Hemofilie registratie

* = verplicht, ** = verplicht door validatie regel

Versie: 2022-06-08 - 1.1.0 (Interne code: hened-2021)

Identificatie

Patiëntnummer HemoNed register		

Patiëntidentificatie

Zorginstelling *		
Uniek Patiëntnummer *		
Land *	☐ Nederland	☐ Duitsland
	☐ België	☐ Zweden
	☐ Onbekend	
Identificatie code *		

Naam

Voorletters of voornaam		
Tussenvoegsels		
Geboortenaam *		
Geboortedatum (DDMMJJJJ) *		
Geslacht *	☐ Man	☐ Vrouw
Etniciteit	☐ Kaukasisch	☐ Aziatisch
	☐ Afrikaans	☐ Gemengd
Bloedgroep	☐ A	☐ B
	☐ O	☐ AB
VastePrik account *	☐ Nee	☐ Ja

VastePrik Accounts

Identificatie

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		

VastePrik Account

Wat is de relatie t.o.v de patiënt?	☐ Patiënt zelf	☐ Moeder
	☐ Vader	☐ Partner
	☐ Ander familielid	☐ Voogd
Wat is het 06-nummer?		
Wat is het e-mailadres?		
Herhaling emailadres		

Status

Wat is de vitale status van de patiënt? **	☐ In leven	☐ Overleden	☐ Onbekend
Datum overlijden (DD-MM-YYYY) * **	☐		
	☐ Datum onbekend		

Informed Consent

Is er informed-consent getekend? *	☐ Ja	☐ Niet gevraagd
	☐ Geweigerd	
Datum Informed Consent (DD-MM-YYYY)		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	☐ Niet akkoord	☐ Akkoord

Algemeen

Identificatie

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Diagnose *	❑ Hemofilie A	❑ Hemofilie B
	❑ Hemofilie B Leyden	❑ Von Willebrand
	❑ Andere stollingsafwijking	❑ Verworven stollingsafwijking
	❑ Draagster	

Ernst

Ernst Hemofilie	❑ Ernstig	❑ Matig
	❑ Mild	❑ Onbekend

Type Von Willebrand

Kies hier het type Von Willebrand	❑ Type 1	❑ Type 2, geen verdere subtypering
	❑ Type 2A	❑ Type 2B
	❑ Type 2M	❑ Type 2N
	❑ Type 2 Vicenza	❑ Type 3
	❑ Type onbekend	❑ Anders namelijk...
Toelichting keuze 'Anders namelijk'		

Andere stollingsafwijking

Kies hier welke stollingsafwijking is gediagnostiseerd	❑ Ziekte van Glanzmann	❑ Bernard-Soulier Syndroom
	❑ Storage pool disease	❑ Grijze bloedplaatjessyndroom
	❑ Bloedplaatjesstoornis: anders, namelijk	❑ Bloedplaatjesstoornis: type onbekend
	❑ Factor I (Fibrinogeen) deficiëntie	❑ Afibrinogenemie
	❑ Hypofibrinogenemie	❑ Hypodysfibrinogenemie
	❑ Dysfibrinogenemie	❑ Factor II (Protrombine) deficiëntie
	❑ Factor V deficiëntie/Parahemofilie	❑ Combinatie factor V+VIII deficiëntie
	❑ Factor VII deficiëntie	❑ Factor X deficiëntie
	❑ Factor XI deficiëntie/Hemofilie C	❑ Factor XIII deficiëntie
	❑ Combinatie factor II+VII+IX+X deficiëntie	❑ Alfa-2-antiplasminedeficiëntie
	❑ Factordeficiëntie: anders, namelijk	❑ Factordeficiëntie: type onbekend
Toelichting keuze 'Anders namelijk'		

De patiënt heeft de volgende aandoening

De patiënt is drager van de volgende aandoening

Aandoening	❑ Hemofilie A	❑ Hemofilie B
	❑ Von Willebrand	❑ Factor V deficiëntie
	❑ Onbekend	❑ Anders, namelijk
Toelichting keuze 'Anders namelijk'		

