45 (5.46)
Week 32				9	4	53.63 (5.52)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.20 SF-36v2 general health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	41.24 (6.84)	24	15	43.99 (9.05)
Week 4	12	8	36.72 (10.63)	23	17	48.15 (10.51)
Week 8	12	5	41.39 (9.61)	23	17	48.71 (7.81)
Week 16	12	7	38.45 (11.47)	23	18	48.04 (6.96)
Week 24	12	8	39.99 (12.25)	23	17	48.63 (10.29)
Week 32				23	16	47.75 (8.76)
Age						
< 18 years						
Baseline	3	1	38.92 (NA)	6	3	44.95 (2.19)
Week 4	3	2	39.64 (7.73)	6	5	47.58 (6.41)
Week 8	3	2	33.69 (4.03)	6	5	46.15 (7.38)
Week 16	3	2	36.07 (7.40)	6	5	46.63 (5.58)
Week 24	3	2	36.07 (7.40)	6	5	49.19 (6.98)
Week 32				6	4	47.00 (5.19)
>= 18 years						
Baseline	9	7	41.57 (7.31)	18	12	43.76 (10.15)
Week 4	9	6	35.75 (11.90)	17	12	48.39 (12.06)
Week 8	9	3	46.53 (8.80)	17	12	49.78 (8.04)
Week 16	9	5	39.40 (13.41)	17	13	48.58 (7.56)
Week 24	9	6	41.30 (13.81)	17	12	48.39 (11.67)
Week 32				17	12	48.00 (9.86)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 general health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	43.77 (7.41)	15	9	42.83 (5.98)
Week 4	7	4	40.58 (11.94)	14	10	49.15 (10.83)
Week 8	7	3	46.53 (8.80)	14	10	48.86 (7.30)
Week 16	7	4	42.73 (12.87)	14	11	47.09 (6.79)
Week 24	7	4	43.32 (15.81)	14	11	48.73 (12.17)
Week 32				14	10	47.10 (9.54)
OECD country						
Baseline	5	3	37.02 (3.29)	9	6	45.74 (12.89)
Week 4	5	4	32.86 (9.01)	9	7	46.73 (10.70)
Week 8	5	2	33.69 (4.03)	9	7	48.50 (9.09)
Week 16	5	3	32.74 (7.79)	9	7	49.52 (7.50)
Week 24	5	4	36.66 (8.38)	9	6	48.43 (6.56)
Week 32				9	6	48.83 (8.02)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.21 SF-36v2 mental health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	45.31 (12.15)	24	15	45.81 (9.35)
Week 4	12	8	41.38 (12.50)	23	17	51.95 (7.63)
Week 8	12	5	48.25 (10.63)	23	17	50.41 (9.31)
Week 16	12	7	43.39 (11.04)	23	18	50.72 (7.90)
Week 24	12	8	41.71 (11.95)	23	17	49.48 (11.88)
Week 32				23	16	52.01 (8.70)
Age						
< 18 years						
Baseline	3	1	37.79 (NA)	6	3	44.76 (4.00)
Week 4	3	2	48.25 (14.80)	6	5	53.48 (4.14)
Week 8	3	2	46.94 (16.65)	6	5	49.82 (5.43)
Week 16	3	2	43.02 (14.79)	6	5	50.87 (7.40)
Week 24	3	2	40.41 (7.40)	6	5	50.34 (10.03)
Week 32				6	4	52.18 (5.45)
>= 18 years						
Baseline	9	7	46.38 (12.70)	18	12	46.07 (10.39)
Week 4	9	6	39.09 (12.24)	17	12	51.30 (8.77)
Week 8	9	3	49.12 (9.19)	17	12	50.65 (10.73)
Week 16	9	5	43.54 (11.31)	17	13	50.67 (8.37)
Week 24	9	6	42.15 (13.71)	17	12	49.12 (12.98)
Week 32				17	12	51.96 (9.75)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 mental health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	43.02 (12.27)	15	9	42.73 (10.00)
Week 4	7	4	43.02 (13.34)	14	10	50.61 (8.40)
Week 8	7	3	49.12 (9.19)	14	10	49.30 (11.45)
Week 16	7	4	45.64 (11.89)	14	11	48.01 (8.39)
Week 24	7	4	43.02 (16.41)	14	11	46.35 (12.82)
Week 32				14	10	49.82 (9.88)
OECD country						
Baseline	5	3	49.13 (13.42)	9	6	50.43 (6.49)
Week 4	5	4	39.75 (13.41)	9	7	53.86 (6.49)
Week 8	5	2	46.94 (16.65)	9	7	51.99 (5.42)
Week 16	5	3	40.40 (11.40)	9	7	54.98 (4.98)
Week 24	5	4	40.41 (7.70)	9	6	55.23 (7.88)
Week 32				9	6	55.67 (5.08)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.22 SF-36v2 role emotional by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	47.90 (10.68)	24	15	43.64 (11.07)
Week 4	12	8	43.98 (11.77)	23	17	50.02 (7.93)
Week 8	12	5	46.42 (9.34)	23	17	50.23 (7.76)
Week 16	12	7	42.74 (12.78)	23	18	46.69 (10.33)
Week 24	12	8	43.55 (11.16)	23	17	45.93 (11.25)
Week 32				23	16	46.81 (12.82)
Age						
< 18 years						
Baseline	3	1	38.76 (NA)	6	3	38.76 (9.21)
Week 4	3	2	49.20 (9.85)	6	5	49.21 (8.88)
Week 8	3	2	45.73 (14.77)	6	5	48.51 (10.56)
Week 16	3	2	42.24 (19.70)	6	5	48.51 (8.67)
Week 24	3	2	42.24 (19.70)	6	5	50.60 (5.28)
Week 32				6	4	50.95 (6.03)
>= 18 years						
Baseline	9	7	49.21 (10.82)	18	12	44.85 (11.51)
Week 4	9	6	42.24 (12.65)	17	12	50.37 (7.90)
Week 8	9	3	46.88 (8.04)	17	12	50.95 (6.72)
Week 16	9	5	42.94 (12.16)	17	13	45.99 (11.15)
Week 24	9	6	43.98 (9.79)	17	12	43.98 (12.64)
Week 32				17	12	45.43 (14.35)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 role emotional by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	46.42 (11.91)	15	9	39.92 (10.87)
Week 4	7	4	43.11 (10.00)	14	10	46.77 (8.54)
Week 8	7	3	46.88 (8.04)	14	10	48.16 (8.85)
Week 16	7	4	44.86 (13.14)	14	11	41.92 (10.38)
Week 24	7	4	43.11 (9.16)	14	11	42.87 (12.63)
Week 32				14	10	42.24 (14.40)
OECD country						
Baseline	5	3	50.37 (10.05)	9	6	49.21 (9.60)
Week 4	5	4	44.85 (14.88)	9	7	54.68 (3.95)
Week 8	5	2	45.73 (14.77)	9	7	53.18 (5.10)
Week 16	5	3	39.92 (14.50)	9	7	54.18 (3.95)
Week 24	5	4	43.98 (14.36)	9	6	51.53 (5.24)
Week 32				9	6	54.43 (2.92)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.23 SF-36v2 role physical by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	39.76 (9.12)	24	15	43.24 (8.41)
Week 4	12	8	38.07 (9.75)	23	17	48.17 (9.72)
Week 8	12	5	45.03 (6.47)	23	17	48.83 (7.73)
Week 16	12	7	36.95 (4.85)	23	18	47.43 (9.77)
Week 24	12	8	39.47 (5.81)	23	17	48.31 (10.49)
Week 32				23	16	48.88 (12.48)
Age						
< 18 years						
Baseline	3	1	36.95 (NA)	6	3	45.93 (9.79)
Week 4	3	2	41.44 (0.00)	6	5	45.03 (5.85)
Week 8	3	2	45.93 (6.35)	6	5	48.17 (6.35)
Week 16	3	2	35.83 (1.59)	6	5	44.58 (8.04)
Week 24	3	2	44.80 (4.76)	6	5	51.32 (8.93)
Week 32				6	4	52.11 (10.10)
>= 18 years						
Baseline	9	7	40.16 (9.78)	18	12	42.56 (8.37)
Week 4	9	6	36.95 (11.27)	17	12	49.48 (10.90)
Week 8	9	3	44.43 (7.88)	17	12	49.11 (8.48)
Week 16	9	5	37.40 (5.81)	17	13	48.52 (10.45)
Week 24	9	6	37.70 (5.25)	17	12	47.05 (11.19)
Week 32				17	12	47.80 (13.40)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 role physical by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	41.44 (11.23)	15	9	41.94 (8.97)
Week 4	7	4	42.00 (10.10)	14	10	45.70 (10.97)
Week 8	7	3	44.43 (7.88)	14	10	45.93 (8.47)
Week 16	7	4	39.19 (4.85)	14	11	44.91 (10.88)
Week 24	7	4	38.63 (4.63)	14	11	46.34 (11.44)
Week 32				14	10	46.16 (14.18)
OECD country						
Baseline	5	3	36.95 (4.49)	9	6	45.18 (7.86)
Week 4	5	4	34.14 (8.87)	9	7	51.70 (6.85)
Week 8	5	2	45.93 (6.35)	9	7	52.99 (4.19)
Week 16	5	3	33.95 (3.43)	9	7	51.38 (6.60)
Week 24	5	4	40.32 (7.45)	9	6	51.92 (8.12)
Week 32				9	6	53.42 (8.12)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.24 SF-36v2 social function by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	45.43 (10.36)	24	15	44.64 (10.70)
Week 4	12	8	42.93 (9.06)	23	17	50.85 (9.17)
Week 8	12	5	50.32 (8.39)	23	17	48.79 (9.17)
Week 16	12	7	44.45 (9.09)	23	18	49.54 (7.73)
Week 24	12	8	42.93 (6.80)	23	17	48.49 (9.95)
Week 32				23	16	47.94 (12.67)
Age						
< 18 years						
Baseline	3	1	37.29 (NA)	6	3	48.98 (7.66)
Week 4	3	2	44.81 (10.63)	6	5	52.33 (5.02)
Week 8	3	2	47.31 (14.18)	6	5	49.32 (7.60)
Week 16	3	2	37.28 (7.09)	6	5	49.32 (5.72)
Week 24	3	2	37.29 (0.00)	6	5	50.32 (6.73)
Week 32				6	4	52.33 (4.09)
>= 18 years						
Baseline	9	7	46.60 (10.61)	18	12	43.55 (11.34)
Week 4	9	6	42.30 (9.51)	17	12	50.24 (10.57)
Week 8	9	3	52.33 (5.02)	17	12	48.57 (10.05)
Week 16	9	5	47.31 (8.69)	17	13	49.63 (8.59)
Week 24	9	6	44.81 (6.91)	17	12	47.73 (11.20)
Week 32				17	12	46.48 (14.31)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 social function by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	45.31 (11.54)	15	9	41.74 (12.14)
Week 4	7	4	46.06 (7.52)	14	10	47.31 (10.30)
Week 8	7	3	52.33 (5.02)	14	10	46.81 (10.15)
Week 16	7	4	51.08 (2.51)	14	11	46.40 (7.71)
Week 24	7	4	46.06 (8.56)	14	11	45.49 (10.81)
Week 32				14	10	43.30 (14.14)
OECD country						
Baseline	5	3	45.64 (10.43)	9	6	48.98 (6.85)
Week 4	5	4	39.80 (10.44)	9	7	55.91 (3.79)
Week 8	5	2	47.31 (14.18)	9	7	51.61 (7.34)
Week 16	5	3	35.61 (5.79)	9	7	54.47 (4.89)
Week 24	5	4	39.80 (2.89)	9	6	54.00 (5.18)
Week 32				9	6	55.67 (2.59)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.25 SF-36v2 vitality by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	51.86 (8.66)	24	15	50.62 (8.23)
Week 4	12	8	44.80 (10.65)	23	17	55.74 (9.88)
Week 8	12	5	47.85 (7.45)	23	17	55.92 (9.03)
Week 16	12	7	50.05 (7.36)	23	18	55.07 (7.78)
Week 24	12	8	49.63 (11.45)	23	17	53.47 (10.75)
Week 32				23	16	55.94 (8.94)
Age						
< 18 years						
Baseline	3	1	46.66 (NA)	6	3	50.62 (6.86)
Week 4	3	2	52.60 (4.20)	6	5	58.54 (4.70)
Week 8	3	2	45.17 (6.30)	6	5	57.35 (6.84)
Week 16	3	2	51.11 (6.30)	6	5	56.76 (7.45)
Week 24	3	2	48.14 (2.10)	6	5	54.98 (5.71)
Week 32				6	4	56.31 (2.84)
>= 18 years						
Baseline	9	7	52.60 (9.07)	18	12	50.62 (8.81)
Week 4	9	6	42.20 (11.08)	17	12	54.58 (11.35)
Week 8	9	3	49.63 (8.91)	17	12	55.32 (10.01)
Week 16	9	5	49.63 (8.40)	17	13	54.43 (8.09)
Week 24	9	6	50.12 (13.47)	17	12	52.85 (12.44)
Week 32				17	12	55.82 (10.33)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 vitality by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	50.22 (5.31)	15	9	47.32 (8.51)
Week 4	7	4	48.14 (7.86)	14	10	54.97 (11.78)
Week 8	7	3	49.63 (8.91)	14	10	55.57 (10.94)
Week 16	7	4	53.34 (1.48)	14	11	54.49 (8.43)
Week 24	7	4	55.57 (10.57)	14	11	52.06 (12.09)
Week 32				14	10	54.08 (10.50)
OECD country						
Baseline	5	3	54.58 (13.72)	9	6	55.57 (4.97)
Week 4	5	4	41.46 (13.15)	9	7	56.84 (7.04)
Week 8	5	2	45.17 (6.30)	9	7	56.42 (6.11)
Week 16	5	3	45.67 (10.44)	9	7	55.99 (7.16)
Week 24	5	4	43.69 (10.00)	9	6	56.07 (8.06)
Week 32				9	6	59.03 (4.76)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.26 SF-36v2 mental component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	51.22 (12.81)	24	15	46.86 (10.41)
Week 4	12	8	44.90 (11.47)	23	17	53.36 (8.96)
Week 8	12	5	49.64 (10.28)	23	17	51.89 (7.79)
Week 16	12	7	46.75 (10.77)	23	18	51.21 (8.24)
Week 24	12	8	44.66 (10.24)	23	17	49.33 (11.71)
Week 32				23	16	51.19 (11.01)
Age						
< 18 years						
Baseline	3	1	39.26 (NA)	6	3	43.76 (4.61)
Week 4	3	2	51.98 (14.53)	6	5	54.89 (6.80)
Week 8	3	2	48.46 (16.73)	6	5	51.12 (8.58)
Week 16	3	2	45.41 (17.22)	6	5	52.53 (6.42)
Week 24	3	2	41.91 (10.37)	6	5	51.45 (4.82)
Week 32				6	4	52.69 (4.16)
>= 18 years						
Baseline	9	7	52.93 (12.81)	18	12	47.64 (11.43)
Week 4	9	6	42.54 (10.74)	17	12	52.72 (9.92)
Week 8	9	3	50.43 (8.32)	17	12	52.21 (7.82)
Week 16	9	5	47.29 (9.93)	17	13	50.71 (9.03)
Week 24	9	6	45.58 (11.01)	17	12	48.45 (13.72)
Week 32				17	12	50.69 (12.62)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 mental component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	47.92 (10.54)	15	9	42.78 (9.91)
Week 4	7	4	44.02 (9.82)	14	10	50.72 (9.31)
Week 8	7	3	50.43 (8.32)	14	10	50.43 (8.47)
Week 16	7	4	49.39 (10.11)	14	11	47.82 (8.18)
Week 24	7	4	46.39 (13.40)	14	11	46.14 (12.59)
Week 32				14	10	47.57 (12.37)
OECD country						
Baseline	5	3	56.72 (16.72)	9	6	52.99 (8.42)
Week 4	5	4	45.77 (14.44)	9	7	57.14 (7.47)
Week 8	5	2	48.46 (16.73)	9	7	53.97 (6.74)
Week 16	5	3	43.24 (12.74)	9	7	56.56 (5.15)
Week 24	5	4	42.93 (7.54)	9	6	55.19 (7.64)
Week 32				9	6	57.22 (4.26)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.27 SF-36v2 physical component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	37.20 (9.61)	24	15	43.71 (7.93)
Week 4	12	8	38.13 (11.74)	23	17	47.27 (9.51)
Week 8	12	5	43.66 (4.91)	23	17	48.59 (7.95)
Week 16	12	7	38.55 (9.95)	23	18	47.47 (7.38)
Week 24	12	8	41.76 (7.26)	23	17	48.79 (7.34)
Week 32				23	16	48.60 (7.42)
Age						
< 18 years						
Baseline	3	1	41.28 (NA)	6	3	49.54 (8.78)
Week 4	3	2	38.66 (4.99)	6	5	46.20 (7.57)
Week 8	3	2	39.56 (1.55)	6	5	48.79 (7.92)
Week 16	3	2	36.61 (4.43)	6	5	46.05 (9.57)
Week 24	3	2	41.31 (1.43)	6	5	50.66 (7.84)
Week 32				6	4	51.12 (6.53)
>= 18 years						
Baseline	9	7	36.62 (10.23)	18	12	42.25 (7.38)
Week 4	9	6	37.96 (13.71)	17	12	47.72 (10.49)
Week 8	9	3	46.39 (4.37)	17	12	48.51 (8.31)
Week 16	9	5	39.33 (11.87)	17	13	48.01 (6.74)
Week 24	9	6	41.91 (8.56)	17	12	48.01 (7.33)
Week 32				17	12	47.76 (7.77)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 physical component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	41.08 (8.02)	15	9	43.80 (8.38)
Week 4	7	4	45.53 (7.62)	14	10	46.99 (10.22)
Week 8	7	3	46.39 (4.37)	14	10	47.64 (7.87)
Week 16	7	4	42.95 (10.01)	14	11	46.69 (6.67)
Week 24	7	4	44.44 (4.71)	14	11	48.36 (8.16)
Week 32				14	10	47.40 (8.15)
OECD country						
Baseline	5	3	30.74 (9.72)	9	6	43.58 (7.98)
Week 4	5	4	30.74 (10.86)	9	7	47.68 (9.19)
Week 8	5	2	39.56 (1.55)	9	7	49.94 (8.48)
Week 16	5	3	32.68 (7.50)	9	7	48.69 (8.80)
Week 24	5	4	39.08 (9.03)	9	6	49.59 (6.16)
Week 32				9	6	50.62 (6.16)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.28 SF-36v2 bodily pain by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	38.92 (7.66)	24	15	43.61 (9.33)
Week 4	12	8	38.92 (10.07)	23	17	47.86 (7.52)
Week 8	12	5	47.97 (10.40)	23	17	49.52 (7.69)
Week 16	12	7	37.63 (13.34)	23	18	49.01 (9.80)
Week 24	12	8	39.67 (11.86)	23	17	50.19 (9.28)
Week 32				23	16	51.97 (7.54)
Age						
< 18 years						
Baseline	3	1	38.21 (NA)	6	3	51.79 (8.85)
Week 4	3	2	40.23 (2.85)	6	5	45.79 (7.22)
Week 8	3	2	43.05 (17.68)	6	5	49.17 (9.15)
Week 16	3	2	36.20 (2.85)	6	5	47.48 (13.09)
Week 24	3	2	38.21 (5.70)	6	5	52.08 (11.04)
Week 32				6	4	52.73 (7.46)
>= 18 years						
Baseline	9	7	39.02 (8.27)	18	12	41.57 (8.59)
Week 4	9	6	38.48 (11.81)	17	12	48.73 (7.77)
Week 8	9	3	51.25 (4.44)	17	12	49.67 (7.44)
Week 16	9	5	38.21 (16.23)	17	13	49.59 (8.81)
Week 24	9	6	40.16 (13.76)	17	12	49.40 (8.87)
Week 32				17	12	51.72 (7.88)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 bodily pain by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	41.03 (9.21)	15	9	45.42 (10.67)
Week 4	7	4	44.66 (8.91)	14	10	47.12 (7.80)
Week 8	7	3	51.25 (4.44)	14	10	48.25 (8.37)
Week 16	7	4	41.13 (17.16)	14	11	49.02 (10.15)
Week 24	7	4	42.14 (15.06)	14	11	50.09 (11.15)
Week 32				14	10	51.84 (8.45)
OECD country						
Baseline	5	3	35.39 (2.45)	9	6	40.90 (6.83)
Week 4	5	4	33.17 (8.32)	9	7	48.92 (7.57)
Week 8	5	2	43.05 (17.68)	9	7	51.34 (6.78)
Week 16	5	3	32.97 (5.94)	9	7	48.98 (10.02)
Week 24	5	4	37.20 (9.25)	9	6	50.37 (5.19)
Week 32				9	6	52.19 (6.48)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

2.3.2.29 SF-36v2 physical functioning by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
All subjects (Total)						
total						
Baseline	12	8	38.16 (10.25)	24	15	43.89 (9.09)
Week 4	12	8	41.03 (11.62)	23	17	48.42 (8.94)
Week 8	12	5	43.38 (4.19)	23	17	48.65 (9.92)
Week 16	12	7	43.05 (10.18)	23	18	46.59 (10.64)
Week 24	12	8	45.58 (10.27)	23	17	46.85 (10.13)
Week 32				23	16	46.65 (10.66)
Age						
< 18 years						
Baseline	3	1	44.15 (NA)	6	3	46.06 (10.13)
Week 4	3	2	42.24 (2.71)	6	5	50.65 (6.43)
Week 8	3	2	40.31 (2.71)	6	5	50.27 (8.92)
Week 16	3	2	41.28 (6.77)	6	5	48.36 (7.70)
Week 24	3	2	42.23 (5.42)	6	5	49.50 (7.70)
Week 32				6	4	51.80 (7.33)
>= 18 years						
Baseline	9	7	37.31 (10.76)	18	12	43.35 (9.21)
Week 4	9	6	40.63 (13.66)	17	12	47.49 (9.90)
Week 8	9	3	45.42 (3.98)	17	12	47.97 (10.61)
Week 16	9	5	43.76 (11.90)	17	13	45.91 (11.78)
Week 24	9	6	46.70 (11.65)	17	12	45.74 (11.10)
Week 32				17	12	44.94 (11.29)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

SF-36v2 physical functioning by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

	No PPX (arm 1)			Concizumab PPX (arm 2)		
	N	n	Mean (SD)	N	n	Mean (SD)
Region						
Non-OECD country						
Baseline	7	5	41.08 (9.44)	15	9	41.38 (9.57)
Week 4	7	4	48.93 (5.53)	14	10	47.59 (10.63)
Week 8	7	3	45.42 (3.98)	14	10	48.16 (11.57)
Week 16	7	4	48.45 (6.51)	14	11	43.80 (11.95)
Week 24	7	4	48.93 (7.07)	14	11	44.49 (11.60)
Week 32				14	10	43.38 (12.08)
OECD country						
Baseline	5	3	33.30 (11.54)	9	6	47.65 (7.50)
Week 4	5	4	33.14 (10.87)	9	7	49.61 (6.39)
Week 8	5	2	40.31 (2.71)	9	7	49.34 (7.79)
Week 16	5	3	35.85 (10.54)	9	7	50.98 (6.80)
Week 24	5	4	42.23 (12.89)	9	6	51.16 (4.94)
Week 32				9	6	52.12 (4.60)

HB: Haemophilia B, OTexBR: On-treatment without data before restart, PPX: Prophylaxis, NA: not applicable, 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. Cut off date for data is 12th July 2022.

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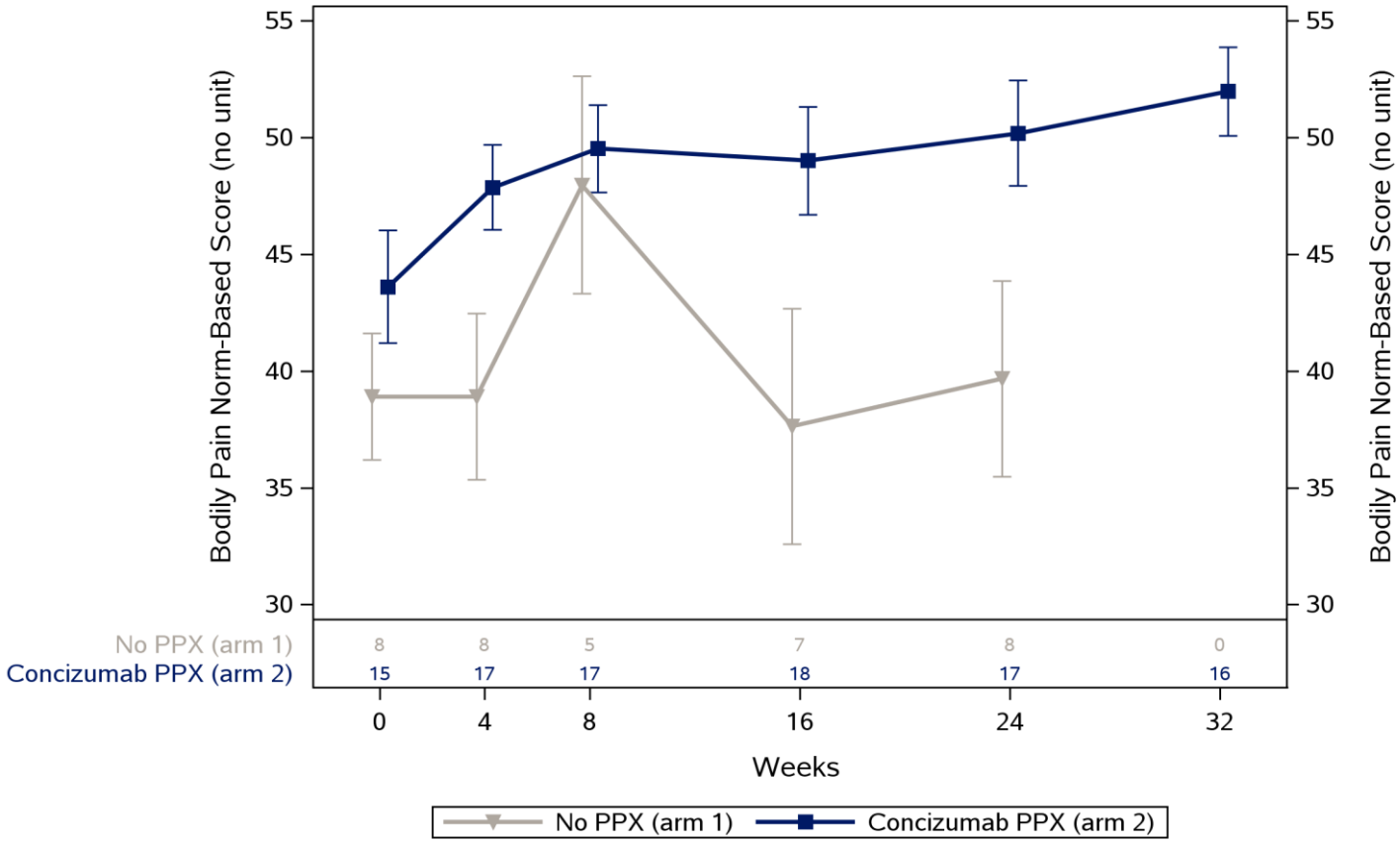
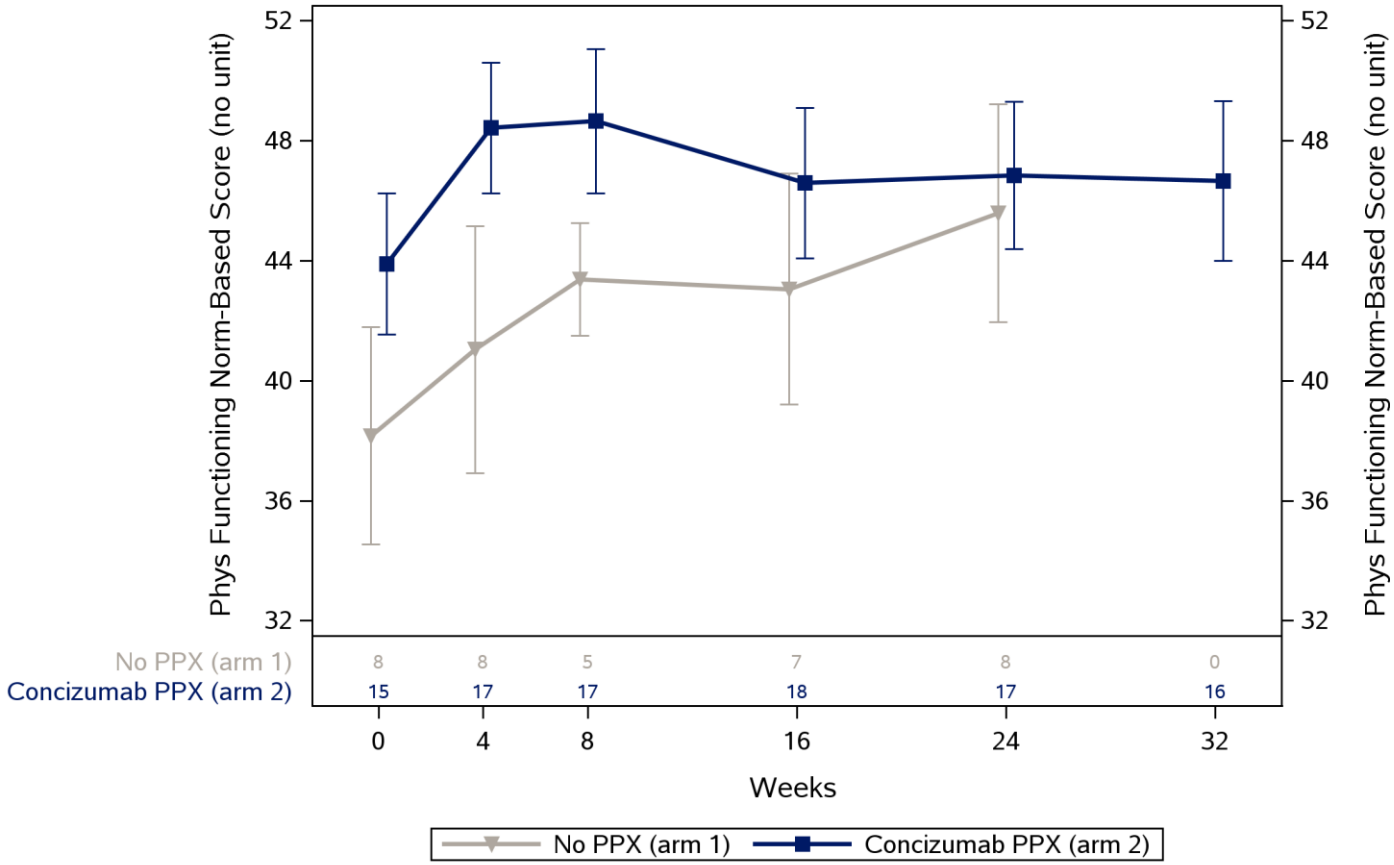
2.3.3.1 SF-36v2 (standard version) - bodily pain - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:03:55 - f-sf36mean.sas/f-sf36bpfasHB.png

2.3.3.2 SF-36v2 (standard version) - physical functioning - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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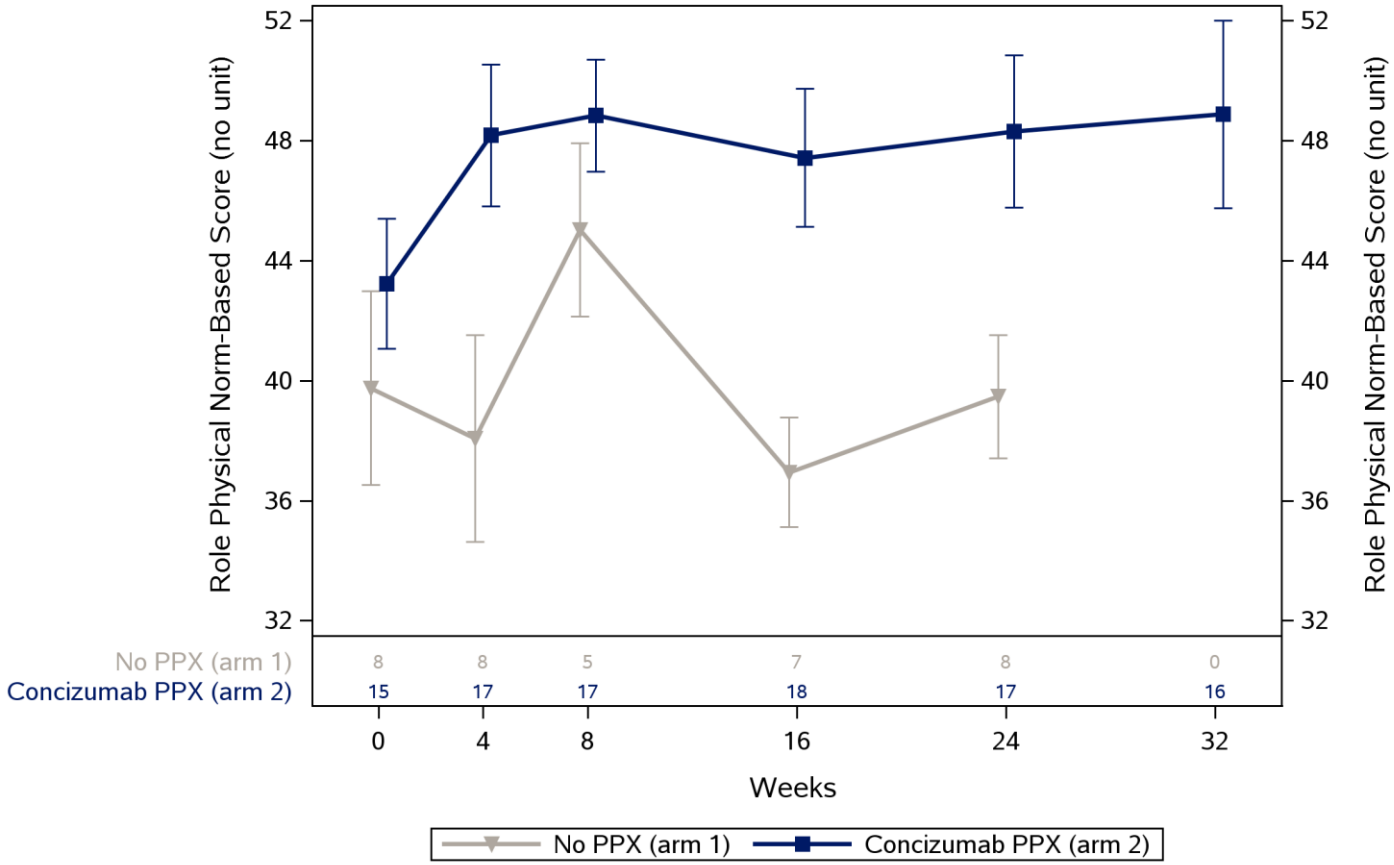
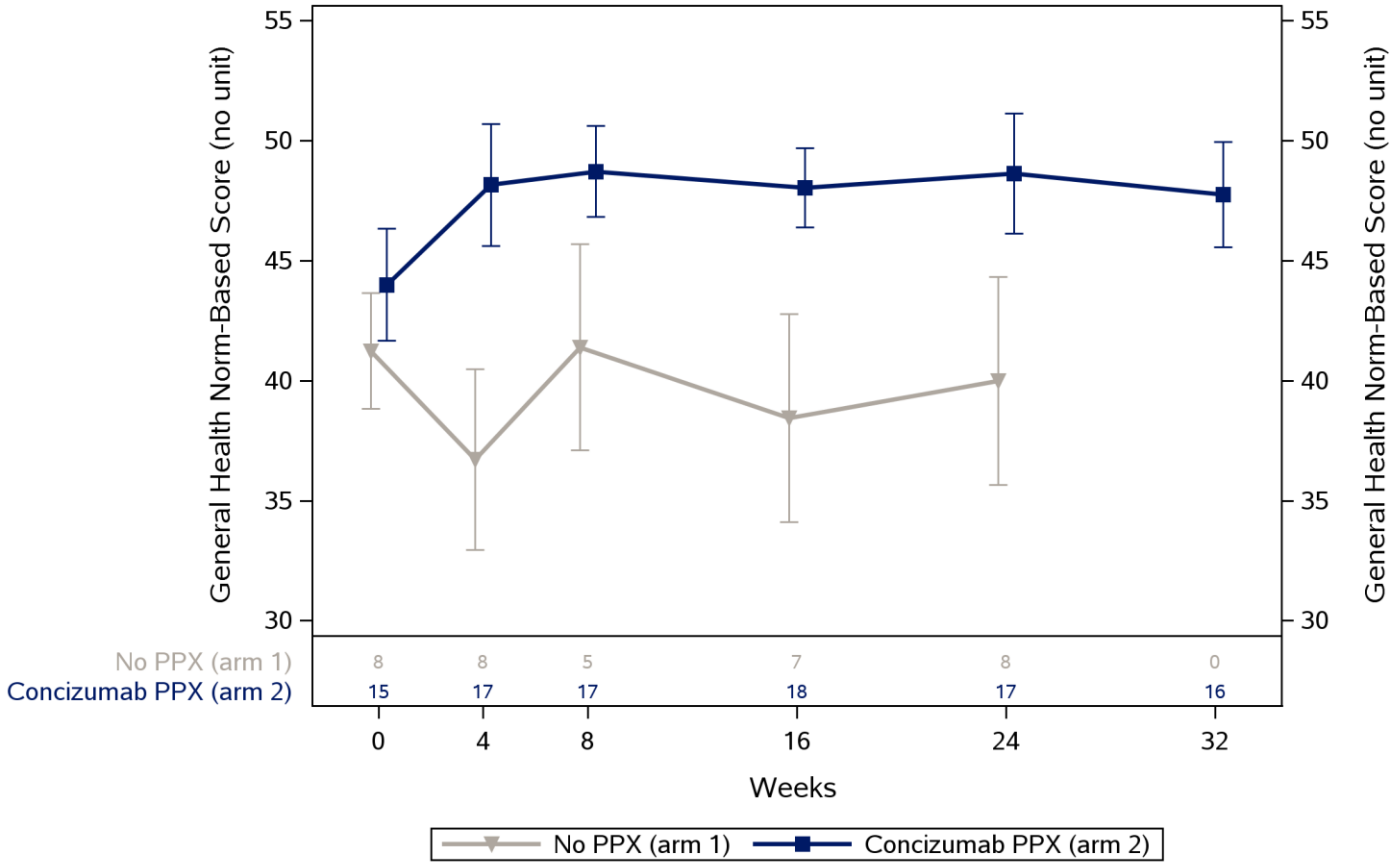
2.3.3.3 SF-36v2 (standard version) - role physical - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:04:05 - f-sf36mean.sas/f-sf36rolephysfasHB.png

2.3.3.4 SF-36v2 (standard version) - general health - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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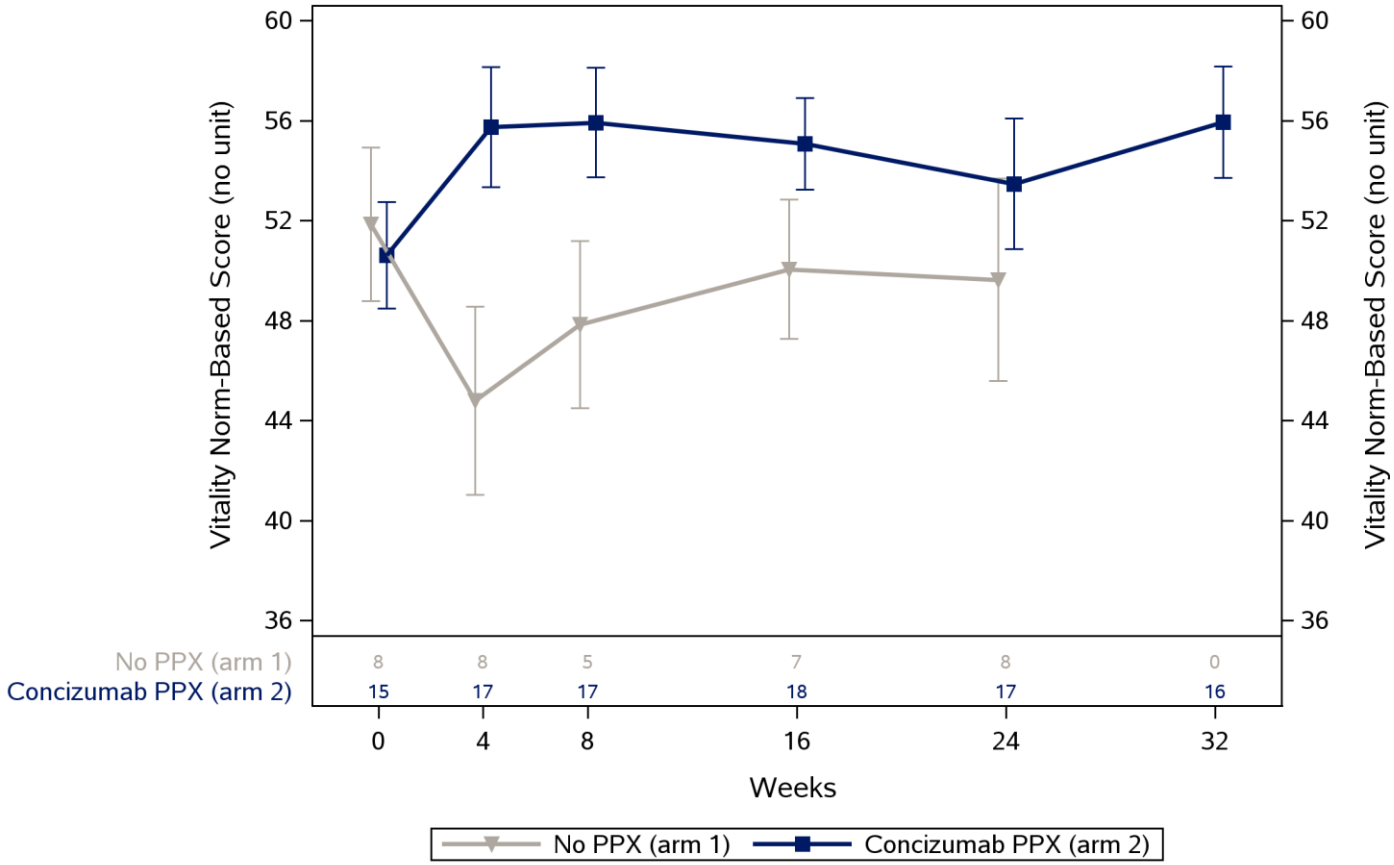
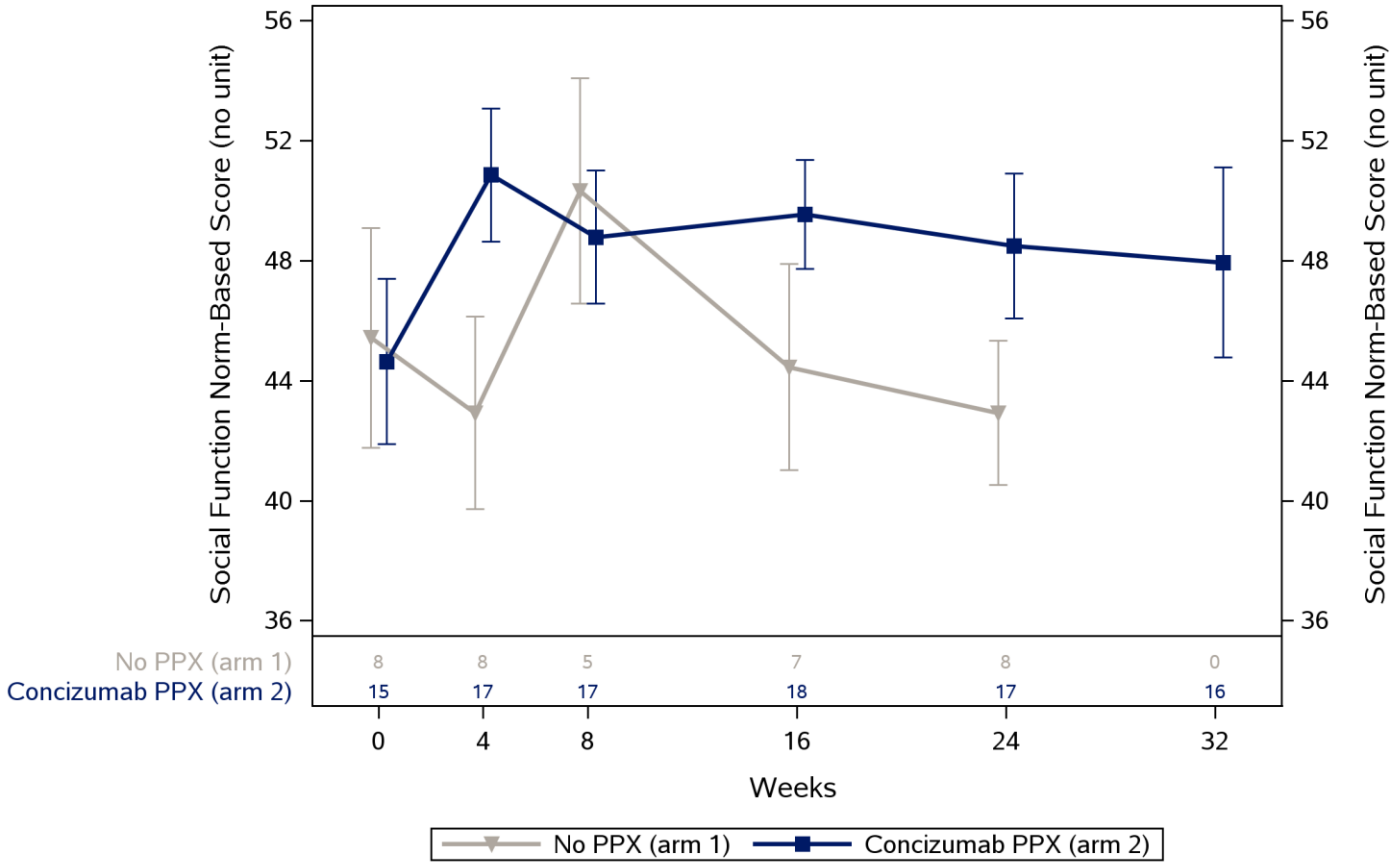
2.3.3.5 SF-36v2 (standard version) - vitality - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:04:14 - f-sf36mean.sas/f-sf36vitalityfasHB.png

2.3.3.6 SF-36v2 (standard version) - social functioning - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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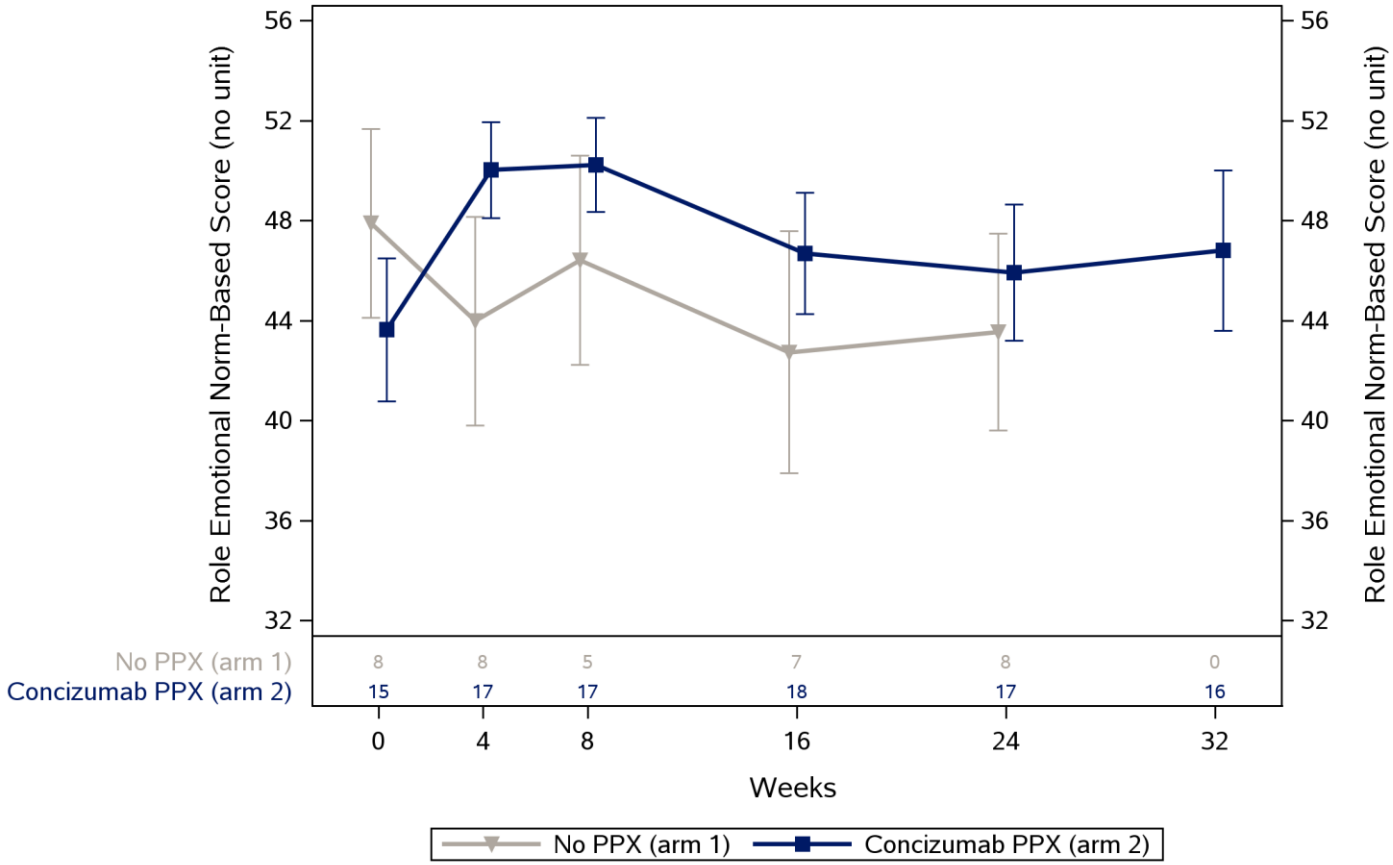
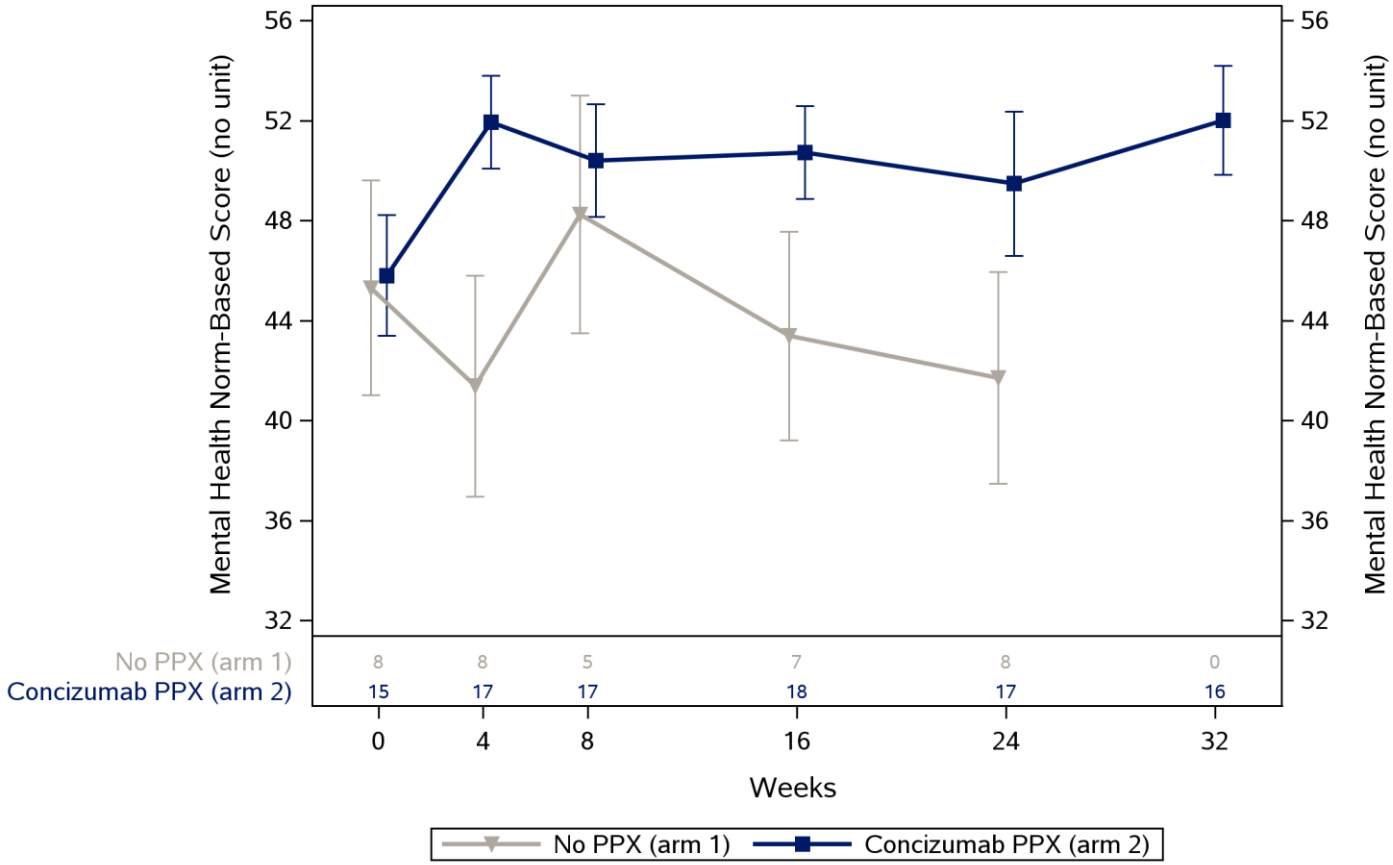
2.3.3.7 SF-36v2 (standard version) - role emotional - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:04:23 - f-sf36mean.sas/f-sf36roleemofasHB.png

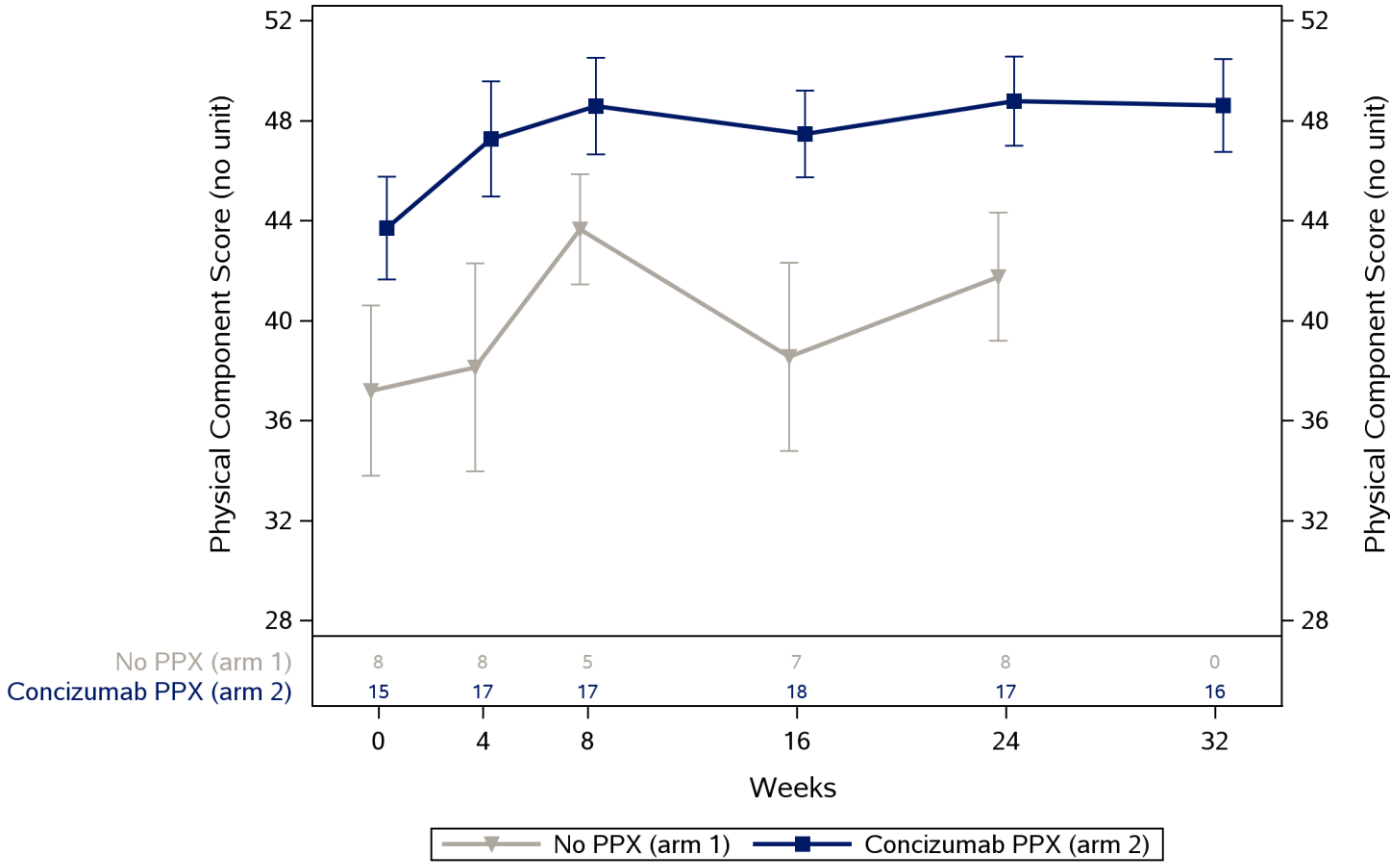
2.3.3.8 SF-36v2 (standard version) - mental health - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:04:28 - f-sf36mean.sas/f-sf36mentalhfasHB.png