Verworven stollingsafwijking

Status	❑ Actief	❑ Afgesloten
Datum afgesloten (DD-MM-YYYY)	❑	
	❑ Datum onbekend	
Is deze geregistreerde diagnose de hoofddiagnose?	❑ Nee	❑ Ja
Reden diagnose	❑ symptomen	❑ positieve familieanamnese
	❑ combinatie	
Familieanamnese	❑ positief	❑ negatief ❑ onbekend

Gen mutatie

Welke genetische mutatie heeft de patiënt?	❑ Intron-22-inversie	❑ Niet getest
	❑ Geen mutatie gevonden	❑ Mutatie bekend
Is deze mutatie vastgesteld bij de patiënt of de familie van de patiënt?	❑ patiënt	❑ familie
Mutatie		

Aantal ‘exposure days’ bij inclusie register	❑< 10		❑10 - 50
	❑50 - 100		❑100 - 1000
	❑> 1000		❑Onbekend

Laagste gemeten labuitslagen + datum en type bepaling

In geval er geen factor gedefinieerd is maar er toch een labuitslag is, dan kunnen de gegevens (gemeten factor, meetwaarde, meeteenheid, en datum) hier ingevuld worden.			
Hoeveelheid *			
Kies de eenheid bij hoeveelheid *	❑%	❑IE/ml	❑g/L
Type bepaling *	❑one-stage		❑two-stage
	❑chromogeen		❑onbekend
Datum bepaling (DD-MM-YYYY) *	❑.....		
	❑Datum onbekend		
Hoeveelheid *			
Kies de eenheid bij hoeveelheid *	❑%	❑IE/ml	❑g/L
Datum bepaling (DD-MM-YYYY) *	❑.....		
	❑Datum onbekend		
3. Welk type VWF activiteit bepaling wilt u invullen? *	❑VWF:RCo		❑VWF:GPIbR
	❑VWF:GPIbM		❑VWF:Ab
Hoeveelheid *			
Is deze waarde onder de detectiegrens? *	❑Nee		❑Ja
Kies de eenheid bij hoeveelheid *	❑%		❑IE/ml
	❑g/L		❑IE/dL
Datum bepaling (DD-MM-YYYY) *	❑.....		
	❑Datum onbekend		
Hoeveelheid *			
Kies de eenheid bij hoeveelheid *	❑%		❑IE/ml
Datum bepaling (DD-MM-YYYY) *	❑.....		
	❑Datum onbekend		
Laagst gemeten Labuitslag van Factor VIII/IX met ander type bepaling toevoegen?	❑Nee		❑Ja

Andere type bepaling (assay) dan gekozen bij 1

Hoeveelheid			
Kies de eenheid bij hoeveelheid	❑%	❑IE/ml	
Type bepaling	❑one-stage		❑two-stage
	❑chromogeen		❑onbekend
Datum bepaling (DD-MM-YYYY)	❑.....		
	❑Datum onbekend		

Remmers

Heeft de patiënt een remmer gehad?	❑Nee, nooit		❑Ja, in het verleden
	❑Ja, nu aanwezig		❑Onbekend

Bloedoverdraagbare infecties

Heeft de patiënt ooit een bloedoverdraagbare infectie gehad?	❑Nee	❑Ja	❑Onbekend
Type infectie(s)			
HIV	❑Nee		❑Ja
Hepatitis C	❑Nee		❑Ja
Wat is de status van de Hepatitis C infectie	❑succesvol behandeld		❑nog geïnfecteerd
	❑spontaan geklaard		❑Onbekend
Hepatitis B	❑Nee		❑Ja
Wat is de status van de Hepatitis B infectie	❑succesvol behandeld		❑nog geïnfecteerd
	❑spontaan geklaard		❑Onbekend

Anders, namelijk	❑ Nee	❑ Ja
Toelichting keuze 'Anders namelijk'		
Wat is de status van deze infectie	❑ succesvol behandeld	❑ nog geïnfecteerd
	❑ spontaan geklaard	❑ Onbekend

Geboorte

Geboorte

Op welke wijze vond de geboorte plaats?	❑ Vaginaal, geen hulpmiddelen	❑ Keizersnede
	❑ Vaginaal, met verlostang	❑ Vaginaal, met vacuümpomp
	❑ Anders, namelijk	❑ onbekend
Toelichting keuze 'Anders namelijk'		

Moeder op de hoogte van diagnose bij bevalling?	❑ Nee	❑ Ja	❑ Onbekend
Intracraniële bloeding in 1e week	❑ Nee	❑ Ja	❑ Onbekend

Accordering

De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Als u een tweede (bijkomende) diagnose wilt registreren, ga dan naar 'Diagnose' in het linker menu, en klik op toevoegen. U kunt maximaal twee diagnoses toevoegen. U kunt maximaal 2 diagnoses registreren.

Algemeen

LET OP: Voeg bij wijzigingen altijd een nieuwe behandelplan toe met ALLE producten die (zo nodig) gebruikt worden. Geef ook aan wanneer er GEEN behandelplan is.

Behandelplan

Is er een behandelplan?	❑ Nee	❑ Ja
Datum behandelplan (DD-MM-YYYY) *		

Identificatie

Ziekenhuis *	
Unieke patiëntcode binnen kliniek *	
Profylaxe	❑ Nee ❑ Ja

Producten

Productlijst

Met welk product wordt de patiënt behandeld?		
Wat is de reden om te starten met Hemlibra? *	❑ Aanwezigheid van remmer met bloedingsneiging	❑ Slecht perifeer te prikken
	❑ Zelf niet in staat profylaxe toe te dienen	❑ Niet goed bloedingsvrij ondanks reguliere profylaxe
	❑ Een zeer actief leven waarbij reguliere profylaxe onvoldoende bescherming biedt (bv sporters of veel verblijf in buitenland)	❑ Arts en patiënt besluiten dat Hemlibra om een andere reden een betere keuze is dan reguliere profylaxe
	❑ Hemlibra wordt al gebruikt, er is een verandering in dosering of frequentie	
Toelichting keuze 'Anders namelijk'		
Wat is de reden voor gebruik van dit product?	❑ Profylaxe	❑ Bloeding/Ingreep
Kies de frequentie	❑ [aantal] keer per dag	❑ Om de [aantal] dagen
	❑ [aantal] keer per week	❑ Eén keer per [aantal] weken
	❑ Anders, namelijk	
[aantal]: *		

Toelichting keuze 'Anders namelijk'		
Dosis profylaxe ([aantal] IE of gram of milligram per keer		
Stopdatum behandelplan (DD-MM-YYYY)		
Wat is de reden om te stoppen met Hemlibra? *	❑ Onvoldoende effectiviteit van Hemlibra	❑ Bijwerkingen van Hemlibra
	❑ Arts en patiënt besluiten om een andere reden dat behandeling met reguliere profylaxe te prefereren is boven gebruik van Hemlibra	❑ Hemlibra wordt niet gestopt, er is een verandering in dosering of frequentie

Accordering

De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Biometrie meting

LET OP: Voeg altijd een nieuwe biometrie toe bij wijzigingen.

Datum (laatste) meting biometrie (DD-MM-YYYY) *		
Gewicht (kg)		
Lengte (cm)		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Demographics

Enrolment date *		
Unique Patient Identifier *		
Date of birth *		
Sex at birth *	❑ Male	❑ Female
Country of residence *	❑ Nederland	❑ Duitsland
	❑ België	❑ Zweden
	❑ Onbekend	
Race *	❑ White	❑ Black
	❑ Asian	❑ Other, specify
	❑ Unknown	
Other race, please specify *		
HTC for GT administration *	❑ Academisch Medisch Centrum, Amsterdam	❑ Academisch Ziekenhuis Maastricht, Maastricht
	❑ Erasmus Medisch Centrum, Rotterdam	❑ HagaZiekenhuis, Den Haag
	❑ Leids Universitair Medisch Centrum, Leiden	❑ Máxima Medisch Centrum, Veldhoven
	❑ Radboudumc, Nijmegen	❑ UMC Utrecht, Utrecht
	❑ Universitair Medisch Centrum Groningen, Groningen	
HTC for follow-up data *	❑ Same as HTC for GT administration	❑ Other HTC
Select other HTC for follow-up data *	❑ Academisch Medisch Centrum, Amsterdam	❑ Academisch Ziekenhuis Maastricht, Maastricht
	❑ Erasmus Medisch Centrum, Rotterdam	❑ HagaZiekenhuis, Den Haag
	❑ Leids Universitair Medisch Centrum, Leiden	❑ Máxima Medisch Centrum, Veldhoven
	❑ Radboudumc, Nijmegen	❑ UMC Utrecht, Utrecht
	❑ Universitair Medisch Centrum Groningen, Groningen	
Specify other HTC for follow-up-data *		