2.3.3.9 SF-36v2 (standard version) - physical component score - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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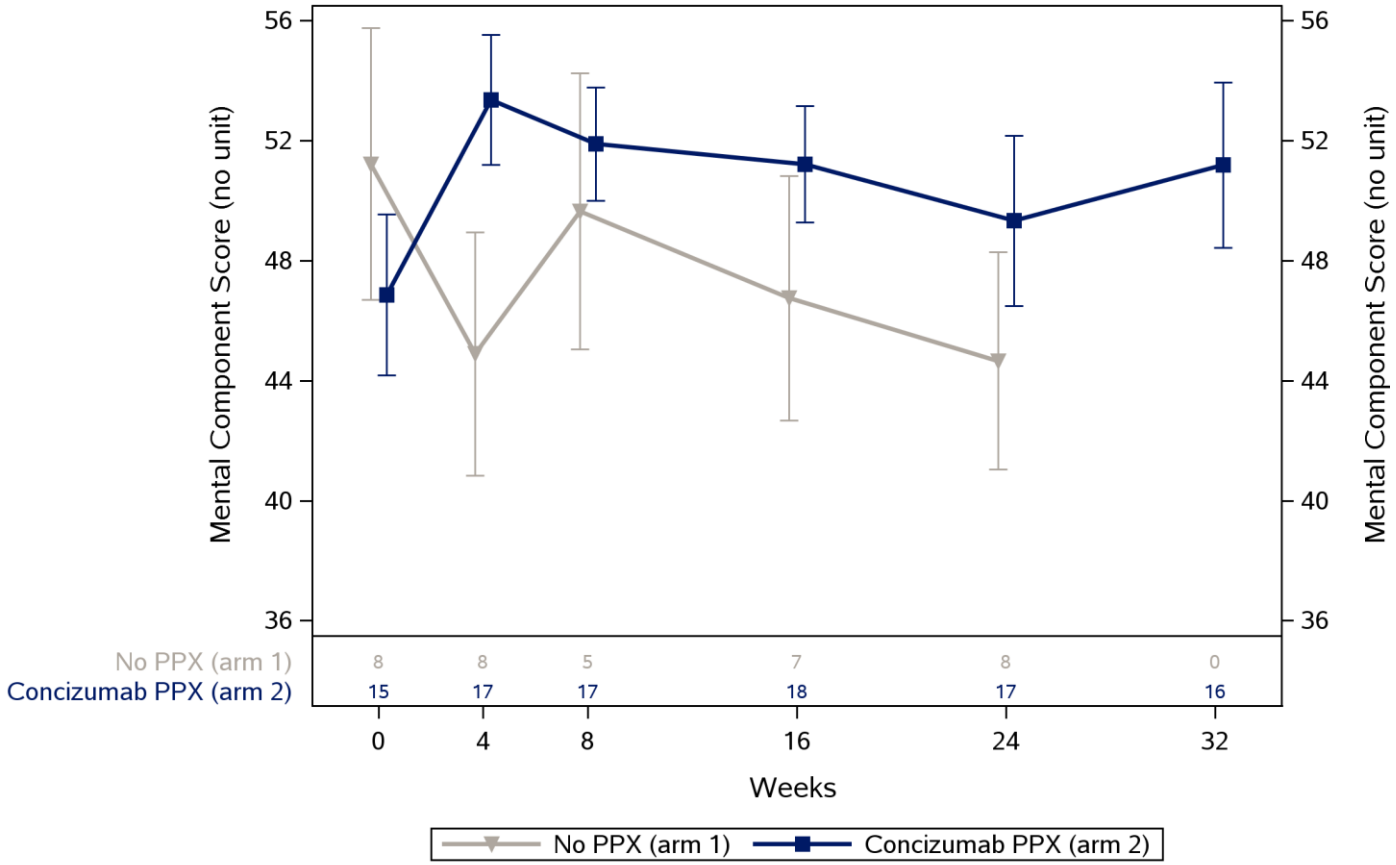
2.3.3.10 SF-36v2 (standard version) - mental component score - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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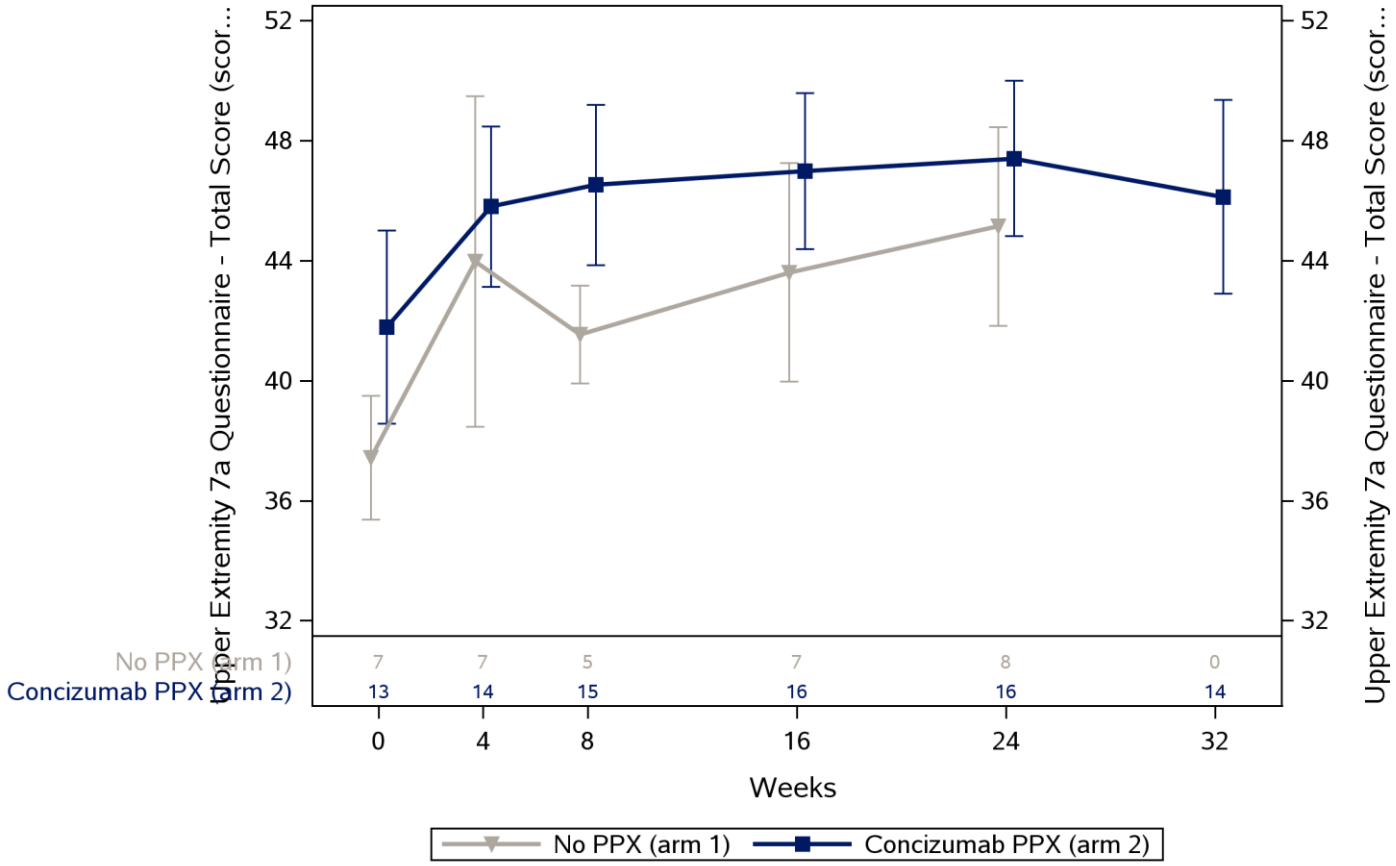
2.3.3.11 PROMIS Short Form v2.0 – Upper Extremity 7a - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
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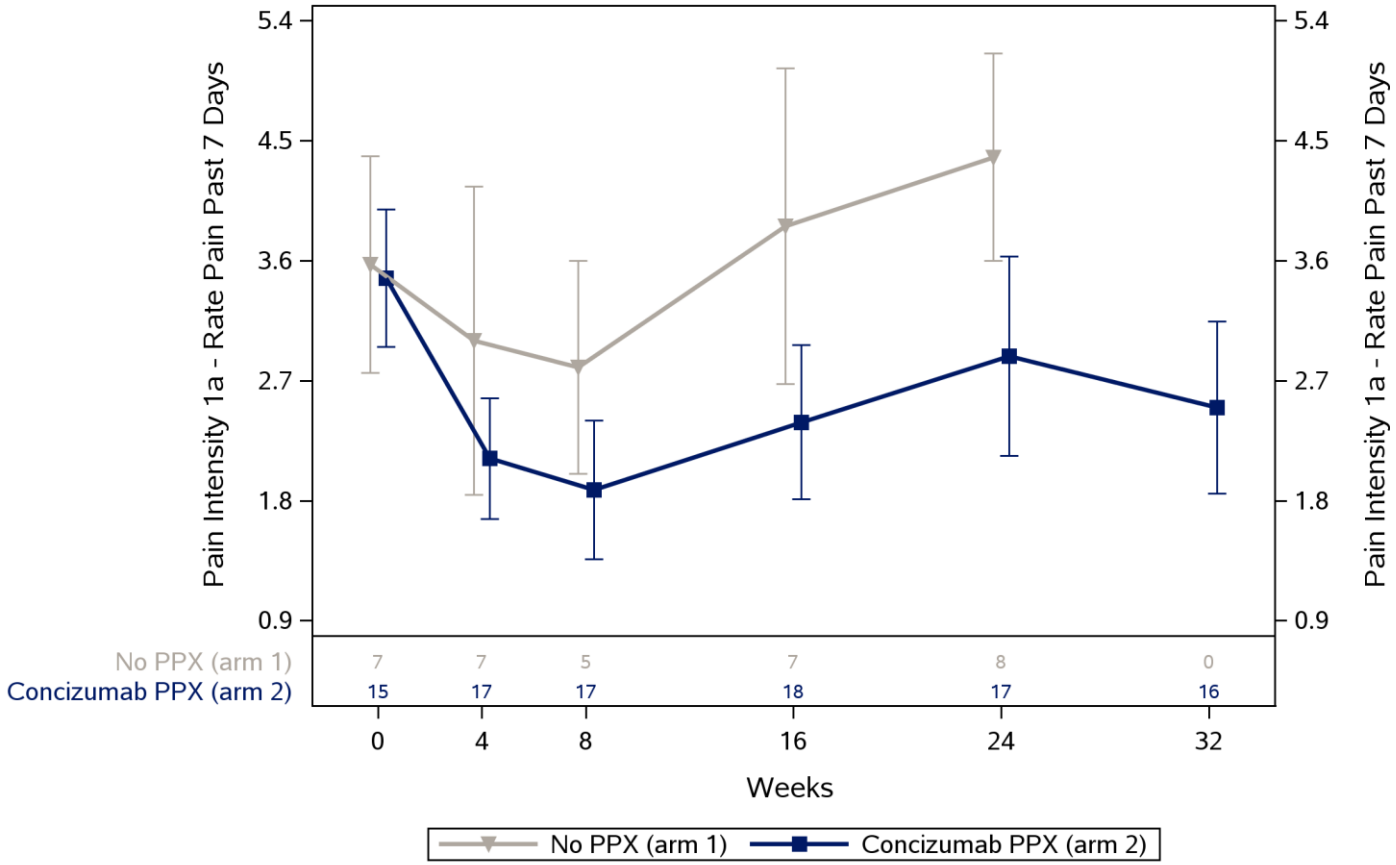
2.3.3.12 PROMIS Numeric Rating Scale v.1.0 – Pain Intensity 1a - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
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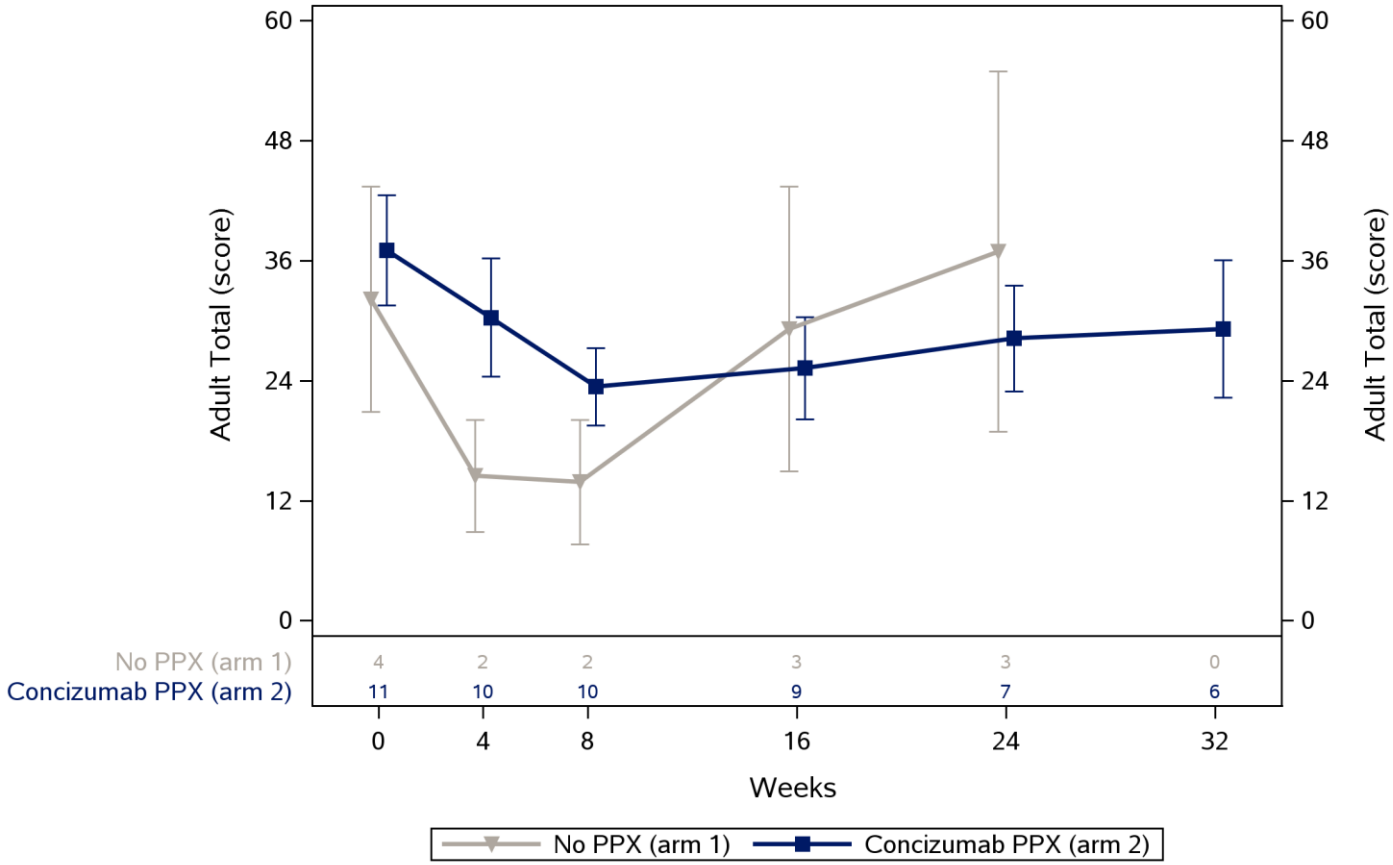
2.3.3.13 HAEM-A-QoL - Total score - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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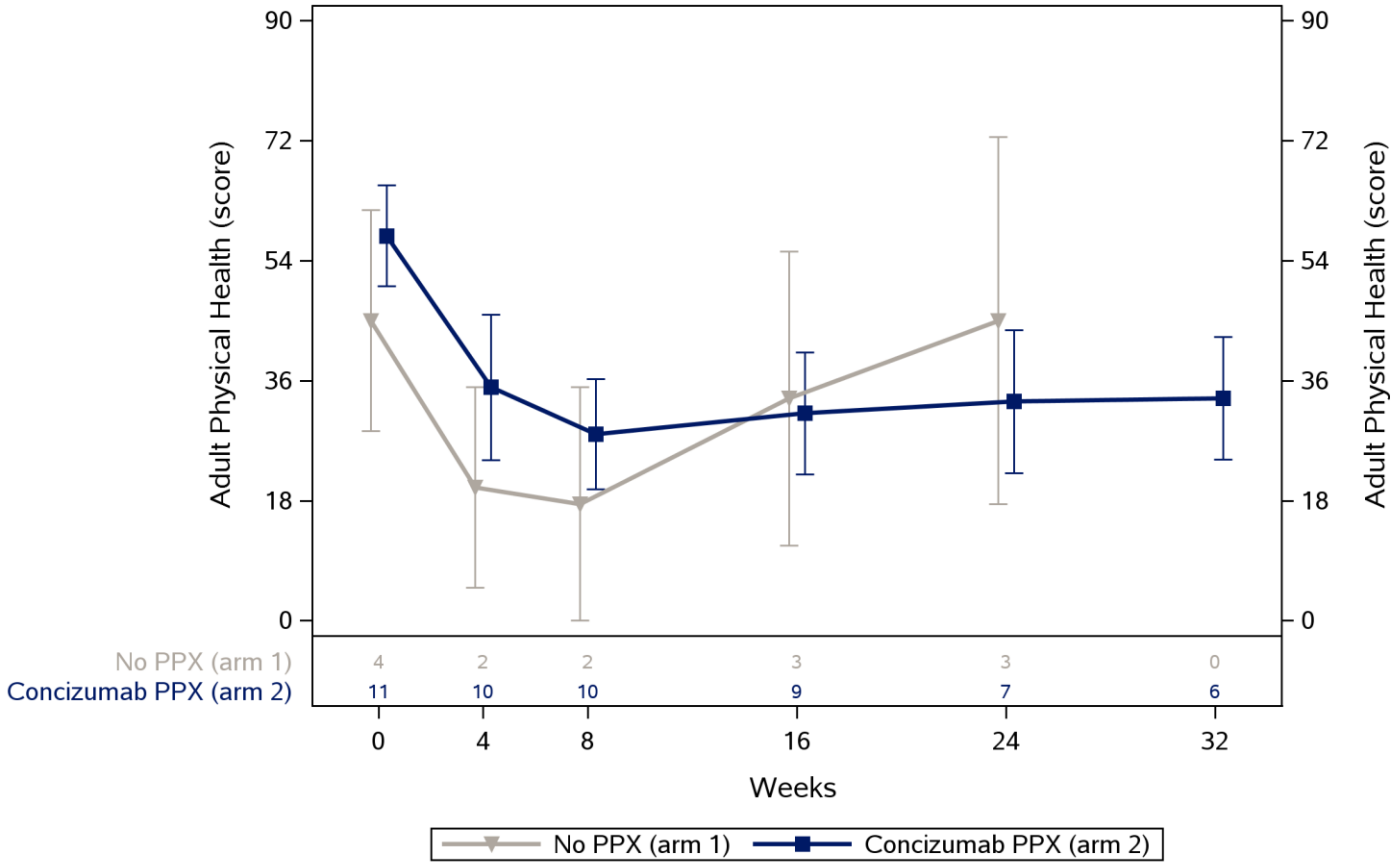
2.3.3.14 HAEM-A-QoL - Physical Health - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
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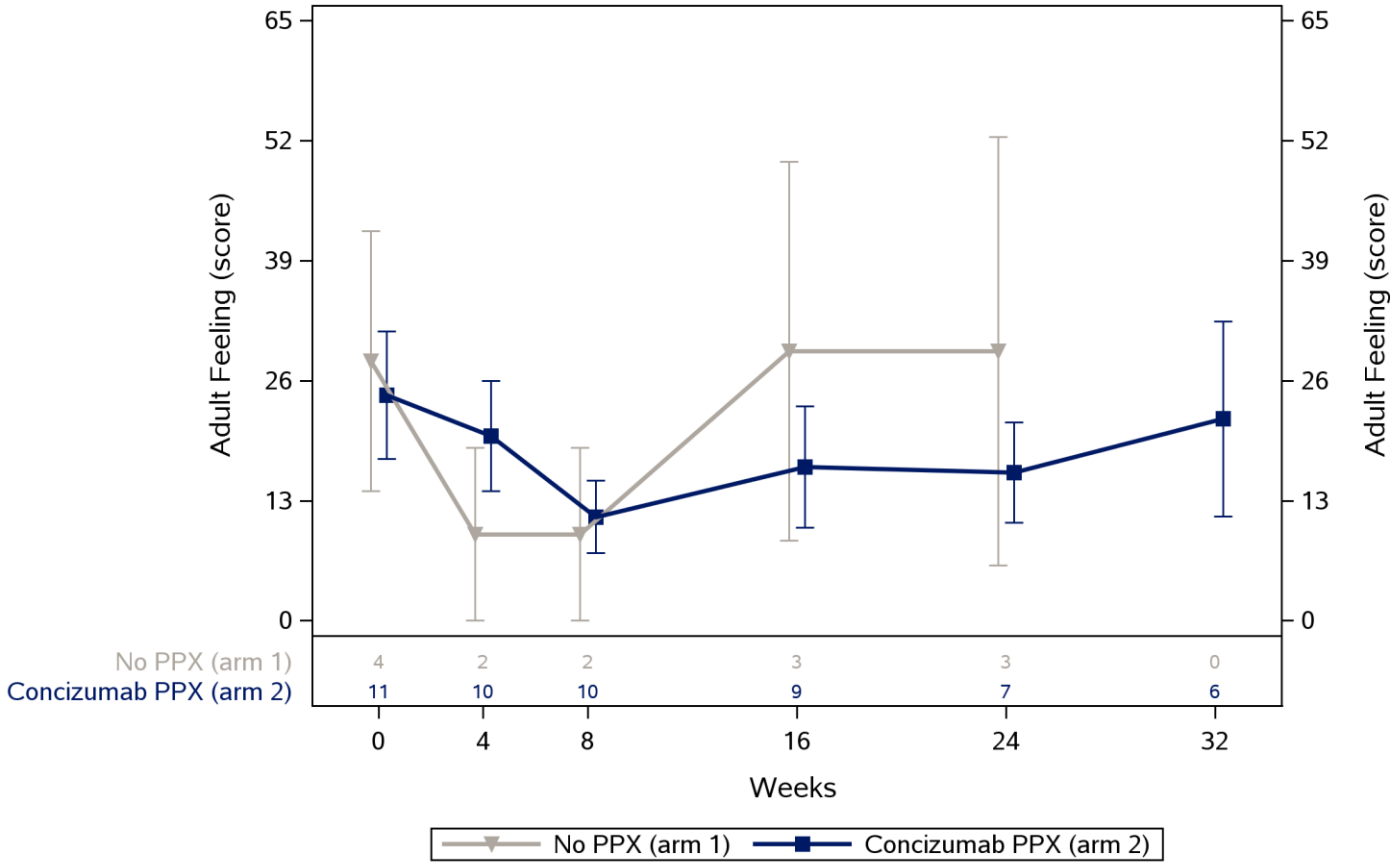
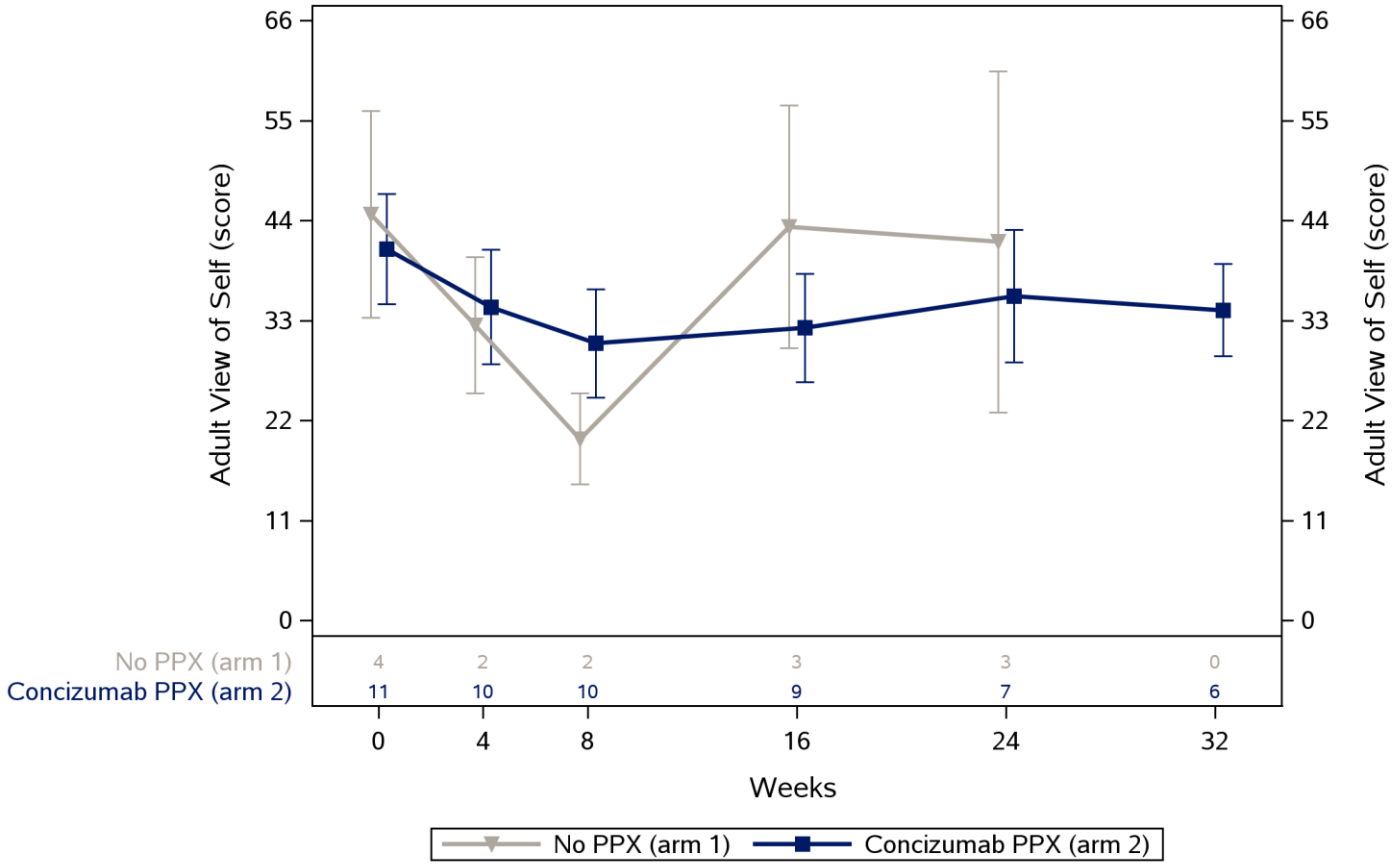
2.3.3.15 HAEM-A-QoL - Feeling - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:04:59 - f-sf36mean.sas/f-HAQ_feelfasHB.png