Diagnosis

Hemophilia Type *	❑ A		❑ B
Severity *	❑ Mild	❑ Moderate	❑ Severe
Year of diagnosis (if known)			
Baseline factor level *			

DNA Variant	❑ Intron 22 inversion	❑ Intron 1 inversion
	❑ Other	❑ Not Done
	❑ Unknown	
Please Specify (using HGVS terminology) *		
DNA Variant type	❑ Inversion	❑ Large structural variant (≥ 50 bp)
	❑ Nonsense	❑ Frameshift
	❑ Small insertion or deletion (indel) (<50 bp)	❑ Splice
	❑ Missense	❑ Synonymous
	❑ Promoter UTR	❑ Other, please specify
	❑ Unknown	
Please specify other *		

Medical / Clinical History

Family history of hemophilia *	❑ Yes	❑ No	❑ Unknown
Factor VIII or IX inhibitor? *	❑ Current	❑ Past	
	❑ Never	❑ Unknown	
Most recent titre *			
Type of test *	❑ Bethesda	❑ Nijmegen-Bethesda	
	❑ Mixing study	❑ Unknown	
Did the patient receive ITI? *	❑ Yes	❑ No	❑ Unknown
Was patient on prescribed prophylaxis at time of GT? *	❑ Yes	❑ No	❑ Unknown
For how many continuous years? *			
Number of exposure days of factor replacement therapy prior to gene therapy infusion? *	❑ <50 days	❑ 50-150 days	
	❑ >150 days		

AAV Neutralizing Antibodies

Test methodology

Transduction inhibition assay *	❑ Yes	❑ No	
Date of test *			
Result *	❑ Positive	❑ Negative	❑ N/A
Titre (if recorded)			
Total antibody *	❑ Yes	❑ No	
Date of test *			
Result *	❑ Positive	❑ Negative	❑ N/A
Titre (if recorded)			
Other *	❑ Yes	❑ No	
Please specify other *			
Date of test *			
Result *	❑ Positive	❑ Negative	❑ N/A
Titre (if recorded)			

Pre-existing / Co-morbidities

Pre-existing /Co-morbidites

Thromboembolic event(s) *	❑ Yes	❑ No	❑ Unknown

Select all thromboembolic events that apply

Deep vein thrombosis **	❑ Yes
Date of onset *	
Myocardial infarction **	❑ Yes
Date of onset *	
Pulmonary embolism **	❑ Yes

Date of onset *			
Non-hemorrhagic stroke **	❑Yes		
Date of onset *			
Thrombotic microangiopathy **	❑Yes		
Date of onset *			
Other (please specify) **	❑Yes		
Date of onset *			
Specify other thromboembolic event *			

Autoimmune disorders

Autoimmune disorders *	❑Yes	❑No	❑Unknown

Select all autoimmune disorders that apply

Systemic lupus erythematosus **	❑Yes		
Rheumatoid arthritis **	❑Yes		
Psoriasis **	❑Yes		
Ulcerative colitis **	❑Yes		
Crohn's disease **	❑Yes		
Multiple sclerosis **	❑Yes		
Sjogren's syndrome **	❑Yes		
Polymyalgia rheumatic **	❑Yes		
Ankylosing spondylitis **	❑Yes		
Type 1 diabetes **	❑Yes		
Other (please specify) **	❑Yes		
Please specify other autoimmune disorder			

History of cancer

History of cancer *	❑Yes	❑No	❑Unknown

Select all types that apply

Lymphoma **	❑Yes		
Leukemia **	❑Yes		
Liver **	❑Yes		
Lung **	❑Yes		
Prostate **	❑Yes		
Colorectal **	❑Yes		
Stomach **	❑Yes		
Breast **	❑Yes		
Other (please specify) **	❑Yes		
Please specify other cancer *			

HIV

HIV-positive *	❑Yes	❑No	❑Unknown

Liver related medical history

Pre-existing liver disease *	❑Yes	❑No	❑Unknown

Select all pre-existing liver diseases that apply

Autoimmune hepatitis **	❑Yes		
Fatty liver disease **	❑Yes		
Gilbert's syndrome **	❑Yes		
Other **	❑Yes		

Please specify pre-existing liver disease *	

Hepatitis C

History of hepatitis C infection *	❑ Yes	❑ No	❑ Unknown
Resolved? *	❑ Ongoing	❑ Resolved	
Month (1-12) *			
Year *			
Estimated duration of Hep C infection (years) to the nearest 10 years *			

Hepatitis B

History of hepatitis B infection *	❑ Yes	❑ No	❑ Unknown
Ongoing infection (HBsAg and/or HBV DNA positive)? *	❑ Yes	❑ No	

Liver assessment in the last 2 years (select all that apply)

Ultrasound **	❑ Yes	
Date (most recent) *		
Result (most recent) *		
Liver biopsy **	❑ Yes	
Date (most recent) *		
Result (most recent) *		
Fibrosis stage **	❑ Yes	
Date (most recent) *		
METAVIR result *		
Methodology *	❑ Radiologic	❑ Serologic
Radiologic methodology *	❑ Fibroscan	❑ Other (Please specify)
Specify other radiologic methodology *		
Score *		
Serologic methodology *	❑ Fibrotest/Fibrosure	❑ Hepascore
	❑ FibroSpect	❑ ELF Score
	❑ Other (please specify)	
Score *		
Score *		
Score *		
Score *		
Score *		
Specify other serologic methodology *		
ALT **	❑ Yes	
Date (most recent) *		
Result (most recent) *		
AST **	❑ Yes	
Date (most recent) *		
Result (most recent) *		
Total bilirubin **	❑ Yes	
Date (most recent) *		
Result (most recent) *		

Concomitant medication

Concomitant medication

Any concomitant medication (prescription, over the counter (OTC), herbal medications, and supplements)? *	❑ Yes	❑ No	❑ Unknown

Which medication *	❑ List of medications (incl. over the counter)	❑ Other, please specify	
	❑ Unknown		
Please specify other concomitant medication *			

Alcohol

Alcohol consumption *	❑ Yes	❑ No	❑ Unknown
Over the past month, on average how many drinks were consumed per week? (One drink equals one bottle of beer or cooler, 150 ml (5 oz) glass of wine, or any drink containing a shot of liquor) *	❑ 0	❑ 1-3	
	❑ 4-7	❑ 8 or more	

Gene Therapy Details

Gene Therapy Details

Vector product *	❑ Optieset 508	❑ Moet nog gevuld worden
	❑ Met assay / reagents	❑ Manufacturer / reagent
	❑ Unknown	
Batch number *		
Lot number (EMA requirement) *		
Date of infusion *		
Dose – total vector genomes *		
Dosing weight (kg) *		
Vector genomes/kg *		
Complications at time of infusion (24 hours) *	❑ Yes	❑ No

Select all complications that apply

Fever (>38.5) **	❑ Yes
Myalgia **	❑ Yes
Hypotension **	❑ Yes
Other **	❑ Yes
Specify other complication *	
Complications during the following 2 weeks *	❑ Yes ❑ No

Select all complications that apply

Fever (>38.5) **	❑ Yes
Myalgia **	❑ Yes
Hypotension **	❑ Yes
Other **	❑ Yes
Specify other complication *	