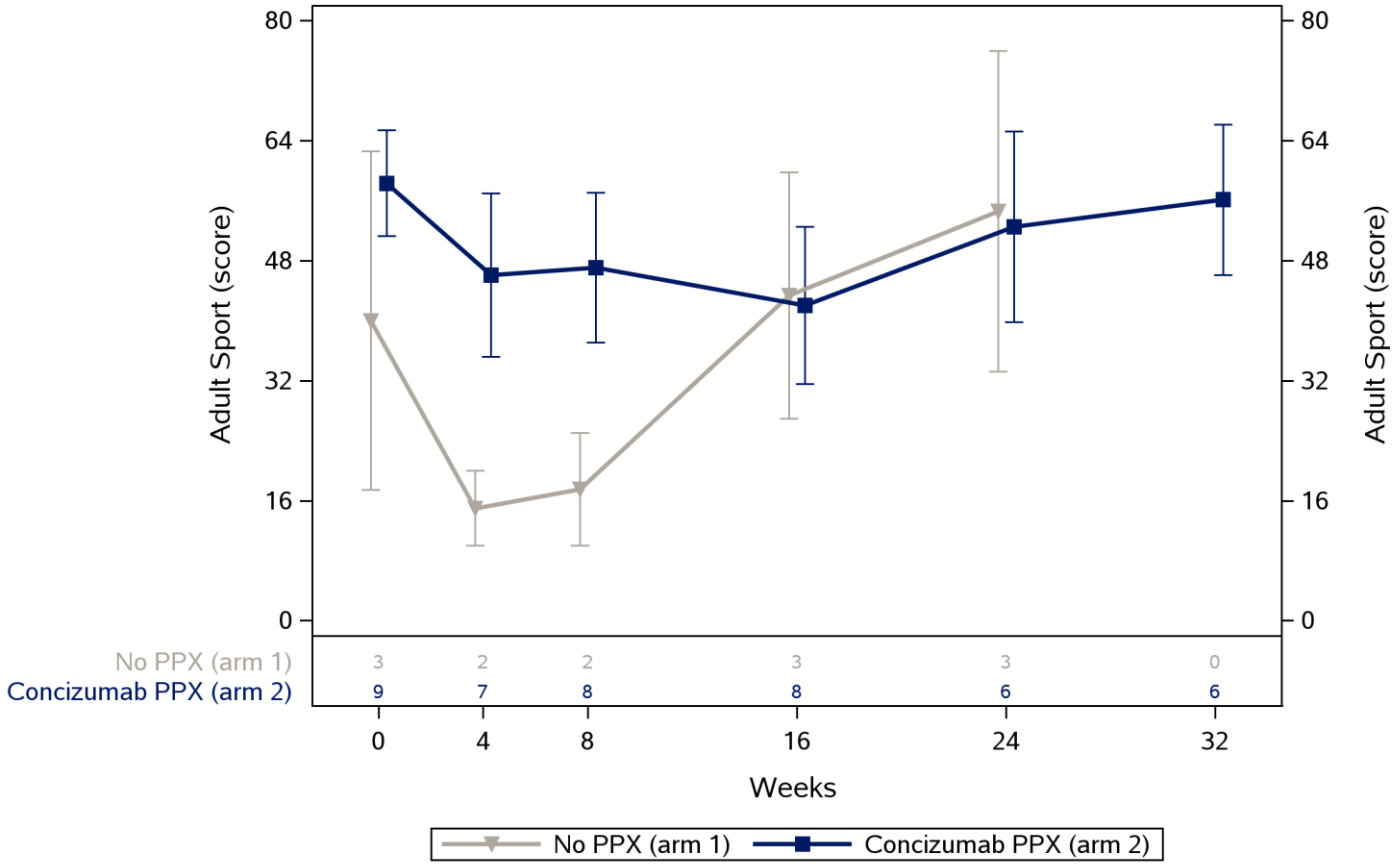
2.3.3.16 HAEM-A-QoL - view of yourself - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:04 - f-sf36mean.sas/f-HAQ_viewfasHB.png

2.3.3.17 HAEM-A-QoL - sport and leisure - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
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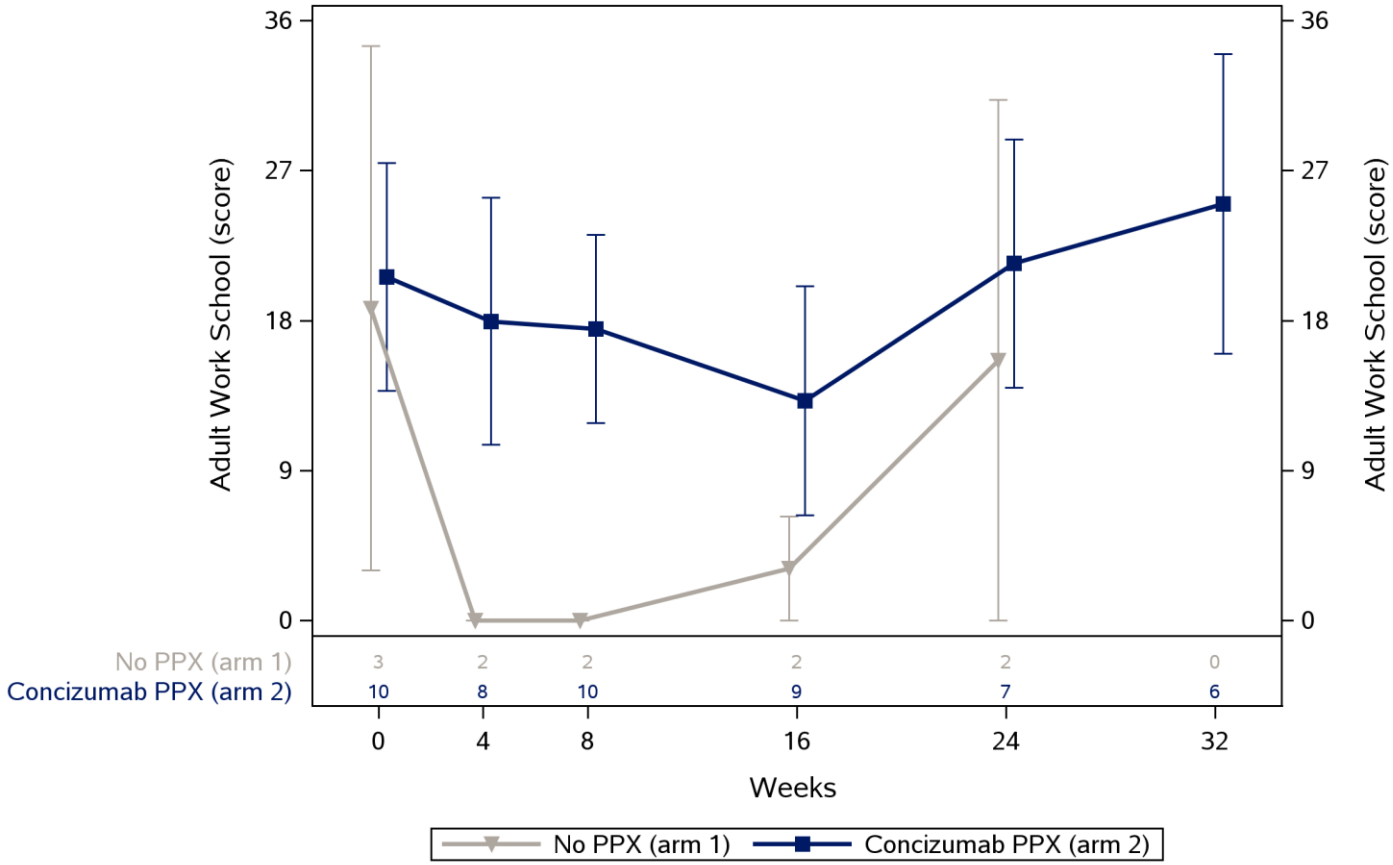
2.3.3.18 HAEM-A-QoL - work and studies - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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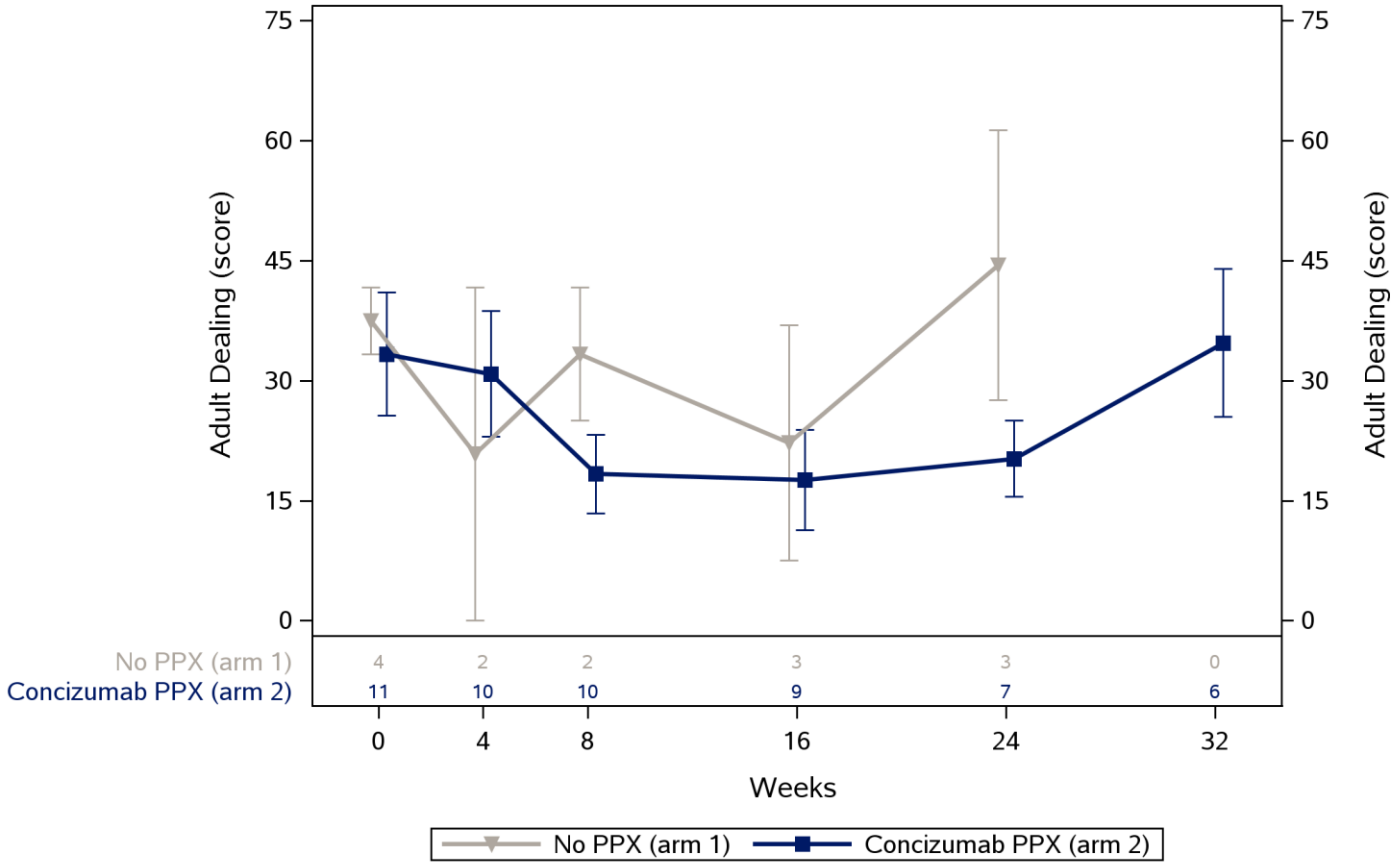
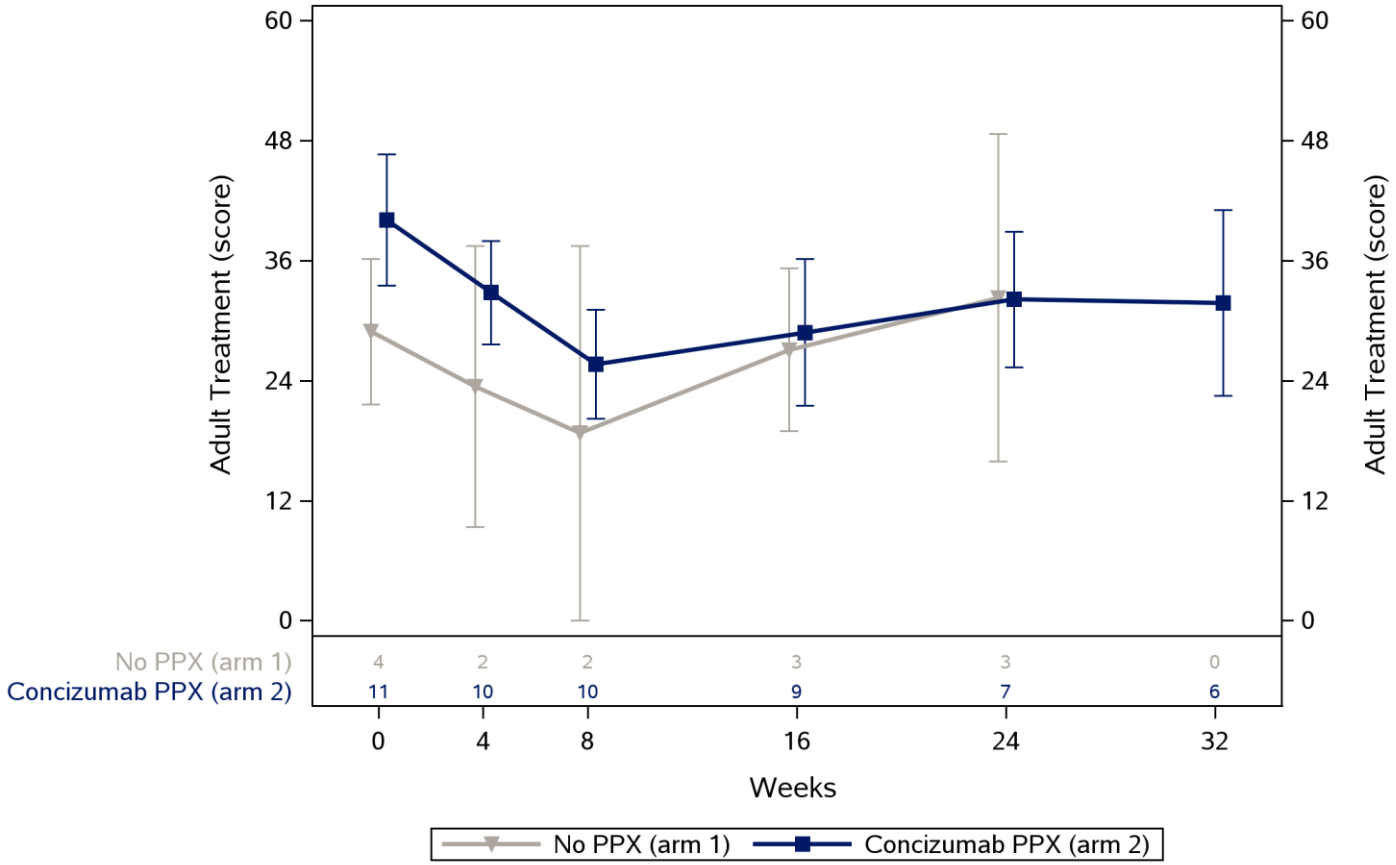
2.3.3.19 HAEM-A-QoL - dealing with haemophilia - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:16 - f-sf36mean.sas/f-HAQ_dealfasHB.png

2.3.3.20 HAEM-A-QoL - treatment - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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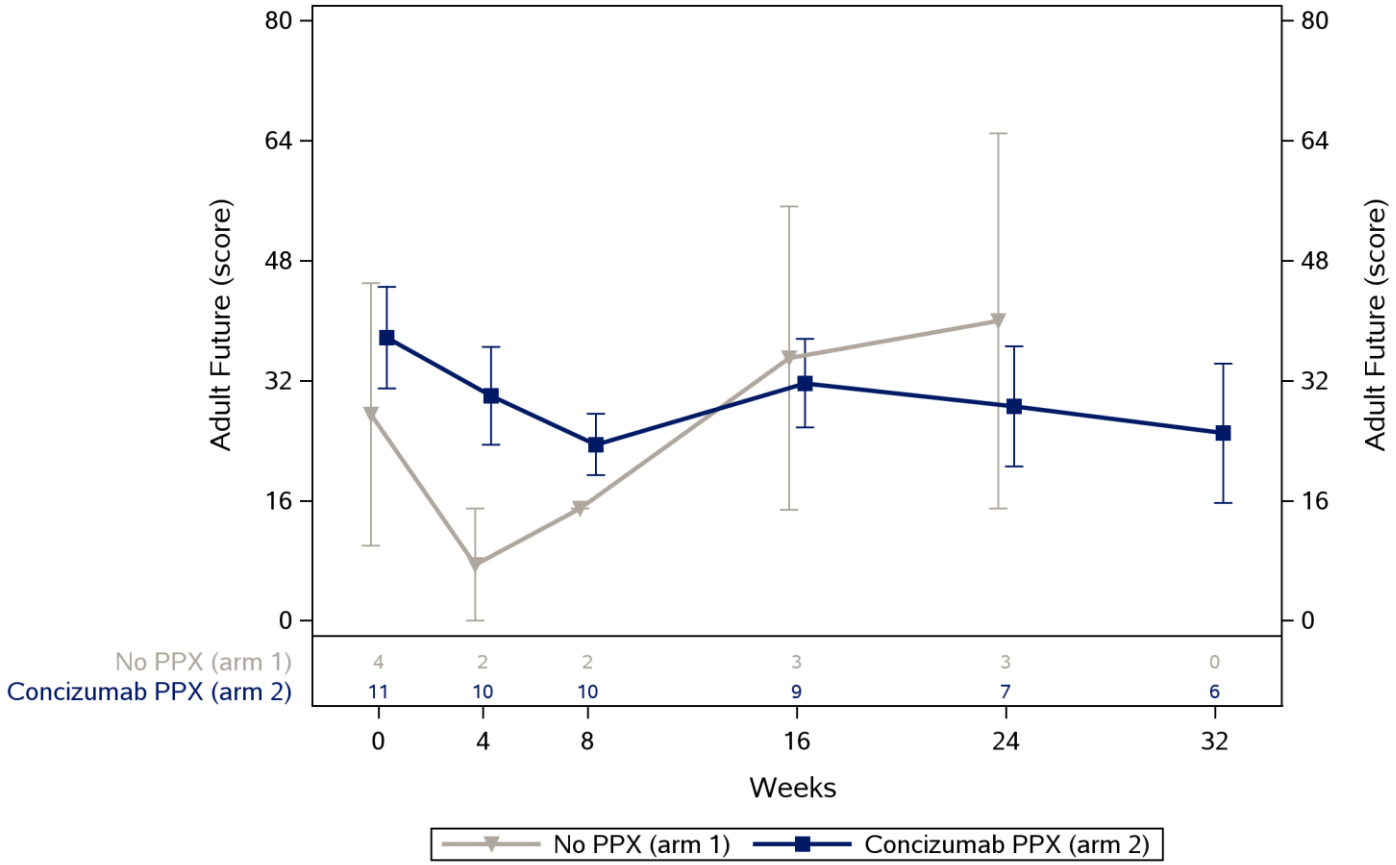
2.3.3.21 HAEM-A-QoL - future - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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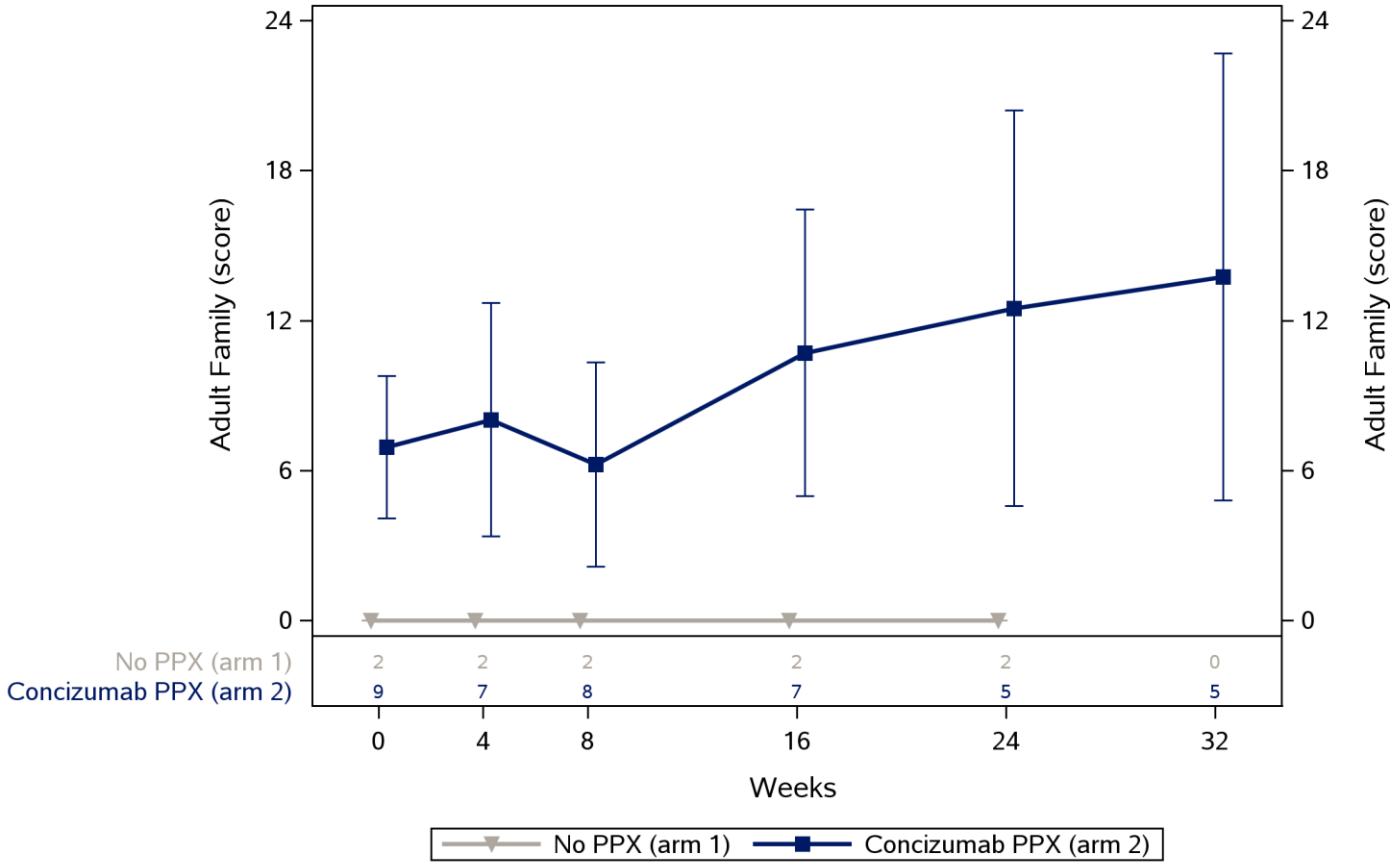
2.3.3.22 HAEM-A-QoL - family planning - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

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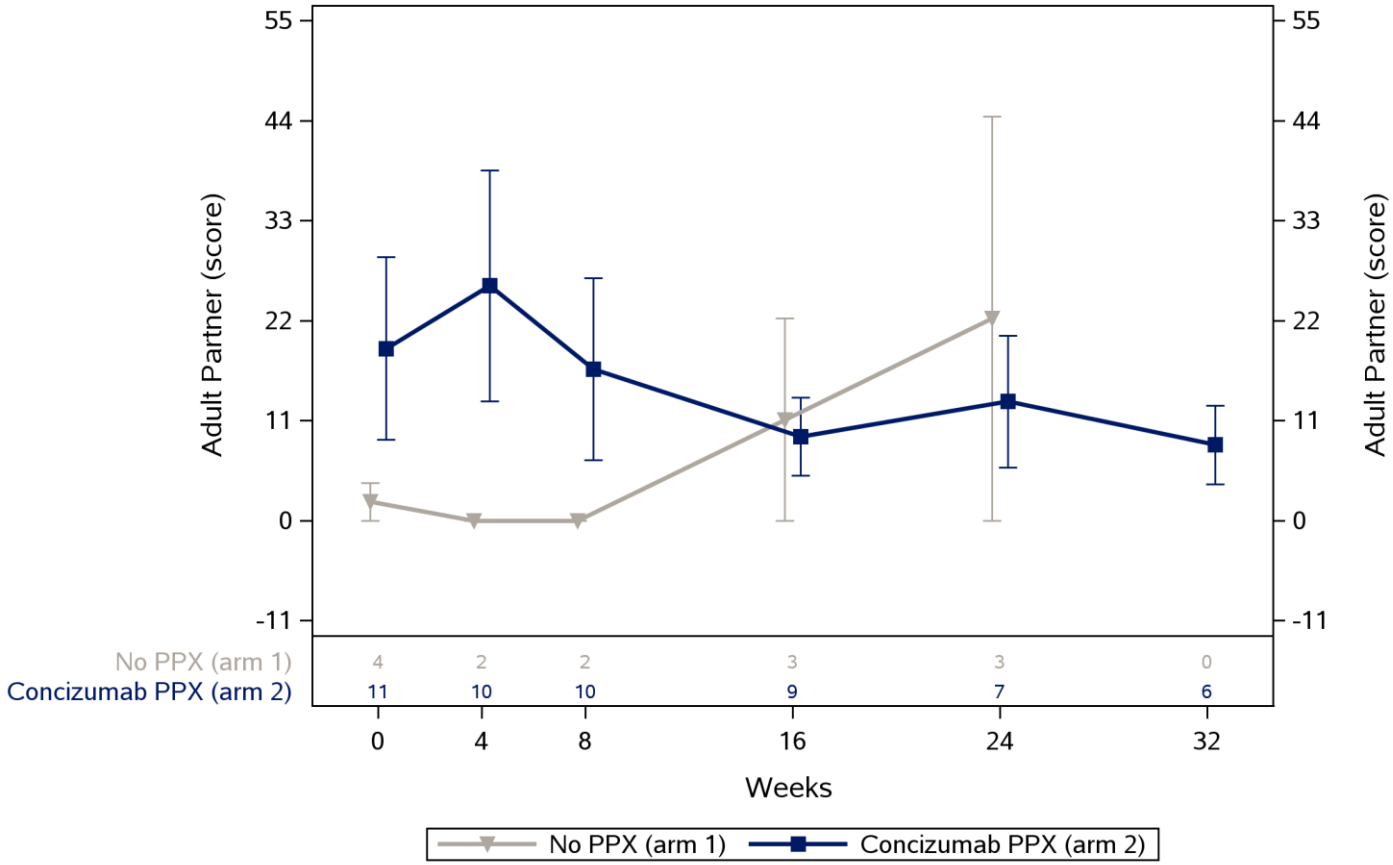
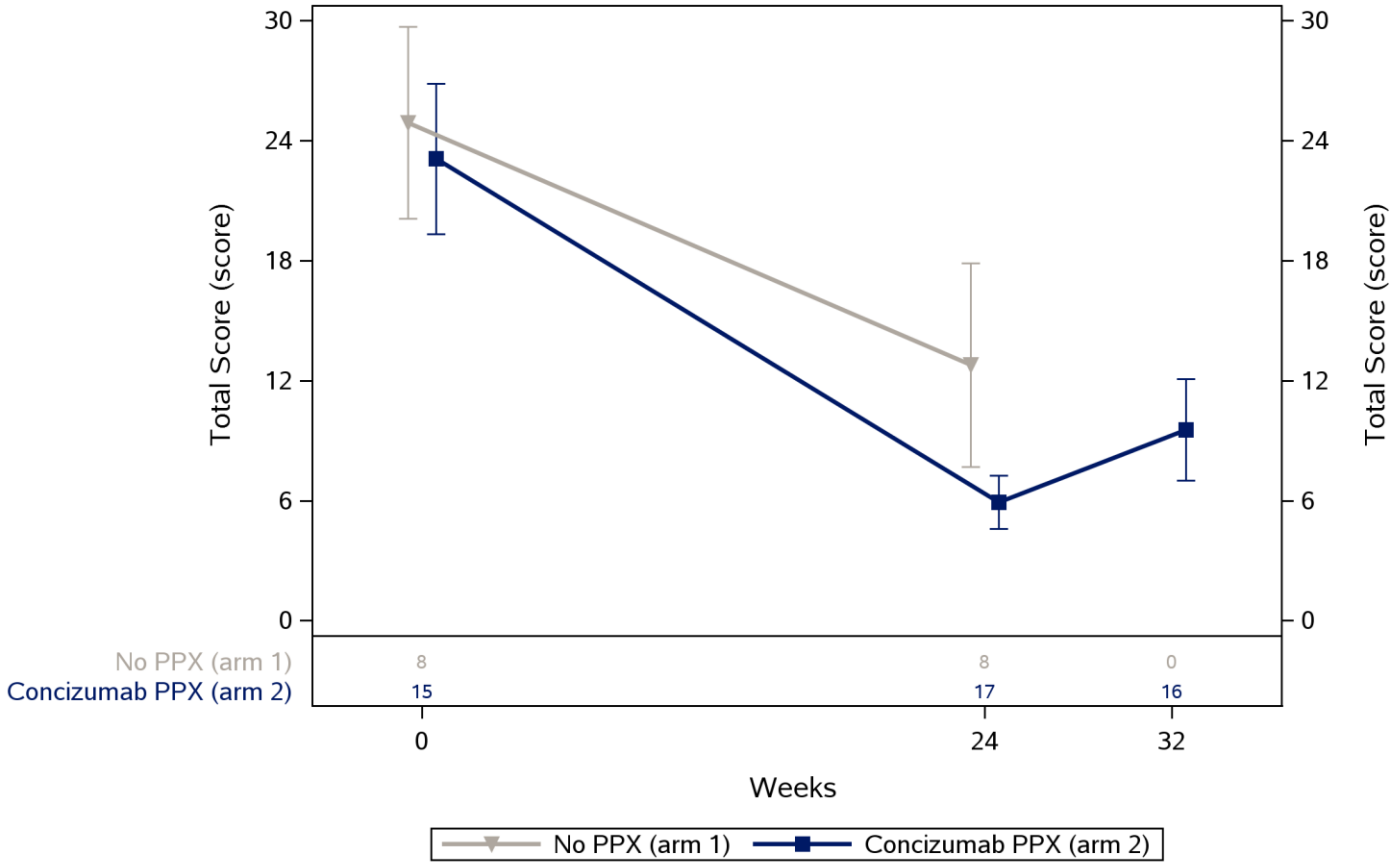
2.3.3.23 HAEM-A-QoL - partnership and sexuality - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:34 - f-sf36mean.sas/f-HAQ_partfasHB.png