Factor Level Tests

Entry date *	

Factor level testing

FVIII/FIX activity level test *	❑ Yes	❑ No	❑ Unknown
Month of test (1-12) *			
Year of test *			
Factor level (IU/dL) *			
Type of assay *	❑ One-stage	❑ Chromogenic	
	❑ Unknown (lab info)		

Assay reagents *	❑ Optieset 508	❑ Moet nog gevuld worden
	❑ Met assay / reagents	❑ Manufacturer / reagent
	❑ Unknown	

Optional second test

Month of test (1-12)		
Year of test		
Factor level (IU/dL)		
Type of assay	❑ One-stage	❑ Chromogenic
	❑ Unknown (lab info)	
Assay reagents	❑ Optieset 508	❑ Moet nog gevuld worden
	❑ Met assay / reagents	❑ Manufacturer / reagent
	❑ Unknown	

Optional third test

Month of test (1-12)		
Year of test		
Factor level (IU/dL)		
Type of assay	❑ One-stage	❑ Chromogenic
	❑ Unknown (lab info)	
Assay reagents	❑ Optieset 508	❑ Moet nog gevuld worden
	❑ Met assay / reagents	❑ Manufacturer / reagent
	❑ Unknown	

Efficacy

Date of visit *		

Bleeding requiring treatment

Bleeding events *	❑ Yes	❑ No	❑ Unknown
Date of bleeding *			
Reason *	❑ Traumatic	❑ Non-traumatic	
Was the bleed treated *	❑ Yes	❑ No	
Bleed Location *	❑ Joint	❑ Muscle	
	❑ Mucosal	❑ Head – intracranial	
	❑ Head – extracranial	❑ Other	

Factor or non-factor treatments

Use of any hemostatic treatment (factor, emicizumab, other) *	❑ Yes	❑ No
Month of treatment (1-12) *		
Year of treatment *		
Treatment drug *		
Specify other *		
Dose *		
Units *	❑ IU	❑ Mg
Frequency *	❑ 3 times per week	❑ 2 times per week
	❑ 1 time per week	❑ 1 time per month
	❑ 2 times per month	❑ Other
Please specify other frequency *		
Type *	❑ Prophylaxis – Continuous	❑ Prophylaxis – Event-based, short term or intermittent
	❑ Episodic (On demand)	❑ Immune Tolerance Induction
	❑ Other	❑ Unknown
Please specify other type *		
Add another treatment drug?	❑ Yes	
Treatment drug *		
Specify other *		

Dose *		
Units *	❑IU	❑Mg
Frequency *	❑3 times per week	❑2 times per week
	❑1 time per week	❑1 time per month
	❑2 times per month	❑Other
Please specify other frequency *		
Type *	❑Prophylaxis – Continuous	❑Prophylaxis – Event-based, short term or intermittent
	❑Episodic (On demand)	❑Immune Tolerance Induction
	❑Other	❑Unknown
Please specify other type *		
Add another treatment drug?	❑Yes	
Treatment drug *		
Specify other *		
Dose *		
Units *	❑IU	❑Mg
Frequency *	❑3 times per week	❑2 times per week
	❑1 time per week	❑1 time per month
	❑2 times per month	❑Other
Please specify other frequency *		
Type *	❑Prophylaxis – Continuous	❑Prophylaxis – Event-based, short term or intermittent
	❑Episodic (On demand)	❑Immune Tolerance Induction
	❑Other	❑Unknown
Please specify other type *		

Concomitant medications

Any change in concomitant medications since last visit (prescription, over-the-counter (OTC), herbal medications, and supplements)? *	❑Yes	❑No	❑Unknown
Medication changed *	❑List of medications (incl. over the counter)	❑Other, please specify	
	❑Unknown		
Please specify other changed medication *			
Dose *			
Start date *			
Ongoing medication *	❑Yes	❑No	
End date *			

Safety data

Date of visit *		
Adverse events of special interest *	❑Yes	❑No
FVIII inhibitors **	❑Yes	
Month of onset (1-12) *		
Year of onset *		
Month of resolution (1-12)		
Year of resolution		
Description *		
FIX inhibitors **	❑Yes	
Month of onset (1-12) *		
Year of onset *		
Month of resolution (1-12)		
Year of resolution		
Description *		
Thromboembolic events **	❑Yes	