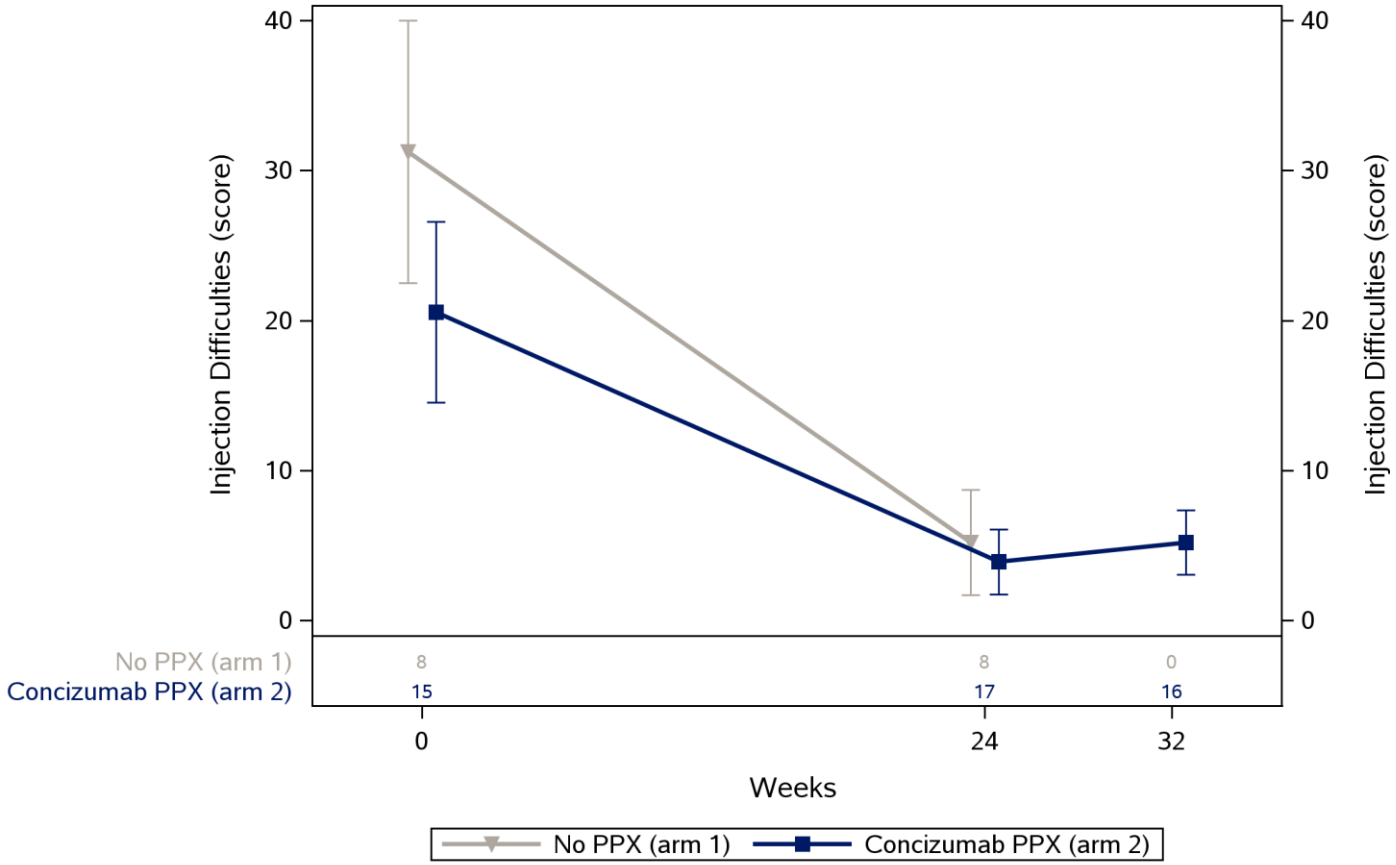
2.3.3.24 Hemo-TEM - Total score - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:38 - f-sf36mean.sas/f-HTEM_totalfasHB.png

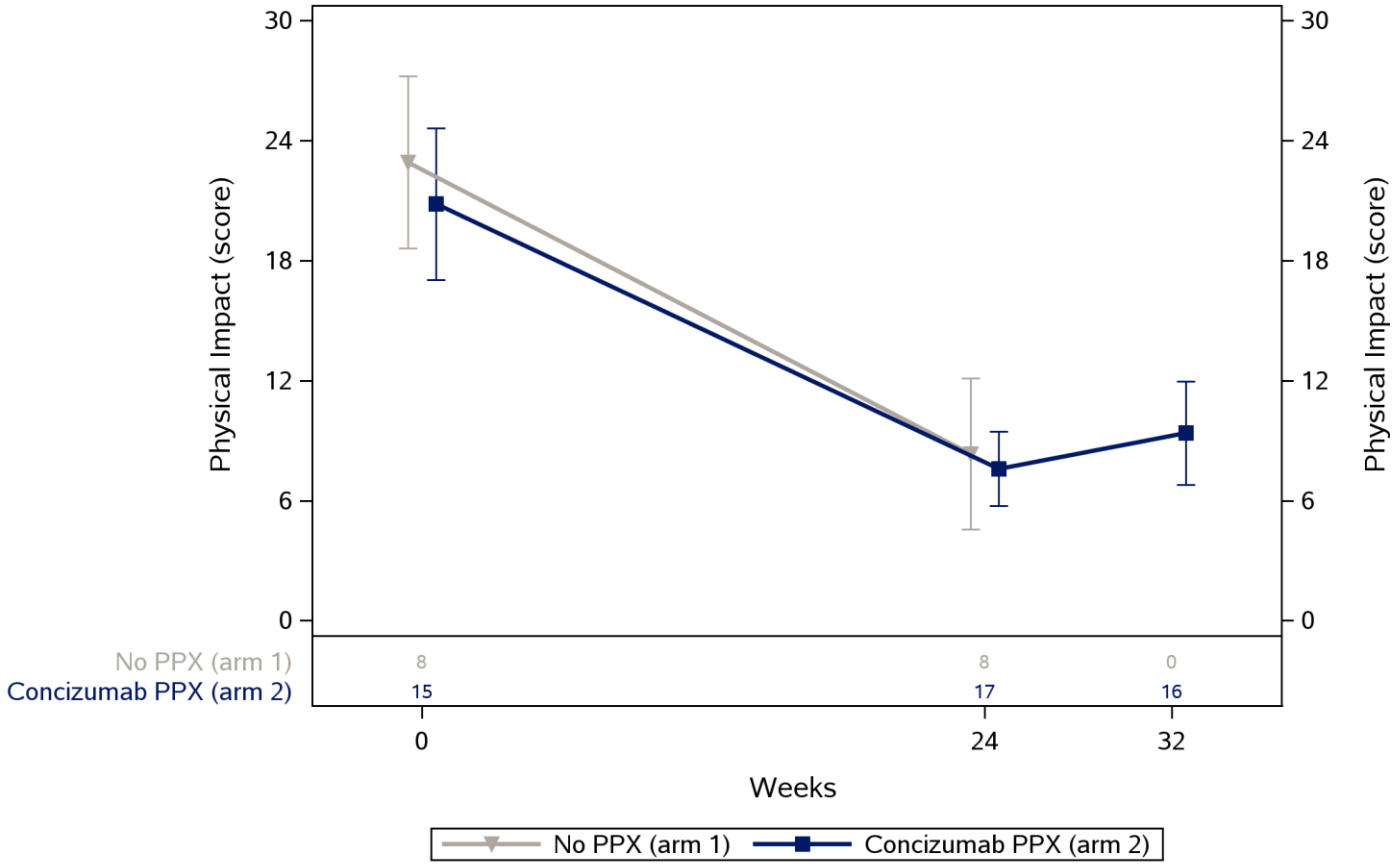
2.3.3.25 Hemo-TEM - Ease of use - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:43 - f-sf36mean.sas/f-HTEM_easefasHB.png

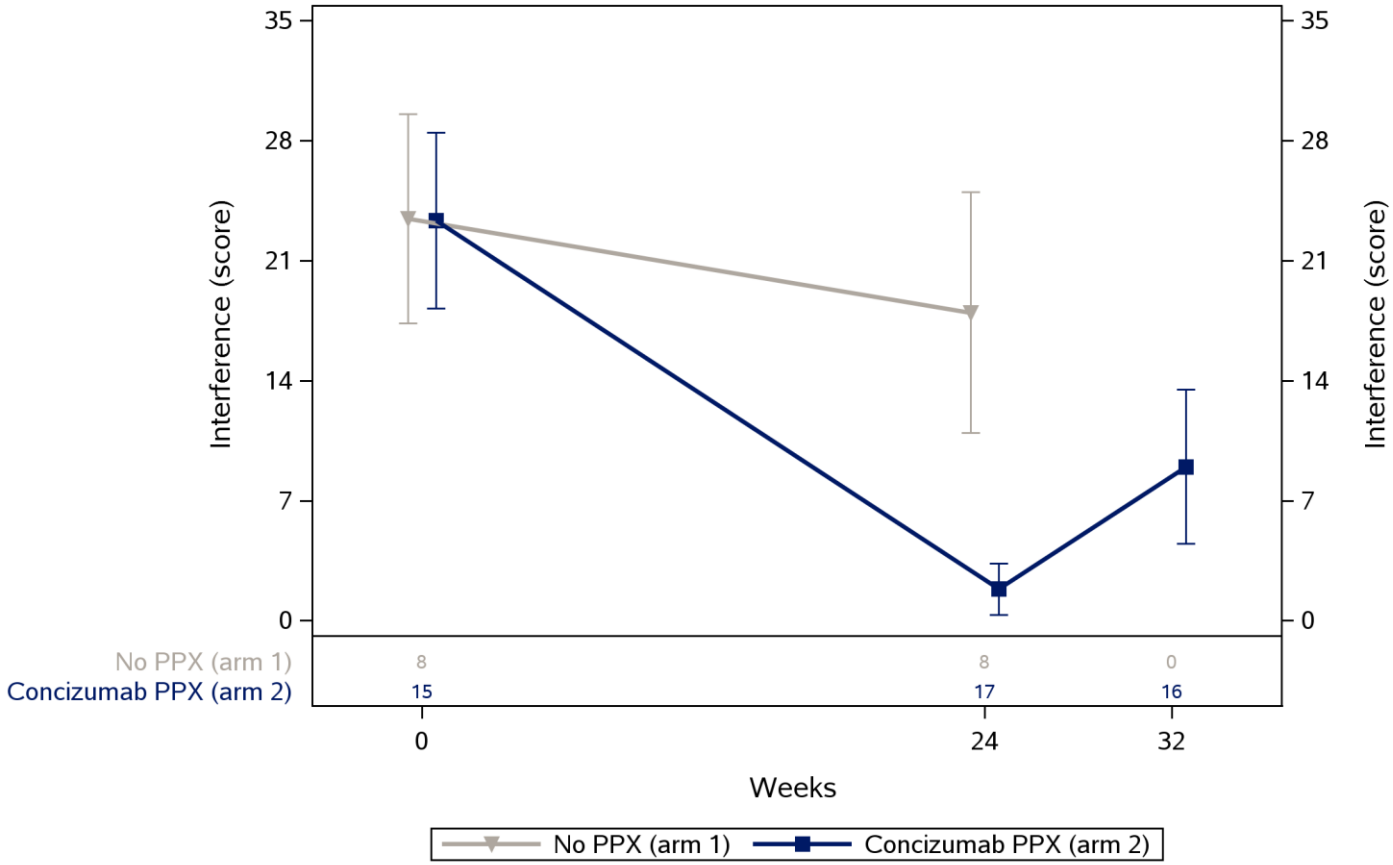
2.3.3.26 Hemo-TEM - Physical impact - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:46 - f-sf36mean.sas/f-HTEM_impactfasHB.png

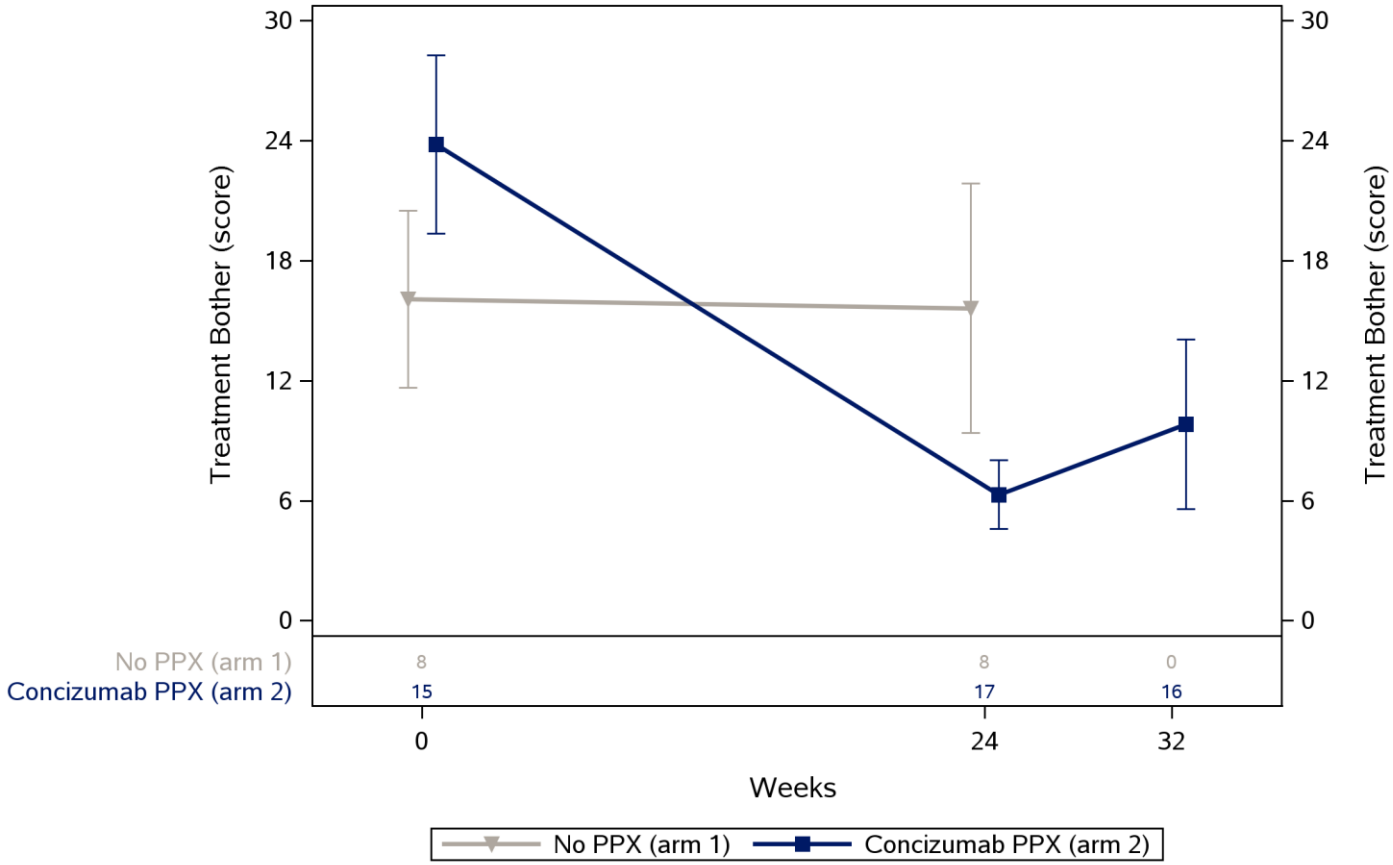
2.3.3.27 Hemo-TEM - Interference - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:50 - f-sf36mean.sas/f-HTEM_interfasHB.png

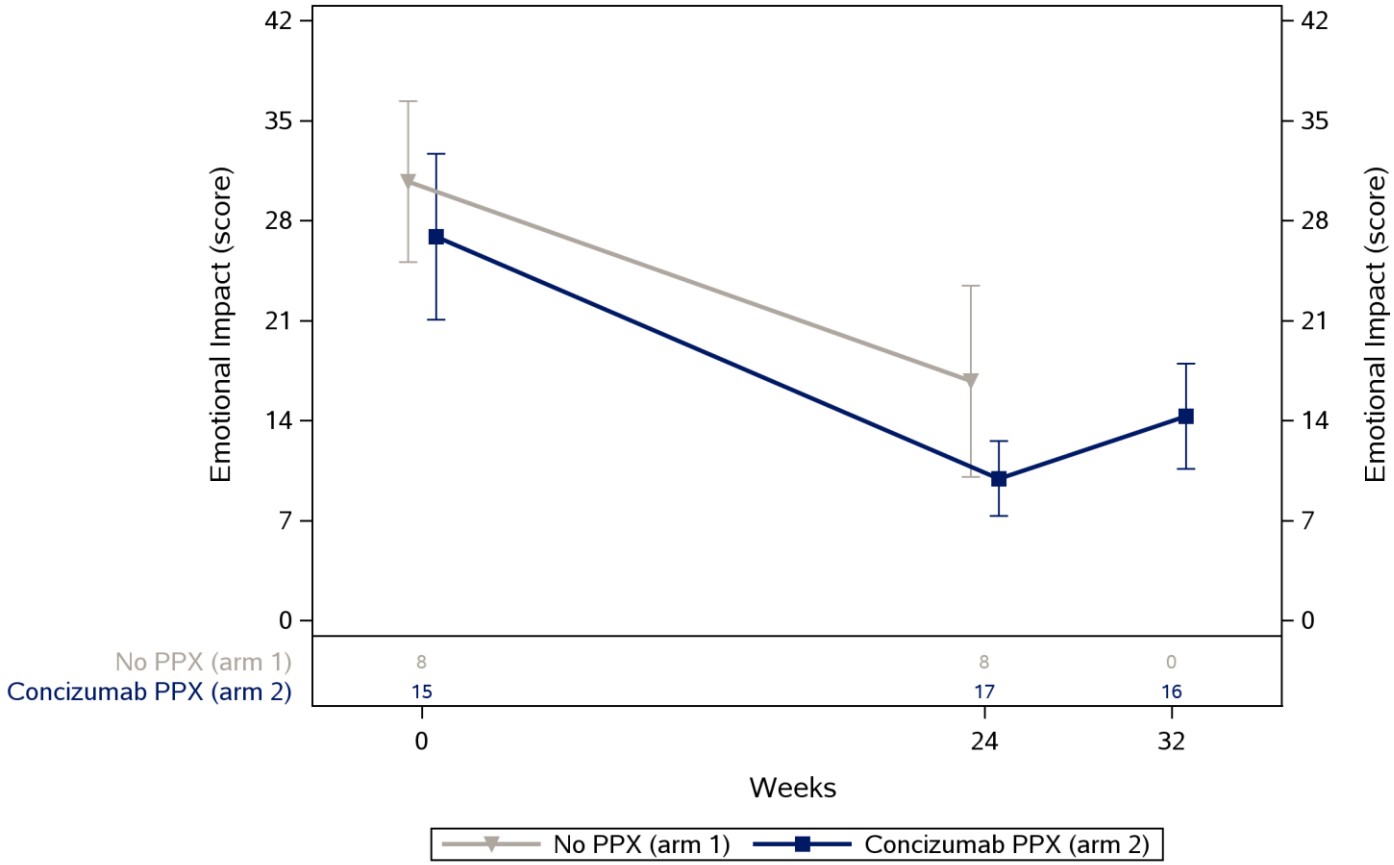
2.3.3.28 Hemo-TEM - Treatment burden - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:53 - f-sf36mean.sas/f-HTEM_burdenfasHB.png

2.3.3.29 Hemo-TEM - Emotional impact - mean plot - HB - OTexBR - full analysis set



HB: haemophilia B, OTexBR: On-treatment without data before restart.
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).
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:05:57 - f-sf36mean.sas/f-HTEM_emoimpfasHB.png

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Statistical documentation

2.3.4.1 Return rates of PGI-C on physical functioning by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Week 24	12	8 (66.7)	23	17 (73.9)
Age					
< 18 years	Week 24	3	2 (66.7)	6	5 (83.3)
>= 18 years	Week 24	9	6 (66.7)	17	12 (70.6)
OECD membership					
Non-OECD country	Week 24	7	4 (57.1)	14	11 (78.6)
OECD country	Week 24	5	4 (80.0)	9	6 (66.7)

PGI-C: Patient Global Impression of Change, HB: haemophilia B, PPX: Prophylaxis, N: number of subjects in the analysis set who did not disc ontinue before the nominal week of the visit, n: number of subjects contributing to analysis. 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".
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:52 - t-returnrtsumfas.sas/t-returnrtsumfas-pgicHB.txt

2.3.4.2 Return rates of PGI-S on physical functioning by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)

PGI-S: Patient Global Impression of Severity, HB: haemophilia B, PPX: Prophylaxis, N: number of subjects in the analysis set who did not di scontinue before the nominal week of the visit, n: number of subjects contributing to analysis. 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.
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:52 - t-returnrtsumfas.sas/t-returnrtsumfas-pgisHB.txt

2.3.4.3 Return rates of Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:53 - t-returnrtsumfas.sas/t-returnrtsumfas-pro1HB.txt

2.3.4.4 Return rates of Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL feeling domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:54 - t-returnrtsumfas.sas/t-returnrtsumfas-pro3HB.txt

2.3.4.5 Return rates of Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL future domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:54 - t-returnrtsumfas.sas/t-returnrtsumfas-pro4HB.txt

2.3.4.6 Return rates of Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

2.3.4.7 Return rates of Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL physical health domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:55 - t-returnrtsumfas.sas/t-returnrtsumfas-pro5HB.txt

2.3.4.8 Return rates of Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	3 (25.0)	24	9 (37.5)
	Week 4	12	2 (16.7)	23	7 (30.4)
	Week 8	12	2 (16.7)	23	8 (34.8)
	Week 16	12	3 (25.0)	23	8 (34.8)
	Week 24	12	3 (25.0)	23	6 (26.1)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	3 (33.3)	18	9 (50.0)
	Week 4	9	2 (22.2)	17	7 (41.2)
	Week 8	9	2 (22.2)	17	8 (47.1)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	4 (26.7)
	Week 4	7	1 (14.3)	14	3 (21.4)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)
OECD country	Baseline	5	2 (40.0)	9	5 (55.6)
	Week 4	5	1 (20.0)	9	4 (44.4)
	Week 8	5	1 (20.0)	9	4 (44.4)
	Week 16	5	2 (40.0)	9	4 (44.4)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL sport and leisure domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 24	5	2 (40.0)	9	2 (22.2)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:55 - t-returnrtsumfas.sas/t-returnrtsumfas-pro7HB.txt

2.3.4.9 Return rates of Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:56 - t-returnrtsumfas.sas/t-returnrtsumfas-pro8HB.txt

Return rates of Haem-A-QoL total score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:56 - t-returnrtsumfas.sas/t-returnrtsumfas-pro8HB.txt

2.3.4.10 Return rates of Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL treatment domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:56 - t-returnrtsumfas.sas/t-returnrtsumfas-pro9HB.txt

2.3.4.11 Return rates of Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	4 (33.3)	24	11 (45.8)
	Week 4	12	2 (16.7)	23	10 (43.5)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	3 (25.0)	23	9 (39.1)
	Week 24	12	3 (25.0)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	4 (44.4)	18	10 (55.6)
	Week 4	9	2 (22.2)	17	9 (52.9)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	3 (33.3)	17	8 (47.1)
	Week 24	9	3 (33.3)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	5 (33.3)
	Week 4	7	1 (14.3)	14	5 (35.7)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL view of yourself domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	2 (40.0)	9	5 (55.6)
	Week 24	5	2 (40.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:59 - t-returnrtsumfas.sas/t-returnrtsumfas-pro10HB.txt

2.3.4.12 Return rates of Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	3 (25.0)	24	10 (41.7)
	Week 4	12	2 (16.7)	23	8 (34.8)
	Week 8	12	2 (16.7)	23	10 (43.5)
	Week 16	12	2 (16.7)	23	9 (39.1)
	Week 24	12	2 (16.7)	23	7 (30.4)
	Week 32			23	6 (26.1)
Age					
>= 18 years	Baseline	9	3 (33.3)	18	9 (50.0)
	Week 4	9	2 (22.2)	17	7 (41.2)
	Week 8	9	2 (22.2)	17	9 (52.9)
	Week 16	9	2 (22.2)	17	8 (47.1)
	Week 24	9	2 (22.2)	17	6 (35.3)
	Week 32			17	5 (29.4)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	4 (26.7)
	Week 4	7	1 (14.3)	14	3 (21.4)
	Week 8	7	1 (14.3)	14	4 (28.6)
	Week 16	7	1 (14.3)	14	4 (28.6)
	Week 24	7	1 (14.3)	14	4 (28.6)
	Week 32			14	4 (28.6)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL work and studies domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	2 (40.0)	9	6 (66.7)
	Week 4	5	1 (20.0)	9	5 (55.6)
	Week 8	5	1 (20.0)	9	6 (66.7)
	Week 16	5	1 (20.0)	9	5 (55.6)
	Week 24	5	1 (20.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:59 - t-returnrtsumfas.sas/t-returnrtsumfas-pro11HB.txt

2.3.4.13 Return rates of Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	2 (16.7)	24	9 (37.5)
	Week 4	12	2 (16.7)	23	7 (30.4)
	Week 8	12	2 (16.7)	23	8 (34.8)
	Week 16	12	2 (16.7)	23	7 (30.4)
	Week 24	12	2 (16.7)	23	5 (21.7)
	Week 32			23	5 (21.7)
Age					
>= 18 years	Baseline	9	2 (22.2)	18	8 (44.4)
	Week 4	9	2 (22.2)	17	6 (35.3)
	Week 8	9	2 (22.2)	17	7 (41.2)
	Week 16	9	2 (22.2)	17	6 (35.3)
	Week 24	9	2 (22.2)	17	4 (23.5)
	Week 32			17	4 (23.5)
< 18 years	Baseline			6	1 (16.7)
	Week 4			6	1 (16.7)
	Week 8			6	1 (16.7)
	Week 16			6	1 (16.7)
	Week 24			6	1 (16.7)
	Week 32			6	1 (16.7)
OECD membership					
Non-OECD country	Baseline	7	1 (14.3)	15	4 (26.7)
	Week 4	7	1 (14.3)	14	3 (21.4)
	Week 8	7	1 (14.3)	14	3 (21.4)
	Week 16	7	1 (14.3)	14	3 (21.4)
	Week 24	7	1 (14.3)	14	2 (14.3)
	Week 32			14	3 (21.4)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

Return rates of Haem-A-QoL family planning domain score for subjects older than 16 years by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Baseline	5	1 (20.0)	9	5 (55.6)
	Week 4	5	1 (20.0)	9	4 (44.4)
	Week 8	5	1 (20.0)	9	5 (55.6)
	Week 16	5	1 (20.0)	9	4 (44.4)
	Week 24	5	1 (20.0)	9	3 (33.3)
	Week 32			9	2 (22.2)

HB: haemophilia B, PPX: Prophylaxis, 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. 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. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:06:53 - t-returnrtsumfas.sas/t-returnrtsumfas-pro2HB.txt

2.3.4.14 Return rates of Hemo-TEM Total Score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.15 Return rates of Hemo-TEM ease of use by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.16 Return rates of Hemo-TEM emotional impact by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.17 Return rates of Hemo-TEM interference by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.18 Return rates of Hemo-TEM physical impact by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.19 Return rates of Hemo-TEM treatment burden by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.20 Return rates of PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	7 (58.3)	24	15 (62.5)
	Week 4	12	7 (58.3)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	6 (66.7)	18	12 (66.7)
	Week 4	9	5 (55.6)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	2 (40.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	3 (60.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.21 Return rates of PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	7 (58.3)	24	13 (54.2)
	Week 4	12	7 (58.3)	23	14 (60.9)
	Week 8	12	5 (41.7)	23	15 (65.2)
	Week 16	12	7 (58.3)	23	16 (69.6)
	Week 24	12	8 (66.7)	23	16 (69.6)
	Week 32			23	14 (60.9)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	6 (66.7)	18	10 (55.6)
	Week 4	9	5 (55.6)	17	9 (52.9)
	Week 8	9	3 (33.3)	17	10 (58.8)
	Week 16	9	5 (55.6)	17	11 (64.7)
	Week 24	9	6 (66.7)	17	11 (64.7)
	Week 32			17	10 (58.8)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	2 (40.0)	9	4 (44.4)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of PROMIS Short Form v2.0 Upper Extremity 7a by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	3 (60.0)	9	4 (44.4)
	Week 8	5	2 (40.0)	9	5 (55.6)
	Week 16	5	3 (60.0)	9	5 (55.6)
	Week 24	5	4 (80.0)	9	5 (55.6)
	Week 32			9	4 (44.4)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.22 Return rates of SF-36v2 general health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 general health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.23 Return rates of SF-36v2 mental health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 mental health by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:07:06 - t-returnrtsumfas.sas/t-returnrtsumfas-pro27HB.txt

2.3.4.24 Return rates of SF-36v2 role emotional by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 role emotional by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.25 Return rates of SF-36v2 role physical by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 role physical by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.26 Return rates of SF-36v2 social function by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 social function by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.27 Return rates of SF-36v2 vitality by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 vitality by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.28 Return rates of SF-36v2 mental component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 mental component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.29 Return rates of SF-36v2 physical component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 physical component score by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:07:06 - t-returnrtsumfas.sas/t-returnrtsumfas-pro28HB.txt

2.3.4.30 Return rates of SF-36v2 bodily pain by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 bodily pain by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

2.3.4.31 Return rates of SF-36v2 physical functioning by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
Total					
All subjects	Baseline	12	8 (66.7)	24	15 (62.5)
	Week 4	12	8 (66.7)	23	17 (73.9)
	Week 8	12	5 (41.7)	23	17 (73.9)
	Week 16	12	7 (58.3)	23	18 (78.3)
	Week 24	12	8 (66.7)	23	17 (73.9)
	Week 32			23	16 (69.6)
Age					
< 18 years	Baseline	3	1 (33.3)	6	3 (50.0)
	Week 4	3	2 (66.7)	6	5 (83.3)
	Week 8	3	2 (66.7)	6	5 (83.3)
	Week 16	3	2 (66.7)	6	5 (83.3)
	Week 24	3	2 (66.7)	6	5 (83.3)
	Week 32			6	4 (66.7)
>= 18 years	Baseline	9	7 (77.8)	18	12 (66.7)
	Week 4	9	6 (66.7)	17	12 (70.6)
	Week 8	9	3 (33.3)	17	12 (70.6)
	Week 16	9	5 (55.6)	17	13 (76.5)
	Week 24	9	6 (66.7)	17	12 (70.6)
	Week 32			17	12 (70.6)
OECD membership					
Non-OECD country	Baseline	7	5 (71.4)	15	9 (60.0)
	Week 4	7	4 (57.1)	14	10 (71.4)
	Week 8	7	3 (42.9)	14	10 (71.4)
	Week 16	7	4 (57.1)	14	11 (78.6)
	Week 24	7	4 (57.1)	14	11 (78.6)
	Week 32			14	10 (71.4)
OECD country	Baseline	5	3 (60.0)	9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

Return rates of SF-36v2 physical functioning by treatment week - Explorer 8 - HB - OTexBR - Full analysis set

		HB			
		No PPX		Concizumab PPX	
		N	n (%)	N	n (%)
OECD country	Week 4	5	4 (80.0)	9	7 (77.8)
	Week 8	5	2 (40.0)	9	7 (77.8)
	Week 16	5	3 (60.0)	9	7 (77.8)
	Week 24	5	4 (80.0)	9	6 (66.7)
	Week 32			9	6 (66.7)

HB: haemophilia B, PPX: Prophylaxis, 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. 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.
Cut off date for data is 12th July 2022.

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2.3.1.1 PGI-C on physical functioning responders a week 24 - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	10 (41.7)	12	1 (8.3)	7.86 (0.87, 71.06)	5.00 (0.72, 34.63)	33.33 (8.16, 58.50)	0.0454
Age group								
< 18 years	6	4 (66.7)	3	0 (0.0)				
>= 18 years	18	6 (33.3)	9	1 (11.1)				
OECD membership								
OECD country	9	3 (33.3)	5	0 (0.0)				
Non-OECD country	15	7 (46.7)	7	1 (14.3)				

PGI-C: Patient Global Impression of Change, responder: Subjects with VERY MUCH BETTER or MODERATELY BETTER at week 24, HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with an observed response at week 24, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. All randomized patients were included in the analysis of PGI-C, whether or not week 24 data was available. Patients without week 24 data were considered non-responders. Cut off date for data is 12th July 2022.

2.3.1.2 PGI-S on physical functioning responders a week 24 - Explorer 8 - HB - OTexBR - Full analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	7 (29.2)	12	0 (0.0)	10.71 (0.56, 205.38)	7.80 (0.48, 126.13)	29.17 (10.98, 47.35)	0.0441

PGI-S: Patient Global Impression of Severity, responder: Subjects who improve at least one level from baseline to week 24, HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with an observed response at week 24, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. All randomized patients were included in the analysis of PGI-S, whether or not week 24 data was available. Patients without week 24 data were considered non-responders. Cut off date for data is 12th July 2022.

2.3.1.3 Change from baseline to week 24 in Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	37.50 (8.33)		24	11	33.33 (25.55)					
Week 24	12	3	44.44 (29.27)		23	7	20.24 (12.60)					
Change from baseline to week 24	12	3	5.56 (37.58)	10.82 (10.80)	23	7	-9.52 (17.63)	-11.10 (6.59)	-21.92 [-48.62; 4.77]	0.1013	-0.96 [-2.29; 0.36]	
Age												
< 18 years												
Baseline					6	1	16.67 (NA)					
Week 24					6	1	25.00 (NA)					
Change from baseline to week 24					6	1	8.33 (NA)	12.99 (21.90)	NE [NE; NE]	NE	NE [NE; NE]	0.8283
>= 18 years												
Baseline	9	4	37.50 (8.33)		18	10	35.00 (26.29)					
Week 24	9	3	44.44 (29.27)		17	6	19.44 (13.61)					
Change from baseline to week 24	9	3	5.56 (37.58)	11.44 (11.13)	17	6	-12.50 (17.28)	-13.43 (7.12)	-24.87 [-53.57; 3.83]	0.0839	-1.05 [-2.41; 0.30]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL dealing with haemophilia domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	33.33 (NA)		15	5	48.33 (33.02)					
Week 24	7	1	75.00 (NA)		14	4	27.08 (7.98)					
Change from baseline to week 24	7	1	41.67 (NA)	41.10 (17.43)	14	4	-10.42 (20.83)	-5.36 (8.22)	-46.46 [-90.25; -2.67]	0.0399	-2.02 [-4.46; 0.41]	0.0046
OECD country												
Baseline	5	3	38.89 (9.62)		9	6	20.83 (4.56)					
Week 24	5	2	29.17 (17.68)		9	3	11.11 (12.73)					
Change from baseline to week 24	5	2	-12.50 (29.46)	-8.37 (13.12)	9	3	-8.33 (16.67)	-18.74 (8.62)	-10.37 [-46.35; 25.60]	0.5306	-0.44 [-2.05; 1.18]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.4 Change from baseline to week 24 in Haem-A-QoL feeling domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	28.12 (28.18)		24	11	24.43 (22.96)					
Week 24	12	3	29.17 (40.18)		23	7	16.07 (14.37)					
Change from baseline to week 24	12	3	0.00 (6.25)	-1.47 (6.87)	23	7	-13.39 (14.63)	-11.09 (4.23)	-9.62 [-26.40; 7.16]	0.2429	-0.66 [-1.96; 0.64]	
Age												
< 18 years												
Baseline					6	1	25.00 (NA)					
Week 24					6	1	31.25 (NA)					
Change from baseline to week 24					6	1	6.25 (NA)	1.48 (12.85)	NE [NE; NE]	NE	NE [NE; NE]	0.6370
>= 18 years												
Baseline	9	4	28.12 (28.18)		18	10	24.38 (24.20)					
Week 24	9	3	29.17 (40.18)		17	6	13.54 (13.93)					
Change from baseline to week 24	9	3	0.00 (6.25)	-1.01 (7.15)	17	6	-16.67 (12.91)	-12.82 (4.66)	-11.81 [-30.19; 6.57]	0.1885	-0.77 [-2.09; 0.56]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL feeling domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	6.25 (NA)		15	5	36.25 (24.37)					
Week 24	7	1	0.00 (NA)		14	4	17.19 (15.62)					
Change from baseline to week 24	7	1	-6.25 (NA)	-7.56 (14.02)	14	4	-12.50 (13.50)	-9.83 (6.34)	-2.27 [-37.95; 33.41]	0.8887	-0.13 [-2.28; 2.02]	0.6771
OECD country												
Baseline	5	3	35.42 (29.54)		9	6	14.58 (17.97)					
Week 24	5	2	43.75 (44.19)		9	3	14.58 (15.73)					
Change from baseline to week 24	5	2	3.12 (4.42)	2.75 (10.72)	9	3	-14.58 (19.09)	-9.99 (6.87)	-12.75 [-40.66; 15.17]	0.3287	-0.67 [-2.30; 0.96]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.5 Change from baseline to week 24 in Haem-A-QoL future domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	27.50 (35.00)		24	11	37.73 (22.51)					
Week 24	12	3	40.00 (43.30)		23	7	28.57 (21.16)					
Change from baseline to week 24	12	3	6.67 (2.89)	3.28 (8.74)	23	7	-12.14 (23.07)	-11.61 (5.01)	-14.89 [-36.14; 6.35]	0.1574	-0.85 [-2.17; 0.46]	
Age												
< 18 years												
Baseline					6	1	20.00 (NA)					
Week 24					6	1	15.00 (NA)					
Change from baseline to week 24					6	1	-5.00 (NA)	-17.93 (16.99)	NE [NE; NE]	NE	NE [NE; NE]	0.9695
>= 18 years												
Baseline	9	4	27.50 (35.00)		18	10	39.50 (22.91)					
Week 24	9	3	40.00 (43.30)		17	6	30.83 (22.23)					
Change from baseline to week 24	9	3	6.67 (2.89)	2.91 (9.16)	17	6	-13.33 (25.03)	-11.05 (5.73)	-13.96 [-37.69; 9.76]	0.2259	-0.73 [-2.05; 0.59]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL future domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	10.00 (NA)		15	5	44.00 (21.62)					
Week 24	7	1	15.00 (NA)		14	4	37.50 (24.66)					
Change from baseline to week 24	7	1	5.00 (NA)	7.77 (13.84)	14	4	0.00 (17.80)	1.68 (6.08)	-6.10 [-41.11; 28.92]	0.7028	-0.36 [-2.52; 1.80]	0.1046
OECD country												
Baseline	5	3	33.33 (40.41)		9	6	32.50 (23.82)					
Week 24	5	2	52.50 (53.03)		9	3	16.67 (7.64)					
Change from baseline to week 24	5	2	7.50 (3.54)	0.55 (10.18)	9	3	-28.33 (20.82)	-27.16 (6.31)	-27.71 [-54.28; -1.14]	0.0426	-1.58 [-3.35; 0.20]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.6 Change from baseline to week 24 in Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	2.08 (4.17)		24	11	18.94 (33.35)					
Week 24	12	3	22.22 (38.49)		23	7	13.10 (19.16)					
Change from baseline to week 24	12	3	19.44 (33.68)	17.28 (16.51)	23	7	-2.38 (10.45)	-4.85 (9.66)	-22.13 [-62.28; 18.02]	0.2610	-0.66 [-1.96; 0.64]	
Age												
< 18 years												
Baseline					6	1	0.00 (NA)					
Week 24					6	1	0.00 (NA)					
Change from baseline to week 24					6	1	0.00 (NA)	-9.58 (31.12)	NE [NE; NE]	NE	NE [NE; NE]	0.9996
>= 18 years												
Baseline	9	4	2.08 (4.17)		18	10	20.83 (34.53)					
Week 24	9	3	22.22 (38.49)		17	6	15.28 (20.01)					
Change from baseline to week 24	9	3	19.44 (33.68)	16.73 (17.82)	17	6	-2.78 (11.39)	-4.27 (11.10)	-21.00 [-67.32; 25.32]	0.3452	-0.57 [-1.88; 0.74]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL partnership and sexuality domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	0.00 (NA)		15	5	41.67 (39.97)					
Week 24	7	1	0.00 (NA)		14	4	22.92 (20.83)					
Change from baseline to week 24	7	1	0.00 (NA)	13.33 (29.83)	14	4	-4.17 (14.43)	-4.88 (15.61)	-18.22 [-98.25; 61.81]	0.6190	-0.42 [-2.58; 1.74]	0.3825
OECD country												
Baseline	5	3	2.78 (4.81)		9	6	0.00 (0.00)					
Week 24	5	2	33.33 (47.14)		9	3	0.00 (0.00)					
Change from baseline to week 24	5	2	29.17 (41.25)	24.62 (23.12)	9	3	0.00 (0.00)	1.38 (16.39)	-23.24 [-81.75; 35.27]	0.3922	-0.52 [-2.14; 1.10]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.7 Change from baseline to week 24 in Haem-A-QoL physical health domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	45.00 (33.17)		24	11	57.73 (25.14)					
Week 24	12	3	45.00 (47.70)		23	7	32.86 (28.41)					
Change from baseline to week 24	12	3	1.67 (20.21)	-1.59 (11.86)	23	7	-27.86 (17.99)	-24.80 (5.93)	-23.21 [-51.88; 5.47]	0.1060	-1.10 [-2.44; 0.24]	
Age												
< 18 years												
Baseline					6	1	90.00 (NA)					
Week 24					6	1	85.00 (NA)					
Change from baseline to week 24					6	1	-5.00 (NA)	-7.00 (19.70)	NE [NE; NE]	NE	NE [NE; NE]	0.4340
>= 18 years												
Baseline	9	4	45.00 (33.17)		18	10	54.50 (23.97)					
Week 24	9	3	45.00 (47.70)		17	6	24.17 (18.28)					
Change from baseline to week 24	9	3	1.67 (20.21)	-1.75 (11.53)	17	6	-31.67 (16.33)	-26.27 (6.05)	-24.52 [-53.20; 4.16]	0.0877	-1.18 [-2.55; 0.19]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL physical health domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	20.00 (NA)		15	5	67.00 (21.68)					
Week 24	7	1	0.00 (NA)		14	4	26.25 (22.87)					
Change from baseline to week 24	7	1	-20.00 (NA)	-19.21 (21.66)	14	4	-32.50 (17.08)	-26.77 (9.49)	-7.56 [-62.91; 47.79]	0.7644	-0.28 [-2.44; 1.87]	0.4907
OECD country												
Baseline	5	3	53.33 (35.12)		9	6	50.00 (27.02)					
Week 24	5	2	67.50 (38.89)		9	3	41.67 (37.86)					
Change from baseline to week 24	5	2	12.50 (10.61)	9.48 (16.39)	9	3	-21.67 (20.82)	-21.13 (8.86)	-30.61 [-73.68; 12.46]	0.1424	-1.21 [-2.92; 0.49]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.8 Change from baseline to week 24 in Haem-A-QoL sport and leisure domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	3	40.00 (39.05)		24	9	58.33 (21.21)					
Week 24	12	3	54.58 (37.09)		23	6	52.50 (31.10)					
Change from baseline to week 24	12	2	17.50 (24.75)	3.91 (19.83)	23	6	-15.83 (31.05)	-20.16 (8.65)	-24.08 [-78.33; 30.18]	0.3497	-0.84 [-2.41; 0.73]	
Age												
>= 18 years												
Baseline	9	3	40.00 (39.05)		18	9	58.33 (21.21)					
Week 24	9	3	54.58 (37.09)		17	6	52.50 (31.10)					
Change from baseline to week 24	9	2	17.50 (24.75)	3.91 (19.83)	17	6	-15.83 (31.05)	-20.16 (8.65)	-24.08 [-78.33; 30.18]	0.3497	-0.84 [-2.41; 0.73]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL sport and leisure domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region									
Non-OECD country									
Baseline	7	1	20.00 (NA)	15	4	71.25 (17.02)			
Week 24	7	1	20.00 (NA)	14	4	67.50 (25.98)			
Change from baseline to week 24	7	1	0.00 (NA) -13.48 (17.44)	14	4	-3.75 (27.50)	3.44 (8.86)	16.93 [-56.33; 90.18]	0.5154 0.69 [-1.54; 2.93] 0.2045
OECD country									
Baseline	5	2	50.00 (49.50)	9	5	48.00 (19.56)			
Week 24	5	2	71.88 (30.94)	9	2	22.50 (10.61)			
Change from baseline to week 24	5	1	35.00 (NA) -14.51 (19.23)	9	2	-40.00 (28.28)	-38.85 (8.51)	-24.34 [-93.94; 45.26]	0.3469 -1.02 [-3.25; 1.20]

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.9 Change from baseline to week 24 in Haem-A-QoL total score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	32.15 (22.51)		24	11	37.02 (18.27)					
Week 24	12	3	36.91 (31.23)		23	7	28.22 (14.02)					
Change from baseline to week 24	12	3	5.70 (8.29)	4.59 (5.31)	23	7	-11.56 (8.67)	-12.27 (2.94)	-16.86 [-29.75; -3.96]	0.0134	-1.64 [-3.05; -0.22]	
Age												
< 18 years												
Baseline					6	1	36.59 (NA)					
Week 24					6	1	30.81 (NA)					
Change from baseline to week 24					6	1	-5.77 (NA)	-10.66 (9.79)	NE [NE; NE]	NE	NE [NE; NE]	0.9842
>= 18 years												
Baseline	9	4	32.15 (22.51)		18	10	37.07 (19.26)					
Week 24	9	3	36.91 (31.23)		17	6	27.79 (15.30)					
Change from baseline to week 24	9	3	5.70 (8.29)	4.68 (5.62)	17	6	-12.52 (9.08)	-12.39 (3.32)	-17.08 [-31.52; -2.64]	0.0240	-1.53 [-2.95; -0.11]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL total score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	13.33 (NA)		15	5	48.85 (18.87)					
Week 24	7	1	9.78 (NA)		14	4	34.61 (14.02)					
Change from baseline to week 24	7	1	-3.55 (NA)	0.61 (8.70)	14	4	-7.51 (6.05)	-5.84 (3.94)	-6.45 [-29.23; 16.33]	0.5378	-0.59 [-2.76; 1.59]	0.3022
OECD country												
Baseline	5	3	38.43 (22.89)		9	6	27.17 (11.24)					
Week 24	5	2	50.47 (29.11)		9	3	19.69 (10.17)					
Change from baseline to week 24	5	2	10.33 (2.99)	5.28 (6.13)	9	3	-16.96 (9.69)	-18.15 (3.92)	-23.43 [-39.58; -7.28]	0.0095	-2.16 [-4.07; -0.24]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.10 Change from baseline to week 24 in Haem-A-QoL treatment domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	28.91 (14.52)		24	11	40.06 (21.78)					
Week 24	12	3	32.29 (28.36)		23	7	32.14 (17.93)					
Change from baseline to week 24	12	3	5.21 (20.33)	2.27 (6.46)	23	7	-15.18 (8.92)	-15.03 (4.11)	-17.30 [-34.16; -0.45]	0.0448	-1.22 [-2.58; 0.13]	
Age												
< 18 years												
Baseline					6	1	43.75 (NA)					
Week 24					6	1	28.12 (NA)					
Change from baseline to week 24					6	1	-15.62 (NA)	-22.03 (11.40)	NE [NE; NE]	NE	NE [NE; NE]	0.8871
>= 18 years												
Baseline	9	4	28.91 (14.52)		18	10	39.69 (22.92)					
Week 24	9	3	32.29 (28.36)		17	6	32.81 (19.54)					
Change from baseline to week 24	9	3	5.21 (20.33)	1.87 (6.72)	17	6	-15.10 (9.77)	-14.15 (4.60)	-16.02 [-34.61; 2.57]	0.0855	-1.06 [-2.41; 0.29]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL treatment domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	15.62 (NA)		15	5	53.75 (21.13)					
Week 24	7	1	0.00 (NA)		14	4	35.16 (24.26)					
Change from baseline to week 24	7	1	-15.62 (NA)	-17.10 (10.01)	14	4	-17.97 (10.00)	-14.54 (5.19)	2.57 [-25.16; 30.30]	0.8388	0.18 [-1.97; 2.33]	0.1227
OECD country												
Baseline	5	3	33.33 (14.09)		9	6	28.65 (15.74)					
Week 24	5	2	48.44 (6.63)		9	3	28.12 (6.25)					
Change from baseline to week 24	5	2	15.62 (13.26)	13.25 (7.16)	9	3	-11.46 (7.22)	-12.02 (4.94)	-25.28 [-44.10; -6.46]	0.0141	-1.86 [-3.71; -0.02]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.11 Change from baseline to week 24 in Haem-A-QoL view of yourself domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	4	44.69 (22.74)		24	11	40.91 (20.10)					
Week 24	12	3	41.67 (32.53)		23	7	35.71 (19.24)					
Change from baseline to week 24	12	3	-3.33 (5.77)	-3.24 (8.34)	23	7	-10.00 (21.21)	-9.70 (5.12)	-6.46 [-26.87; 13.96]	0.5135	-0.36 [-1.65; 0.92]	
Age												
< 18 years												
Baseline					6	1	55.00 (NA)					
Week 24					6	1	30.00 (NA)					
Change from baseline to week 24					6	1	-25.00 (NA)	-25.99 (15.41)	NE [NE; NE]	NE	NE [NE; NE]	0.8241
>= 18 years												
Baseline	9	4	44.69 (22.74)		18	10	39.50 (20.61)					
Week 24	9	3	41.67 (32.53)		17	6	36.67 (20.90)					
Change from baseline to week 24	9	3	-3.33 (5.77)	-3.87 (8.60)	17	6	-7.50 (22.08)	-7.64 (5.64)	-3.77 [-25.96; 18.42]	0.7193	-0.20 [-1.50; 1.09]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL view of yourself domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	20.00 (NA)		15	5	52.00 (20.19)					
Week 24	7	1	10.00 (NA)		14	4	47.50 (15.55)					
Change from baseline to week 24	7	1	-10.00 (NA)	-18.91 (13.19)	14	4	1.25 (22.50)	4.51 (5.91)	23.43 [-10.37; 57.23]	0.1514	1.42 [-0.87; 3.71]	0.0663
OECD country												
Baseline	5	3	52.92 (19.22)		9	6	31.67 (16.02)					
Week 24	5	2	57.50 (24.75)		9	3	20.00 (10.00)					
Change from baseline to week 24	5	2	0.00 (0.00)	6.01 (9.80)	9	3	-25.00 (0.00)	-23.80 (6.41)	-29.81 [-55.61; -4.02]	0.0281	-1.68 [-3.48; 0.12]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.12 Change from baseline to week 24 in Haem-A-QoL work and studies domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	3	18.75 (27.24)		24	10	20.62 (21.66)					
Week 24	12	2	15.62 (22.10)		23	7	21.43 (19.72)					
Change from baseline to week 24	12	2	12.50 (17.68)	-0.36 (11.15)	23	7	-7.14 (20.86)	-4.70 (4.95)	-4.34 [-30.74; 22.06]	0.7311	-0.26 [-1.78; 1.27]	
Age												
< 18 years												
Baseline					6	1	43.75 (NA)					
Week 24					6	1	50.00 (NA)					
Change from baseline to week 24					6	1	6.25 (NA)	15.46 (12.80)	NE [NE; NE]	NE	NE [NE; NE]	0.1259
>= 18 years												
Baseline	9	3	18.75 (27.24)		18	9	18.06 (21.30)					
Week 24	9	2	15.62 (22.10)		17	6	16.67 (16.61)					
Change from baseline to week 24	9	2	12.50 (17.68)	-1.37 (8.95)	17	6	-9.38 (21.92)	-6.93 (4.33)	-5.55 [-27.77; 16.66]	0.5931	-0.39 [-1.93; 1.15]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL work and studies domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	0.00 (NA)		15	4	21.88 (27.24)					
Week 24	7	1	0.00 (NA)		14	4	23.44 (16.44)					
Change from baseline to week 24	7	1	0.00 (NA)	-6.69 (16.44)	14	4	1.56 (17.95)	1.13 (7.83)	7.82 [-35.83; 51.47]	0.6845	0.36 [-1.84; 2.57]	0.2813
OECD country												
Baseline	5	2	28.12 (30.94)		9	6	19.79 (19.93)					
Week 24	5	1	31.25 (NA)		9	3	18.75 (27.24)					
Change from baseline to week 24	5	1	25.00 (NA)	9.92 (18.17)	9	3	-18.75 (21.65)	-11.04 (7.33)	-20.97 [-67.86; 25.93]	0.3255	-0.98 [-3.16; 1.20]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.13 Change from baseline to week 24 in Haem-A-QoL family planning domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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	12	2	0.00 (0.00)	24	9	6.94 (8.53)				
Week 24	12	2	0.00 (0.00)	23	5	12.50 (17.68)				
Change from baseline to week 24	12	1	0.00 (NA) / 4.67 (10.58)	23	5	3.75 (8.39) / 0.91 (4.95)	-3.77 [-33.43; 25.90]	0.7728	-0.24 [-2.32; 1.84]	
Age										
< 18 years										
Baseline				6	1	0.00 (NA)				
Week 24				6	1	0.00 (NA)				
Change from baseline to week 24				6	1	0.00 (NA) / 0.05 (13.49)	NE [NE; NE]	NE	NE [NE; NE]	0.8478
>= 18 years										
Baseline	9	2	0.00 (0.00)	18	8	7.81 (8.68)				
Week 24	9	2	0.00 (0.00)	17	4	15.62 (18.75)				
Change from baseline to week 24	9	1	0.00 (NA) / 4.76 (11.79)	17	4	4.69 (9.38) / 0.80 (6.10)	-3.96 [-49.12; 41.20]	0.7985	-0.21 [-2.31; 1.88]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Haem-A-QoL family planning domain score for subjects older than 16 years - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	1	0.00 (NA)		15	4	10.94 (10.67)					
Week 24	7	1	0.00 (NA)		14	2	31.25 (8.84)					
Change from baseline to week 24	7	1	0.00 (NA)	NE (NE)	14	2	12.50 (0.00)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]	NE
OECD country												
Baseline	5	1	0.00 (NA)		9	5	3.75 (5.59)					
Week 24	5	1	0.00 (NA)		9	3	0.00 (0.00)					
Change from baseline to week 24	5	0	NA (NA)	NE (NE)	9	3	-2.08 (3.61)	NE (NE)	NE [NE; NE]	NE	NE [NE; NE]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. 1 patient below the age of 17 filled out the questionnaire at baseline and post baseline. These data are included. Cut off date for data is 12th July 2022.

2.3.1.14 Change from baseline to week 24 in Hemo-TEM Total Score - Explorer 8 - HB - OTexBR - 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	12	8	24.88 (13.56)		24	15	23.08 (14.59)					
Week 24	12	8	12.78 (14.43)		23	17	5.92 (5.52)					
Change from baseline to week 24	12	5	-4.79 (24.29)	-4.04 (4.31)	23	10	-15.95 (13.47)	-18.56 (3.13)	-14.52 [-26.34; -2.70]	0.0205	-1.39 [-2.57; -0.21]	
Age												
< 18 years												
Baseline	3	1	30.12 (NA)		6	3	23.28 (23.83)					
Week 24	3	2	15.77 (22.31)		6	5	6.36 (6.46)					
Change from baseline to week 24	3	1	1.43 (NA)	10.93 (9.47)	6	3	-14.90 (25.14)	-15.82 (5.23)	-26.74 [-51.52; -1.97]	0.0373	-1.69 [-4.23; 0.86]	0.2251
>= 18 years												
Baseline	9	7	24.13 (14.47)		18	12	23.04 (12.95)					
Week 24	9	6	11.78 (13.68)		17	12	5.74 (5.40)					
Change from baseline to week 24	9	4	-6.34 (27.75)	-7.86 (4.61)	17	7	-16.39 (7.79)	-19.59 (3.61)	-11.73 [-25.31; 1.86]	0.0826	-1.14 [-2.45; 0.18]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Hemo-TEM Total Score - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	28.48 (11.97)		15	9	26.95 (16.49)					
Week 24	7	4	10.62 (14.12)		14	11	7.46 (5.83)					
Change from baseline to week 24	7	3	-17.38 (20.59)	-11.56 (5.41)	14	7	-17.52 (15.86)	-18.08 (3.33)	-6.52 [-20.95; 7.92]	0.3341	-0.66 [-2.04; 0.73]	0.1792
OECD country												
Baseline	5	3	18.89 (16.46)		9	6	17.28 (9.69)					
Week 24	5	4	14.94 (16.55)		9	6	3.10 (3.85)					
Change from baseline to week 24	5	2	14.11 (17.93)	6.66 (6.57)	9	3	-12.26 (5.75)	-17.51 (5.62)	-24.18 [-42.42; -5.94]	0.0150	-1.83 [-3.95; 0.29]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.15 Change from baseline to week 24 in Hemo-TEM ease of use - Explorer 8 - HB - OTexBR - 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	12	8	31.25 (24.70)		24	15	20.56 (23.33)					
Week 24	12	8	5.21 (9.90)		23	17	3.92 (8.90)					
Change from baseline to week 24	12	5	-18.33 (25.28)	-15.63 (5.04)	23	10	-14.17 (20.43)	-21.59 (3.76)	-5.96 [-19.99; 8.08]	0.3704	-0.48 [-1.57; 0.61]	
Age												
< 18 years												
Baseline	3	1	25.00 (NA)		6	3	22.22 (25.46)					
Week 24	3	2	12.50 (17.68)		6	5	0.00 (0.00)					
Change from baseline to week 24	3	1	0.00 (NA)	-1.05 (11.78)	6	3	-22.22 (25.46)	-23.94 (6.50)	-22.88 [-53.67; 7.90]	0.1270	-1.16 [-3.56; 1.24]	0.3991
>= 18 years												
Baseline	9	7	32.14 (26.54)		18	12	20.14 (23.96)					
Week 24	9	6	2.78 (6.80)		17	12	5.56 (10.26)					
Change from baseline to week 24	9	4	-22.92 (26.68)	-19.56 (5.77)	17	7	-10.71 (19.07)	-19.85 (4.64)	-0.29 [-17.74; 17.15]	0.9705	-0.02 [-1.25; 1.21]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Hemo-TEM ease of use - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	31.67 (22.36)		15	9	28.70 (26.39)					
Week 24	7	4	4.17 (8.33)		14	11	3.03 (5.62)					
Change from baseline to week 24	7	3	-30.56 (26.79)	-19.16 (6.91)	14	7	-20.24 (21.44)	-23.95 (4.29)	-4.78 [-23.66; 14.09]	0.5804	-0.38 [-1.74; 0.99]	0.3969
OECD country												
Baseline	5	3	30.56 (33.68)		9	6	8.33 (10.54)					
Week 24	5	4	6.25 (12.50)		9	6	5.56 (13.61)					
Change from baseline to week 24	5	2	0.00 (0.00)	-11.18 (8.25)	9	3	0.00 (8.33)	-13.19 (7.20)	-2.01 [-25.25; 21.23]	0.8492	-0.12 [-1.91; 1.67]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.16 Change from baseline to week 24 in Hemo-TEM emotional impact - Explorer 8 - HB - OTexBR - 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	12	8	30.73 (15.90)		24	15	26.89 (22.45)					
Week 24	12	8	16.77 (18.95)		23	17	9.95 (10.77)					
Change from baseline to week 24	12	5	-5.00 (28.63)	-2.59 (5.93)	23	10	-13.83 (21.93)	-20.55 (4.40)	-17.95 [-34.42; -1.49]	0.0352	-1.23 [-2.39; -0.07]	
Age												
< 18 years												
Baseline	3	1	37.50 (NA)		6	3	23.33 (25.17)					
Week 24	3	2	20.83 (29.46)		6	5	8.33 (10.62)					
Change from baseline to week 24	3	1	4.17 (NA)	20.49 (12.85)	6	3	-15.00 (30.41)	-21.30 (7.11)	-41.79 [-75.61; -7.97]	0.0209	-1.94 [-4.57; 0.69]	0.1953
>= 18 years												
Baseline	9	7	29.76 (16.91)		18	12	27.78 (22.84)					
Week 24	9	6	15.42 (17.90)		17	12	10.62 (11.23)					
Change from baseline to week 24	9	4	-7.29 (32.52)	-8.48 (6.22)	17	7	-13.33 (20.30)	-20.06 (4.89)	-11.58 [-29.89; 6.73]	0.1864	-0.83 [-2.10; 0.45]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Hemo-TEM emotional impact - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	36.67 (11.93)		15	9	30.93 (27.92)					
Week 24	7	4	14.79 (18.64)		14	11	14.24 (10.74)					
Change from baseline to week 24	7	3	-20.83 (22.05)	-11.59 (7.03)	14	7	-12.62 (25.76)	-17.46 (4.50)	-5.88 [-25.19; 13.44]	0.5086	-0.44 [-1.81; 0.92]	0.1336
OECD country												
Baseline	5	3	20.83 (19.09)		9	6	20.83 (9.50)					
Week 24	5	4	18.75 (21.92)		9	6	2.08 (5.10)					
Change from baseline to week 24	5	2	18.75 (20.62)	10.36 (8.43)	9	3	-16.67 (12.50)	-25.81 (7.21)	-36.17 [-60.39; -11.95]	0.0082	-2.14 [-4.36; 0.09]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.17 Change from baseline to week 24 in Hemo-TEM interference - Explorer 8 - HB - OTexBR - 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	12	8	23.44 (17.28)		24	15	23.33 (19.83)					
Week 24	12	8	17.97 (19.89)		23	17	1.84 (6.16)					
Change from baseline to week 24	12	5	2.50 (22.79)	4.57 (5.12)	23	10	-21.25 (24.15)	-20.17 (3.61)	-24.74 [-38.59; -10.89]	0.0023	-2.04 [-3.34; -0.74]	
Age												
< 18 years												
Baseline	3	1	37.50 (NA)		6	3	25.00 (22.53)					
Week 24	3	2	18.75 (26.52)		6	5	5.00 (11.18)					
Change from baseline to week 24	3	1	0.00 (NA)	20.12 (11.54)	6	3	-16.67 (29.54)	-16.65 (6.41)	-36.77 [-66.97; -6.57]	0.0223	-1.89 [-4.51; 0.72]	0.3047
>= 18 years												
Baseline	9	7	21.43 (17.62)		18	12	22.92 (20.18)					
Week 24	9	6	17.71 (20.32)		17	12	0.52 (1.80)					
Change from baseline to week 24	9	4	3.12 (26.27)	0.63 (5.65)	17	7	-23.21 (23.86)	-21.46 (4.27)	-22.10 [-38.55; -5.64]	0.0141	-1.79 [-3.22; -0.35]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Hemo-TEM interference - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	30.00 (12.02)		15	9	26.39 (22.49)					
Week 24	7	4	17.19 (21.27)		14	11	2.84 (7.58)					
Change from baseline to week 24	7	3	-8.33 (15.73)	-4.06 (6.28)	14	7	-23.21 (27.88)	-20.78 (3.97)	-16.72 [-33.15; -0.29]	0.0468	-1.43 [-2.92; 0.06]	0.1778
OECD country												
Baseline	5	3	12.50 (21.65)		9	6	18.75 (15.81)					
Week 24	5	4	18.75 (21.65)		9	6	0.00 (0.00)					
Change from baseline to week 24	5	2	18.75 (26.52)	16.33 (7.41)	9	3	-16.67 (15.73)	-18.07 (6.49)	-34.40 [-56.01; -12.79]	0.0057	-2.28 [-4.55; 0.00]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.18 Change from baseline to week 24 in Hemo-TEM physical impact - Explorer 8 - HB - OTexBR - 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	12	8	22.92 (12.20)		24	15	20.83 (14.69)					
Week 24	12	8	8.33 (10.68)		23	17	7.60 (7.69)					
Change from baseline to week 24	12	5	-6.67 (16.82)	-8.09 (3.83)	23	10	-15.83 (13.29)	-15.72 (2.72)	-7.62 [-17.97; 2.72]	0.1331	-0.84 [-1.95; 0.28]	
Age												
< 18 years												
Baseline	3	1	29.17 (NA)		6	3	20.83 (25.34)					
Week 24	3	2	12.50 (17.68)		6	5	9.17 (6.85)					
Change from baseline to week 24	3	1	-4.17 (NA)	3.95 (8.39)	6	3	-11.11 (19.69)	-11.97 (4.63)	-15.92 [-37.87; 6.03]	0.1352	-1.13 [-3.53; 1.26]	0.2214
>= 18 years												
Baseline	9	7	22.02 (12.89)		18	12	20.83 (12.56)					
Week 24	9	6	6.94 (9.38)		17	12	6.94 (8.21)					
Change from baseline to week 24	9	4	-7.29 (19.36)	-11.23 (4.09)	17	7	-17.86 (10.95)	-17.18 (3.08)	-5.96 [-17.75; 5.84]	0.2827	-0.67 [-1.93; 0.59]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Hemo-TEM physical impact - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	23.33 (8.12)		15	9	24.54 (17.61)					
Week 24	7	4	6.25 (9.92)		14	11	9.09 (8.70)					
Change from baseline to week 24	7	3	-15.28 (13.39)	-13.96 (4.48)	14	7	-17.26 (15.85)	-16.91 (2.89)	-2.95 [-14.98; 9.08]	0.5927	-0.35 [-1.71; 1.01]	0.1512
OECD country												
Baseline	5	3	22.22 (19.69)		9	6	15.28 (6.80)					
Week 24	5	4	10.42 (12.50)		9	6	4.86 (4.87)					
Change from baseline to week 24	5	2	6.25 (14.73)	0.95 (5.60)	9	3	-12.50 (4.17)	-12.38 (4.56)	-13.33 [-29.31; 2.65]	0.0918	-1.23 [-3.17; 0.72]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.19 Change from baseline to week 24 in Hemo-TEM treatment burden - Explorer 8 - HB - OTexBR - 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	12	8	16.07 (12.52)		24	15	23.81 (17.22)					
Week 24	12	8	15.62 (17.59)		23	17	6.30 (7.09)					
Change from baseline to week 24	12	5	3.57 (32.64)	0.14 (5.75)	23	10	-14.64 (14.33)	-13.57 (4.07)	-13.71 [-29.26; 1.84]	0.0784	-1.00 [-2.14; 0.13]	
Age												
< 18 years												
Baseline	3	1	21.43 (NA)		6	3	25.00 (21.72)					
Week 24	3	2	14.29 (20.20)		6	5	9.29 (10.59)					
Change from baseline to week 24	3	1	7.14 (NA)	9.13 (12.91)	6	3	-9.52 (23.78)	-4.47 (7.22)	-13.60 [-47.69; 20.49]	0.3903	-0.62 [-2.93; 1.68]	0.2764
>= 18 years												
Baseline	9	7	15.31 (13.32)		18	12	23.51 (17.06)					
Week 24	9	6	16.07 (18.73)		17	12	5.06 (5.15)					
Change from baseline to week 24	9	4	2.68 (37.61)	-2.31 (6.27)	17	7	-16.84 (10.04)	-17.43 (4.75)	-15.13 [-33.21; 2.96]	0.0910	-1.10 [-2.41; 0.21]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in Hemo-TEM treatment burden - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	20.71 (11.68)		15	9	24.21 (13.34)					
Week 24	7	4	10.71 (14.58)		14	11	8.12 (7.67)					
Change from baseline to week 24	7	3	-11.90 (29.09)	-9.23 (6.31)	14	7	-14.29 (16.75)	-11.58 (4.12)	-2.35 [-19.23; 14.53]	0.7603	-0.19 [-1.55; 1.16]	0.0873
OECD country												
Baseline	5	3	8.33 (11.48)		9	6	23.21 (23.34)					
Week 24	5	4	20.54 (21.10)		9	6	2.98 (4.75)					
Change from baseline to week 24	5	2	26.79 (27.78)	14.98 (8.11)	9	3	-15.48 (8.99)	-18.22 (6.50)	-33.21 [-55.80; -10.62]	0.0089	-2.13 [-4.36; 0.09]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.20 Change from baseline to week 24 in PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a - Explorer 8 - HB - OTexBR - 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	12	7	3.57 (2.15)		24	15	3.47 (2.00)					
Week 24	12	8	4.38 (2.20)		23	17	2.88 (3.08)					
Change from baseline to week 24	12	4	1.25 (1.71)	0.47 (1.11)	23	10	-0.50 (4.12)	-1.22 (0.70)	-1.69 [-4.28; 0.91]	0.1944	-0.65 [-1.72; 0.41]	
Age												
< 18 years												
Baseline	3	1	4.00 (NA)		6	3	4.33 (2.52)					
Week 24	3	2	4.00 (1.41)		6	5	1.00 (1.73)					
Change from baseline to week 24	3	1	1.00 (NA)	3.45 (2.20)	6	3	-4.00 (3.00)	-3.53 (1.21)	-6.98 [-12.18; -1.78]	0.0109	-1.90 [-4.52; 0.72]	0.3025
>= 18 years												
Baseline	9	6	3.50 (2.35)		18	12	3.25 (1.91)					
Week 24	9	6	4.50 (2.51)		17	12	3.67 (3.23)					
Change from baseline to week 24	9	3	1.33 (2.08)	-0.53 (1.34)	17	7	1.00 (3.70)	-0.09 (0.89)	0.44 [-2.57; 3.44]	0.7660	0.15 [-1.03; 1.33]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in PROMIS Numeric Rating Scale v.1.0 Pain Intensity 1a - Explorer 8 - HB - OTexBR - 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.
Region										
Non-OECD country										
Baseline	7	5	2.80 (1.79)	15	9	3.33 (2.45)				
Week 24	7	4	4.00 (2.83)	14	11	3.36 (3.67)				
Change from baseline to week 24	7	3	1.33 (2.08) -1.27 (1.33)	14	7	0.00 (4.93) -1.02 (0.81)	0.25 [-2.80; 3.29]	0.8666	0.10 [-1.25; 1.46]	0.3239
OECD country										
Baseline	5	2	5.50 (2.12)	9	6	3.67 (1.21)				
Week 24	5	4	4.75 (1.71)	9	6	2.00 (1.41)				
Change from baseline to week 24	5	1	1.00 (NA) 4.03 (2.20)	9	3	-1.67 (0.58) -2.12 (1.21)	-6.15 [-11.29; -1.01]	0.0214	-1.86 [-3.77; 0.05]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.21 Change from baseline to week 24 in PROMIS Short Form v2.0 Upper Extremity 7a - Explorer 8 - HB - OTexBR - 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	12	7	37.44 (5.46)		24	13	41.79 (11.62)					
Week 24	12	8	45.15 (9.37)		23	16	47.41 (10.36)					
Change from baseline to week 24	12	4	5.51 (5.31)	3.40 (4.38)	23	9	5.04 (8.58)	5.31 (3.05)	1.91 [-8.88; 12.70]	0.7182	0.19 [-0.90; 1.29]	
Age												
< 18 years												
Baseline	3	1	39.32 (NA)		6	3	40.05 (8.05)					
Week 24	3	2	42.34 (5.96)		6	5	52.83 (7.41)					
Change from baseline to week 24	3	1	-1.20 (NA)	-1.23 (10.13)	6	3	9.21 (7.56)	9.19 (5.49)	10.42 [-14.48; 35.32]	0.3880	0.63 [-1.68; 2.93]	0.9082
>= 18 years												
Baseline	9	6	37.12 (5.91)		18	10	42.31 (12.82)					
Week 24	9	6	46.08 (10.56)		17	11	44.94 (10.85)					
Change from baseline to week 24	9	3	7.74 (3.51)	4.33 (5.15)	17	6	2.95 (8.90)	2.96 (4.09)	-1.37 [-15.19; 12.45]	0.8359	-0.12 [-1.39; 1.14]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in PROMIS Short Form v2.0 Upper Extremity 7a - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	38.74 (4.92)		15	9	36.04 (8.72)					
Week 24	7	4	46.61 (8.32)		14	11	45.12 (11.43)					
Change from baseline to week 24	7	3	7.74 (3.51)	8.18 (4.76)	14	7	7.00 (8.76)	7.14 (3.26)	-1.03 [-13.15; 11.09]	0.8587	-0.11 [-1.46; 1.24]	0.4085
OECD country												
Baseline	5	2	34.19 (7.27)		9	4	54.71 (4.02)					
Week 24	5	4	43.68 (11.39)		9	5	52.45 (5.46)					
Change from baseline to week 24	5	1	-1.20 (NA)	-6.42 (8.01)	9	2	-1.82 (2.58)	-3.96 (6.91)	2.46 [-19.50; 24.41]	0.8154	0.13 [-1.83; 2.09]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.22 Change from baseline to week 24 in SF-36v2 general health - Explorer 8 - HB - OTexBR - 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	12	8	41.24 (6.84)		24	15	43.99 (9.05)					
Week 24	12	8	39.99 (12.25)		23	17	48.63 (10.29)					
Change from baseline to week 24	12	5	-0.57 (9.43)	-1.34 (3.50)	23	10	2.52 (10.23)	2.67 (2.40)	4.00 [-4.73; 12.74]	0.3571	0.45 [-0.54; 1.45]	
Age												
< 18 years												
Baseline	3	1	38.92 (NA)		6	3	44.95 (2.19)					
Week 24	3	2	36.07 (7.40)		6	5	49.19 (6.98)					
Change from baseline to week 24	3	1	2.38 (NA)	0.51 (9.55)	6	3	4.75 (4.76)	5.01 (4.97)	4.49 [-18.93; 27.92]	0.6951	0.30 [-1.97; 2.57]	0.9039
>= 18 years												
Baseline	9	7	41.57 (7.31)		18	12	43.76 (10.15)					
Week 24	9	6	41.30 (13.81)		17	12	48.39 (11.67)					
Change from baseline to week 24	9	4	-1.31 (10.72)	-1.64 (4.05)	17	7	1.56 (12.08)	1.80 (3.00)	3.43 [-7.07; 13.94]	0.5060	0.36 [-0.75; 1.46]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 general health - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	43.77 (7.41)		15	9	42.83 (5.98)					
Week 24	7	4	43.32 (15.81)		14	11	48.73 (12.17)					
Change from baseline to week 24	7	3	1.74 (10.80)	2.19 (4.60)	14	7	1.77 (10.98)	1.76 (3.11)	-0.43 [-11.87; 11.01]	0.9385	-0.05 [-1.40; 1.31]	0.7995
OECD country												
Baseline	5	3	37.02 (3.29)		9	6	45.74 (12.89)					
Week 24	5	4	36.66 (8.38)		9	6	48.43 (6.56)					
Change from baseline to week 24	5	2	-4.04 (9.08)	-6.35 (5.83)	9	3	4.28 (10.13)	4.66 (4.24)	11.01 [-3.20; 25.22]	0.1226	0.99 [-0.52; 2.50]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.23 Change from baseline to week 24 in SF-36v2 mental health - Explorer 8 - HB - OTexBR - 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	12	8	45.31 (12.15)		24	15	45.81 (9.35)					
Week 24	12	8	41.71 (11.95)		23	17	49.48 (11.88)					
Change from baseline to week 24	12	5	-5.75 (16.27)	-6.65 (4.58)	23	10	0.52 (12.44)	0.68 (3.24)	7.33 [-4.13; 18.79]	0.2017	0.62 [-0.38; 1.62]	
Age												
< 18 years												
Baseline	3	1	37.79 (NA)		6	3	44.76 (4.00)					
Week 24	3	2	40.41 (7.40)		6	5	50.34 (10.03)					
Change from baseline to week 24	3	1	-2.62 (NA)	-7.27 (12.30)	6	3	3.49 (9.90)	3.39 (6.44)	10.66 [-18.37; 39.70]	0.4552	0.55 [-1.75; 2.84]	0.9946
>= 18 years												
Baseline	9	7	46.38 (12.70)		18	12	46.07 (10.39)					
Week 24	9	6	42.15 (13.71)		17	12	49.12 (12.98)					
Change from baseline to week 24	9	4	-6.54 (18.68)	-6.57 (5.61)	17	7	-0.75 (13.90)	-0.49 (4.20)	6.08 [-8.71; 20.88]	0.4039	0.45 [-0.65; 1.56]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 mental health - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	43.02 (12.27)		15	9	42.73 (10.00)					
Week 24	7	4	43.02 (16.41)		14	11	46.35 (12.82)					
Change from baseline to week 24	7	3	1.75 (10.57)	0.51 (5.87)	14	7	-2.61 (12.08)	-2.61 (3.73)	-3.12 [-17.50; 11.27]	0.6580	-0.28 [-1.64; 1.07]	0.3580
OECD country												
Baseline	5	3	49.13 (13.42)		9	6	50.43 (6.49)					
Week 24	5	4	40.41 (7.70)		9	6	55.23 (7.88)					
Change from baseline to week 24	5	2	-17.00 (20.34)	-15.46 (7.02)	9	3	7.85 (11.99)	7.80 (5.69)	23.27 [4.60; 41.94]	0.0168	1.61 [-0.02; 3.25]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.24 Change from baseline to week 24 in SF-36v2 role emotional - Explorer 8 - HB - OTexBR - 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	12	8	47.90 (10.68)		24	15	43.64 (11.07)					
Week 24	12	8	43.55 (11.16)		23	17	45.93 (11.25)					
Change from baseline to week 24	12	5	-8.36 (11.70)	-6.29 (4.14)	23	10	2.09 (14.60)	-0.21 (3.00)	6.08 [-4.50; 16.67]	0.2502	0.56 [-0.44; 1.56]	
Age												
< 18 years												
Baseline	3	1	38.76 (NA)		6	3	38.76 (9.21)					
Week 24	3	2	42.24 (19.70)		6	5	50.60 (5.28)					
Change from baseline to week 24	3	1	-10.45 (NA)	-21.41 (9.96)	6	3	11.60 (10.64)	8.13 (5.55)	29.55 [6.33; 52.76]	0.0149	1.76 [-0.81; 4.33]	0.2479
>= 18 years												
Baseline	9	7	49.21 (10.82)		18	12	44.85 (11.51)					
Week 24	9	6	43.98 (9.79)		17	12	43.98 (12.64)					
Change from baseline to week 24	9	4	-7.84 (13.45)	-1.99 (4.79)	17	7	-1.99 (14.75)	-4.56 (3.51)	-2.57 [-15.26; 10.12]	0.6789	-0.23 [-1.32; 0.87]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 role emotional - Explorer 8 - HB - OTexBR - 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.
Region										
Non-OECD country										
Baseline	7	5	46.42 (11.91)	15	9	39.92 (10.87)				
Week 24	7	4	43.11 (9.16)	14	11	42.87 (12.63)				
Change from baseline to week 24	7	3	-3.48 (12.55) / -1.70 (5.31)	14	7	-0.50 (16.87) / -2.75 (3.54)	-1.05 [-14.37; 12.27]	0.8718	-0.10 [-1.46; 1.25]	0.6388
OECD country										
Baseline	5	3	50.37 (10.05)	9	6	49.21 (9.60)				
Week 24	5	4	43.98 (14.36)	9	6	51.53 (5.24)				
Change from baseline to week 24	5	2	-15.67 (7.38) / -13.04 (6.41)	9	3	8.12 (5.32) / 4.65 (5.33)	17.68 [0.44; 34.92]	0.0449	1.32 [-0.25; 2.89]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.25 Change from baseline to week 24 in SF-36v2 role physical - Explorer 8 - HB - OTexBR - 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	12	8	39.76 (9.12)		24	15	43.24 (8.41)					
Week 24	12	8	39.47 (5.81)		23	17	48.31 (10.49)					
Change from baseline to week 24	12	5	-3.15 (16.08)	-5.52 (3.91)	23	10	5.61 (10.44)	6.28 (2.75)	11.80 [1.98; 21.62]	0.0201	1.18 [0.12; 2.23]	
Age												
< 18 years												
Baseline	3	1	36.95 (NA)		6	3	45.93 (9.79)					
Week 24	3	2	44.80 (4.76)		6	5	51.32 (8.93)					
Change from baseline to week 24	3	1	4.49 (NA)	0.33 (9.93)	6	3	11.23 (9.79)	14.13 (5.49)	13.79 [-10.48; 38.07]	0.2518	0.83 [-1.51; 3.16]	0.3157
>= 18 years												
Baseline	9	7	40.16 (9.78)		18	12	42.56 (8.37)					
Week 24	9	6	37.70 (5.25)		17	12	47.05 (11.19)					
Change from baseline to week 24	9	4	-5.05 (17.90)	-7.10 (4.48)	17	7	3.21 (10.44)	2.80 (3.37)	9.90 [-1.90; 21.71]	0.0961	0.92 [-0.23; 2.06]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 role physical - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	41.44 (11.23)		15	9	41.94 (8.97)					
Week 24	7	4	38.63 (4.63)		14	11	46.34 (11.44)					
Change from baseline to week 24	7	3	-3.00 (21.34)	-3.39 (4.89)	14	7	2.57 (11.11)	3.68 (3.21)	7.07 [-5.03; 19.16]	0.2392	0.75 [-0.64; 2.14]	0.5656
OECD country												
Baseline	5	3	36.95 (4.49)		9	6	45.18 (7.86)					
Week 24	5	4	40.32 (7.45)		9	6	51.92 (8.12)					
Change from baseline to week 24	5	2	-3.37 (11.12)	-7.03 (5.85)	9	3	12.72 (3.43)	10.78 (4.72)	17.81 [2.42; 33.19]	0.0252	1.49 [-0.12; 3.09]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.26 Change from baseline to week 24 in SF-36v2 social function - Explorer 8 - HB - OTexBR - 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	12	8	45.43 (10.36)		24	15	44.64 (10.70)					
Week 24	12	8	42.93 (6.80)		23	17	48.49 (9.95)					
Change from baseline to week 24	12	5	-1.00 (10.87)	-0.90 (3.81)	23	10	2.01 (8.91)	2.82 (2.71)	3.72 [-5.81; 13.26]	0.4322	0.38 [-0.61; 1.37]	
Age												
< 18 years												
Baseline	3	1	37.29 (NA)		6	3	48.98 (7.66)					
Week 24	3	2	37.29 (0.00)		6	5	50.32 (6.73)					
Change from baseline to week 24	3	1	0.00 (NA)	-4.90 (9.86)	6	3	3.34 (5.79)	5.23 (5.41)	10.13 [-13.98; 34.24]	0.3936	0.62 [-1.69; 2.92]	0.6448
>= 18 years												
Baseline	9	7	46.60 (10.61)		18	12	43.55 (11.34)					
Week 24	9	6	44.81 (6.91)		17	12	47.73 (11.20)					
Change from baseline to week 24	9	4	-1.25 (12.53)	-0.08 (4.48)	17	7	1.43 (10.32)	1.86 (3.33)	1.94 [-9.80; 13.69]	0.7355	0.18 [-0.91; 1.28]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 social function - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	45.31 (11.54)		15	9	41.74 (12.14)					
Week 24	7	4	46.06 (8.56)		14	11	45.49 (10.81)					
Change from baseline to week 24	7	3	3.34 (10.43)	3.30 (4.28)	14	7	-0.72 (7.34)	-0.40 (2.79)	-3.70 [-14.28; 6.88]	0.4764	-0.45 [-1.82; 0.91]	0.0985
OECD country												
Baseline	5	3	45.64 (10.43)		9	6	48.98 (6.85)					
Week 24	5	4	39.80 (2.89)		9	6	54.00 (5.18)					
Change from baseline to week 24	5	2	-7.52 (10.63)	-5.83 (5.12)	9	3	8.35 (10.43)	8.31 (4.19)	14.14 [0.57; 27.71]	0.0418	1.34 [-0.24; 2.91]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.27 Change from baseline to week 24 in SF-36v2 vitality - Explorer 8 - HB - OTexBR - 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	12	8	51.86 (8.66)		24	15	50.62 (8.23)					
Week 24	12	8	49.63 (11.45)		23	17	53.47 (10.75)					
Change from baseline to week 24	12	5	-5.35 (20.84)	-5.50 (4.90)	23	10	1.78 (11.73)	1.27 (3.43)	6.77 [-5.35; 18.89]	0.2634	0.54 [-0.45; 1.54]	
Age												
< 18 years												
Baseline	3	1	46.66 (NA)		6	3	50.62 (6.86)					
Week 24	3	2	48.14 (2.10)		6	5	54.98 (5.71)					
Change from baseline to week 24	3	1	0.00 (NA)	-8.87 (12.64)	6	3	4.95 (4.54)	5.58 (6.89)	14.45 [-15.61; 44.52]	0.3303	0.69 [-1.62; 3.01]	0.7885
>= 18 years												
Baseline	9	7	52.60 (9.07)		18	12	50.62 (8.81)					
Week 24	9	6	50.12 (13.47)		17	12	52.85 (12.44)					
Change from baseline to week 24	9	4	-6.68 (23.81)	-4.04 (5.81)	17	7	0.42 (13.87)	-0.36 (4.22)	3.69 [-11.19; 18.56]	0.6130	0.27 [-0.83; 1.37]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 vitality - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	50.22 (5.31)		15	9	47.32 (8.51)					
Week 24	7	4	55.57 (10.57)		14	11	52.06 (12.09)					
Change from baseline to week 24	7	3	4.95 (6.18)	5.66 (6.12)	14	7	0.00 (13.17)	-0.25 (3.99)	-5.91 [-21.00; 9.19]	0.4266	-0.50 [-1.88; 0.87]	0.3500
OECD country												
Baseline	5	3	54.58 (13.72)		9	6	55.57 (4.97)					
Week 24	5	4	43.69 (10.00)		9	6	56.07 (8.06)					
Change from baseline to week 24	5	2	-20.80 (29.41)	-20.35 (7.06)	9	3	5.94 (7.86)	3.42 (5.43)	23.77 [5.98; 41.56]	0.0110	1.70 [0.04; 3.35]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.28 Change from baseline to week 24 in SF-36v2 mental component score - Explorer 8 - HB - OTexBR - 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	12	8	51.22 (12.81)		24	15	46.86 (10.41)					
Week 24	12	8	44.66 (10.24)		23	17	49.33 (11.71)					
Change from baseline to week 24	12	5	-7.35 (15.84)	-6.20 (4.27)	23	10	0.24 (12.13)	-0.76 (3.04)	5.44 [-5.33; 16.22]	0.3109	0.49 [-0.50; 1.49]	
Age												
< 18 years												
Baseline	3	1	39.26 (NA)		6	3	43.76 (4.61)					
Week 24	3	2	41.91 (10.37)		6	5	51.45 (4.82)					
Change from baseline to week 24	3	1	-4.68 (NA)	-13.16 (11.14)	6	3	5.97 (4.68)	4.55 (6.03)	17.71 [-8.19; 43.61]	0.1705	0.97 [-1.39; 3.33]	0.7806
>= 18 years												
Baseline	9	7	52.93 (12.81)		18	12	47.64 (11.43)					
Week 24	9	6	45.58 (11.01)		17	12	48.45 (13.72)					
Change from baseline to week 24	9	4	-8.02 (18.21)	-4.31 (5.23)	17	7	-2.22 (13.79)	-3.33 (3.81)	0.98 [-12.76; 14.72]	0.8834	0.08 [-1.01; 1.17]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 mental component score - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	47.92 (10.54)		15	9	42.78 (9.91)					
Week 24	7	4	46.39 (13.40)		14	11	46.14 (12.59)					
Change from baseline to week 24	7	3	0.66 (6.73)	0.25 (5.34)	14	7	-2.44 (13.20)	-3.46 (3.53)	-3.71 [-16.82; 9.39]	0.5633	-0.36 [-1.72; 1.00]	0.4479
OECD country												
Baseline	5	3	56.72 (16.72)		9	6	52.99 (8.42)					
Week 24	5	4	42.93 (7.54)		9	6	55.19 (7.64)					
Change from baseline to week 24	5	2	-19.37 (20.77)	-15.40 (6.59)	9	3	6.49 (7.52)	5.12 (5.19)	20.52 [3.24; 37.81]	0.0220	1.55 [-0.07; 3.16]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.29 Change from baseline to week 24 in SF-36v2 physical component score - Explorer 8 - HB - OTexBR - 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	12	8	37.20 (9.61)		24	15	43.71 (7.93)					
Week 24	12	8	41.76 (7.26)		23	17	48.79 (7.34)					
Change from baseline to week 24	12	5	0.82 (4.54)	-0.90 (2.78)	23	10	5.56 (5.23)	5.91 (2.02)	6.82 [-0.47; 14.10]	0.0657	0.93 [-0.09; 1.96]	
Age												
< 18 years												
Baseline	3	1	41.28 (NA)		6	3	49.54 (8.78)					
Week 24	3	2	41.31 (1.43)		6	5	50.66 (7.84)					
Change from baseline to week 24	3	1	1.04 (NA)	1.15 (7.14)	6	3	5.89 (4.87)	6.38 (4.43)	5.23 [-12.76; 23.22]	0.5534	0.39 [-1.89; 2.67]	0.8253
>= 18 years												
Baseline	9	7	36.62 (10.23)		18	12	42.25 (7.38)					
Week 24	9	6	41.91 (8.56)		17	12	48.01 (7.33)					
Change from baseline to week 24	9	4	0.76 (5.24)	-1.52 (3.32)	17	7	5.42 (5.75)	5.72 (2.43)	7.23 [-1.52; 15.98]	0.1008	0.92 [-0.22; 2.07]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 physical component score - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	41.08 (8.02)		15	9	43.80 (8.38)					
Week 24	7	4	44.44 (4.71)		14	11	48.36 (8.16)					
Change from baseline to week 24	7	3	1.85 (5.84)	2.21 (3.25)	14	7	3.73 (4.77)	4.64 (2.37)	2.42 [-5.62; 10.46]	0.5392	0.36 [-1.00; 1.72]	0.2804
OECD country												
Baseline	5	3	30.74 (9.72)		9	6	43.58 (7.98)					
Week 24	5	4	39.08 (9.03)		9	6	49.59 (6.16)					
Change from baseline to week 24	5	2	-0.73 (2.50)	-4.64 (4.12)	9	3	9.82 (4.01)	8.47 (2.89)	13.11 [2.77; 23.45]	0.0152	1.70 [0.05; 3.36]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.30 Change from baseline to week 24 in SF-36v2 bodily pain - Explorer 8 - HB - OTexBR - 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	12	8	38.92 (7.66)		24	15	43.61 (9.33)					
Week 24	12	8	39.67 (11.86)		23	17	50.19 (9.28)					
Change from baseline to week 24	12	5	-2.10 (11.55)	-3.70 (3.74)	23	10	9.55 (9.43)	11.38 (2.75)	15.08 [5.44; 24.73]	0.0033	1.53 [0.43; 2.63]	
Age												
< 18 years												
Baseline	3	1	38.21 (NA)		6	3	51.79 (8.85)					
Week 24	3	2	38.21 (5.70)		6	5	52.08 (11.04)					
Change from baseline to week 24	3	1	-4.03 (NA)	-9.11 (9.31)	6	3	8.06 (7.69)	14.16 (5.85)	23.27 [-1.01; 47.54]	0.0595	1.31 [-1.13; 3.75]	0.8580
>= 18 years												
Baseline	9	7	39.02 (8.27)		18	12	41.57 (8.59)					
Week 24	9	6	40.16 (13.76)		17	12	49.40 (8.87)					
Change from baseline to week 24	9	4	-1.61 (13.28)	-2.30 (4.34)	17	7	10.19 (10.58)	10.38 (3.26)	12.68 [1.23; 24.13]	0.0314	1.22 [0.03; 2.40]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 bodily pain - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	41.03 (9.21)		15	9	45.42 (10.67)					
Week 24	7	4	42.14 (15.06)		14	11	50.09 (11.15)					
Change from baseline to week 24	7	3	0.54 (15.39)	1.42 (4.40)	14	7	6.85 (9.92)	10.37 (3.38)	8.95 [-2.21; 20.11]	0.1107	0.94 [-0.48; 2.35]	0.1302
OECD country												
Baseline	5	3	35.39 (2.45)		9	6	40.90 (6.83)					
Week 24	5	4	37.20 (9.25)		9	6	50.37 (5.19)					
Change from baseline to week 24	5	2	-6.05 (2.85)	-9.83 (5.60)	9	3	15.86 (4.43)	13.37 (4.62)	23.19 [8.95; 37.43]	0.0026	1.99 [0.26; 3.73]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

2.3.1.31 Change from baseline to week 24 in SF-36v2 physical functioning - Explorer 8 - HB - OTexBR - 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	12	8	38.16 (10.25)		24	15	43.89 (9.09)					
Week 24	12	8	45.58 (10.27)		23	17	46.85 (10.13)					
Change from baseline to week 24	12	5	0.00 (6.49)	-1.10 (3.81)	23	10	0.96 (8.38)	-0.08 (2.84)	1.02 [-9.00; 11.04]	0.8368	0.10 [-0.88; 1.08]	
Age												
< 18 years												
Baseline	3	1	44.15 (NA)		6	3	46.06 (10.13)					
Week 24	3	2	42.23 (5.42)		6	5	49.50 (7.70)					
Change from baseline to week 24	3	1	-5.75 (NA)	-6.45 (9.34)	6	3	2.55 (4.42)	1.44 (5.38)	7.90 [-14.67; 30.46]	0.4766	0.48 [-1.80; 2.77]	0.3564
>= 18 years												
Baseline	9	7	37.31 (10.76)		18	12	43.35 (9.21)					
Week 24	9	6	46.70 (11.65)		17	12	45.74 (11.10)					
Change from baseline to week 24	9	4	1.44 (6.51)	-0.07 (4.28)	17	7	0.27 (9.85)	-0.63 (3.29)	-0.56 [-12.20; 11.08]	0.9214	-0.05 [-1.15; 1.04]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

Change from baseline to week 24 in SF-36v2 physical functioning - Explorer 8 - HB - OTexBR - 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.
Region												
Non-OECD country												
Baseline	7	5	41.08 (9.44)		15	9	41.38 (9.57)					
Week 24	7	4	48.93 (7.07)		14	11	44.49 (11.60)					
Change from baseline to week 24	7	3	4.47 (2.93)	4.57 (4.77)	14	7	-1.10 (9.24)	-1.12 (3.24)	-5.69 [-17.37; 5.98]	0.3238	-0.61 [-1.98; 0.77]	0.4432
OECD country												
Baseline	5	3	33.30 (11.54)		9	6	47.65 (7.50)					
Week 24	5	4	42.23 (12.89)		9	6	51.16 (4.94)					
Change from baseline to week 24	5	2	-6.70 (1.34)	-8.37 (5.58)	9	3	5.75 (3.32)	4.05 (4.20)	12.42 [-2.66; 27.51]	0.1019	1.14 [-0.40; 2.68]	

HB: Haemophilia B, OTexBR: On-treatment excluding data before restart, PPX: Prophylaxis, NA: not applicable, NE: not estimable, 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). Only patients with available data for week 24 were included. Cut off date for data is 12th July 2022.

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2.4.1.1 Any adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX				
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value	p-value int.
All subjects (total)	24	11 (45.8)	12	5 (41.7)	1.18 (0.29, 4.81)	1.10 (0.50, 2.44)	4.17 (-30.12, 38.45)	0.8944	
Age group									0.4494
< 18 years	6	1 (16.7)	3	1 (33.3)	0.40 (0.02, 10.02)	0.50 (0.05, 5.51)	-16.67 (-77.78, 44.45)	0.7315	
>= 18 years	18	10 (55.6)	9	4 (44.4)	1.56 (0.31, 7.82)	1.25 (0.54, 2.89)	11.11 (-28.65, 50.87)	0.6862	
OECD membership									
OECD country	9	6 (66.7)	5	3 (60.0)					
Non-OECD country	15	5 (33.3)	7	2 (28.6)					

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.1.2 Severe adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	1 (4.2)	12	0 (0.0)	1.60 (0.06, 42.13)	1.56 (0.07, 35.67)	4.17 (-3.83, 12.16)	0.5925

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:10 - chef-safety-output.R/SevAE_HB_24saf_e8.txt

2.4.1.3 Moderate adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	5 (20.8)	12	2 (16.7)	1.32 (0.22, 8.04)	1.25 (0.28, 5.53)	4.17 (-22.45, 30.79)	0.8420

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:12 - chef-safety-output.R/ModAE_HB_24saf_e8.txt

2.4.1.4 Mild adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX				
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value	p-value int.
All subjects (total)	24	9 (37.5)	12	4 (33.3)	1.20 (0.28, 5.15)	1.12 (0.43, 2.92)	4.17 (-28.80, 37.13)	0.8843	
Age group									0.4448
< 18 years	6	1 (16.7)	3	1 (33.3)	0.40 (0.02, 10.02)	0.50 (0.05, 5.51)	-16.67 (-77.78, 44.45)	0.7315	
>= 18 years	18	8 (44.4)	9	3 (33.3)	1.60 (0.30, 8.49)	1.33 (0.46, 3.84)	11.11 (-27.30, 49.52)	0.6506	
OECD membership									
OECD country	9	6 (66.7)	5	3 (60.0)					
Non-OECD country	15	3 (20.0)	7	1 (14.3)					

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.1.5 Serious adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	3 (12.5)	12	2 (16.7)	0.71 (0.10, 4.98)	0.75 (0.14, 3.90)	-4.17 (-29.06, 20.73)	0.8251

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:17 - chef-safety-output.R/SerAE_HB_24saf_e8.txt

2.4.1.6 Adverse events leading to premature treatment discontinuation - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:19 - chef-safety-output.R/DisAE_HB_24saf_e8.txt

2.4.1.7 Any adverse events of special interest - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:21 - chef-safety-output.R/AnyAESI_HB_24saf_e8.txt

2.4.1.8 Overall Mortality - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:23 - chef-safety-output.R/MORT_HB_24saf_e8.txt

2.4.1.9 Any adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX				
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value	p-value int.
All subjects (total)	24	15 (62.5)	12	5 (41.7)	2.33 (0.57, 9.60)	1.50 (0.72, 3.14)	20.83 (-13.13, 54.79)	0.3003	
Age group									0.4894
< 18 years	6	2 (33.3)	3	1 (33.3)	1.00 (0.05, 18.91)	1.00 (0.14, 7.10)	0.00 (-65.33, 65.33)	0.9961	
>= 18 years	18	13 (72.2)	9	4 (44.4)	3.25 (0.61, 17.28)	1.62 (0.74, 3.56)	27.78 (-10.72, 66.28)	0.1745	
OECD membership									0.8968
OECD country	9	7 (77.8)	5	3 (60.0)	2.33 (0.22, 25.24)	1.30 (0.58, 2.87)	17.78 (-33.03, 68.59)	0.5896	
Non-OECD country	15	8 (53.3)	7	2 (28.6)	2.86 (0.42, 19.65)	1.87 (0.53, 6.60)	24.76 (-17.16, 66.68)	0.3144	

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:26 - chef-safety-output.R/AnyAE_HB_saf_e8.txt

2.4.1.10 Severe adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	2 (8.3)	12	0 (0.0)	2.78 (0.12, 62.54)	2.60 (0.13, 50.25)	8.33 (-2.72, 19.39)	0.3963

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:28 - chef-safety-output.R/SevAE_HB_saf_e8.txt

2.4.1.11 Moderate adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	8 (33.3)	12	2 (16.7)	2.50 (0.44, 14.23)	2.00 (0.50, 8.00)	16.67 (-11.62, 44.96)	0.3122
Age group								
< 18 years	6	1 (16.7)	3	0 (0.0)				
>= 18 years	18	7 (38.9)	9	2 (22.2)				
OECD membership								
OECD country	9	3 (33.3)	5	1 (20.0)				
Non-OECD country	15	5 (33.3)	7	1 (14.3)				

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.1.12 Mild adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX				
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value	p-value int.
All subjects (total)	24	11 (45.8)	12	4 (33.3)	1.69 (0.40, 7.17)	1.38 (0.55, 3.42)	12.50 (-20.80, 45.80)	0.5289	
Age group									0.6864
< 18 years	6	2 (33.3)	3	1 (33.3)	1.00 (0.05, 18.91)	1.00 (0.14, 7.10)	0.00 (-65.33, 65.33)	0.9961	
>= 18 years	18	9 (50.0)	9	3 (33.3)	2.00 (0.38, 10.58)	1.50 (0.53, 4.21)	16.67 (-21.83, 55.16)	0.4816	
OECD membership									0.9689
OECD country	9	7 (77.8)	5	3 (60.0)	2.33 (0.22, 25.24)	1.30 (0.58, 2.87)	17.78 (-33.03, 68.59)	0.5896	
Non-OECD country	15	4 (26.7)	7	1 (14.3)	2.18 (0.20, 24.21)	1.87 (0.25, 13.78)	12.38 (-21.87, 46.63)	0.6037	

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.1.13 Serious adverse events - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
All subjects (total)	24	5 (20.8)	12	2 (16.7)	1.32 (0.22, 8.04)	1.25 (0.28, 5.53)	4.17 (-22.45, 30.79)	0.8420

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:35 - chef-safety-output.R/SerAE_HB_saf_e8.txt

2.4.1.14 Adverse events leading to premature treatment discontinuation - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:37 - chef-safety-output.R/DisAE_HB_saf_e8.txt

2.4.1.15 Any adverse events of special interest - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:39 - chef-safety-output.R/AnyAESI_HB_saf_e8.txt

2.4.1.16 Overall Mortality - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

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2.4.2.1 Any adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
COVID-19								
All subjects (total)	24	3 (12.5)	12	1 (8.3)	1.57 (0.15, 16.94)	1.50 (0.17, 12.94)	4.17 (-16.32, 24.65)	0.7873
Arthropathy								
All subjects (total)	24	0 (0.0)	12	2 (16.7)	0.09 (0.00, 1.94)	0.10 (0.01, 2.01)	-16.67 (-37.75, 4.42)	0.0441

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.2.2 Any adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	24	7 (29.2)	12	2 (16.7)	2.06 (0.36, 11.91)	1.75 (0.43, 7.17)	12.50 (-15.34, 40.34)	0.4302
Musculoskeletal and connective tissue disorders								
All subjects (total)	24	3 (12.5)	12	2 (16.7)	0.71 (0.10, 4.98)	0.75 (0.14, 3.90)	-4.17 (-29.06, 20.73)	0.8251
Nervous system disorders								
All subjects (total)	24	4 (16.7)	12	1 (8.3)	2.20 (0.22, 22.20)	2.00 (0.25, 15.99)	8.33 (-13.27, 29.94)	0.6068
Injury, poisoning and procedural complications								
All subjects (total)	24	3 (12.5)	12	0 (0.0)	4.07 (0.19, 85.43)	3.64 (0.20, 65.26)	12.50 (-0.73, 25.73)	0.2927

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:54 - chef-safety-output.R/AnyAESOC_HB_24saf_e8.txt

2.4.2.3 Severe adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:56 - chef-safety-output.R/SevAEPT_HB_24saf_e8.txt

2.4.2.4 Severe adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:35:58 - chef-safety-output.R/SevAESOC_HB_24saf_e8.txt

2.4.2.5 Moderate adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:00 - chef-safety-output.R/ModAEPT_HB_24saf_e8.txt

2.4.2.6 Moderate adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:02 - chef-safety-output.R/ModAESOC_HB_24saf_e8.txt

2.4.2.7 Mild adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:05 - chef-safety-output.R/MilAEPT_HB_24saf_e8.txt

2.4.2.8 Mild adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	24	6 (25.0)	12	1 (8.3)	3.67 (0.39, 34.65)	3.00 (0.41, 22.18)	16.67 (-6.67, 40.00)	0.3003

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:07 - chef-safety-output.R/MilAESOC_HB_24saf_e8.txt

2.4.2.9 Serious adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:09 - chef-safety-output.R/SerAEPT_HB_24saf_e8.txt

2.4.2.10 Serious adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:11 - chef-safety-output.R/SerAESOC_HB_24saf_e8.txt

2.4.2.11 Adverse events leading to premature treatment discontinuation by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:13 - chef-safety-output.R/DisAEPT_HB_24saf_e8.txt

2.4.2.12 Adverse events leading to premature treatment discontinuation by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 24 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:15 - chef-safety-output.R/DisAESOC_HB_24saf_e8.txt

2.4.2.13 Any adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
COVID-19								
All subjects (total)	24	3 (12.5)	12	1 (8.3)	1.57 (0.15, 16.94)	1.50 (0.17, 12.94)	4.17 (-16.32, 24.65)	0.7873
Arthralgia								
All subjects (total)	24	3 (12.5)	12	0 (0.0)	4.07 (0.19, 85.43)	3.64 (0.20, 65.26)	12.50 (-0.73, 25.73)	0.2927
Arthropathy								
All subjects (total)	24	1 (4.2)	12	2 (16.7)	0.22 (0.02, 2.68)	0.25 (0.03, 2.49)	-12.50 (-35.05, 10.05)	0.2927
Headache								
All subjects (total)	24	3 (12.5)	12	0 (0.0)	4.07 (0.19, 85.43)	3.64 (0.20, 65.26)	12.50 (-0.73, 25.73)	0.2927

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.2.14 Any adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	24	10 (41.7)	12	2 (16.7)	3.57 (0.64, 19.97)	2.50 (0.65, 9.65)	25.00 (-3.87, 53.87)	0.1503
Injury, poisoning and procedural complications								
All subjects (total)	24	7 (29.2)	12	0 (0.0)	10.71 (0.56, 205.38)	7.80 (0.48, 126.13)	29.17 (10.98, 47.35)	0.0441
Musculoskeletal and connective tissue disorders								
All subjects (total)	24	4 (16.7)	12	2 (16.7)	1.00 (0.16, 6.42)	1.00 (0.21, 4.71)	0.00 (-25.82, 25.82)	1.0000
Nervous system disorders								
All subjects (total)	24	5 (20.8)	12	1 (8.3)	2.89 (0.30, 28.07)	2.50 (0.33, 19.08)	12.50 (-10.05, 35.05)	0.4204
Gastrointestinal disorders								
All subjects (total)	24	4 (16.7)	12	1 (8.3)	2.20 (0.22, 22.20)	2.00 (0.25, 15.99)	8.33 (-13.27, 29.94)	0.6068

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.2.15 Severe adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:22 - chef-safety-output.R/SevAEPT_HB_saf_e8.txt

2.4.2.16 Severe adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:25 - chef-safety-output.R/SevAESOC_HB_saf_e8.txt

2.4.2.17 Moderate adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:27 - chef-safety-output.R/ModAEPT_HB_saf_e8.txt

2.4.2.18 Moderate adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

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There is no data for this output
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nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:29 - chef-safety-output.R/ModAESOC_HB_saf_e8.txt

2.4.2.19 Mild adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

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There is no data for this output
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nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:31 - chef-safety-output.R/MilAEPT_HB_saf_e8.txt

2.4.2.20 Mild adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

	Concizumab PPX		No PPX		Concizumab PPX vs. No PPX			
	N	n (%)	N	n (%)	OR (95% CI)	RR (95% CI)	RD (95% CI)	p-value
Infections and infestations								
All subjects (total)	24	8 (33.3)	12	1 (8.3)	5.50 (0.60, 50.44)	4.00 (0.56, 28.40)	25.00 (0.50, 49.50)	0.1260
Injury, poisoning and procedural complications								
All subjects (total)	24	5 (20.8)	12	0 (0.0)	7.05 (0.36, 138.95)	5.72 (0.34, 95.62)	20.83 (4.59, 37.08)	0.1003
Musculoskeletal and connective tissue disorders								
All subjects (total)	24	3 (12.5)	12	1 (8.3)	1.57 (0.15, 16.94)	1.50 (0.17, 12.94)	4.17 (-16.32, 24.65)	0.7873
Nervous system disorders								
All subjects (total)	24	3 (12.5)	12	1 (8.3)	1.57 (0.15, 16.94)	1.50 (0.17, 12.94)	4.17 (-16.32, 24.65)	0.7873
Gastrointestinal disorders								
All subjects (total)	24	3 (12.5)	12	0 (0.0)	4.07 (0.19, 85.43)	3.64 (0.20, 65.26)	12.50 (-0.73, 25.73)	0.2927

HB: Haemophilia B, PPX: Prophylaxis, N: number of subjects, n: number of subjects with at least one event, 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 Q-test for homogeneity across 2x2xk contingency tables for k levels of each subgroup. Cut off date for data is 12th July 2022.

2.4.2.21 Serious adverse events by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:36 - chef-safety-output.R/SerAEPT_HB_saf_e8.txt

2.4.2.22 Serious adverse events by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:38 - chef-safety-output.R/SerAESOC_HB_saf_e8.txt

2.4.2.23 Adverse events leading to premature treatment discontinuation by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:40 - chef-safety-output.R/DisAEPT_HB_saf_e8.txt

2.4.2.24 Adverse events leading to premature treatment discontinuation by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:42 - chef-safety-output.R/DisAESOC_HB_saf_e8.txt

2.4.2.25 Any adverse events of special interest by preferred term - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:44 - chef-safety-output.R/AnyAESIPT_HB_saf_e8.txt

2.4.2.26 Any adverse events of special interest by system organ class - Explorer 8 - HB - on-treatment excluding data before restart - 32 weeks (Concizumab PPX) vs 24 weeks (No PPX) - safety analysis set

There is no data for this output

nn7415/nn7415-summary/amnog_8_20250520_er
21MAY2025:14:36:47 - chef-safety-output.R/AnyAESISOC_HB_saf_e8.txt