Select all thromboembolic events that apply

Deep vein thrombosis **	❑Yes
Myocardial infarction **	❑Yes
Pulmonary embolism **	❑Yes
Non-hemorrhagic stroke **	❑Yes
Thrombotic microangiopathy **	❑Yes
Other (please specify) **	❑Yes
Please specify other *	
Month of onset (1-12) *	
Year of onset *	
Month of resolution (1-12)	
Year of resolution	
Description *	
Autoimmune disorders **	❑Yes

Select all autoimmune disorders that apply

Systemic lupus erythematosus **	❑Yes
Rheumatoid arthritis **	❑Yes
Psoriasis **	❑Yes
Ulcerative colitis **	❑Yes
Crohn's disease **	❑Yes
Multiple sclerosis **	❑Yes
Sjogren's syndrome **	❑Yes
Polymyalgia rheumatic **	❑Yes
Ankylosing spondylitis **	❑Yes
Type 1 diabetes **	❑Yes
Other (please specify) **	❑Yes
Specify other *	
Month of onset (1-12) *	
Year of onset *	
Month of resolution (1-12)	
Year of resolution	
Description *	
Malignancies **	❑Yes

Select all malignancies that apply

Leukemia **	❑Yes
Lymphoma **	❑Yes
Liver **	❑Yes
Lung **	❑Yes
Prostate **	❑Yes
Colorectal **	❑Yes
Stomach **	❑Yes
Breast **	❑Yes
Other (please specify) **	❑Yes
Specify other *	
Month of onset (1-12) *	
Year of onset *	
Month of resolution (1-12)	
Year of resolution	
Description *	
Liver disease **	❑Yes

Month of onset (1-12) *			
Year of onset *			
Month of resolution (1-12)			
Year of resolution			
Description *			
Sensory paresthesias **	❑Yes		
Has the patient developed new sensory disturbances which may include tingling, numbness or pain not attributed to another cause (carpal tunnel, shingles, etc)? *	❑Yes	❑No	❑Unknown
Month of onset (1-12) *			
Year of onset *			
Month of resolution (1-12)			
Year of resolution			
Description *			
Other **	❑Yes		

Other adverse advent

Specify other *	
Month of onset (1-12) *	
Year of onset *	
Month of resolution (1-12)	
Year of resolution	
Description *	

Inhibitor testing

Inhibitors tested against FVIII/FIX *	❑Yes	❑No	❑Unknown
Date of test *			
Type of test *	❑Bethesda	❑Nijmegen-Bethesda	
	❑Mixing study	❑Unknown	
Result *	❑Positive	❑Negative	❑N/A
Titre (BU/mL) *			

Liver function

Liver function tests *	❑Yes	❑No	❑Unknown

ALT

ALT **	❑Yes	
Test date (dd-mm-yyyy) *		
Result *		
Value out of normal range *	❑Yes	❑No
Reference ranges (min/max) *		

AST

AST **	❑Yes	
Test date (dd-mm-yyyy) *		
Result *		
Value out of normal range *	❑Yes	❑No
Reference ranges (min/max) *		

Bilirubin

Bilirubin **	❑Yes
Test date (dd-mm-yyyy) *	

Result *		
Value out of normal range *	❑Yes	❑No
Reference ranges (min/max) *		

Other

Other (specify) **	❑Yes
Test date (dd-mm-yyyy) *	
Specify other *	
Result *	
Value out of normal range *	❑Yes ❑No
Reference ranges (min/max) *	

If elevated enzymes: are there alternative diagnoses? (select all that apply)

High alcohol intake **	❑Yes
Nonalcoholic fatty liver disease **	❑Yes
Extreme exercise/exertion **	❑Yes
Concurrent viral infection **	❑Yes
Acetaminophen **	❑Yes
Gilbert's syndrome **	❑Yes
Other (please specify) **	❑Yes
Specify other *	

Has patient been diagnosed liver disease?

Liver failure **	❑Yes		
Date of diagnosis *			
Cirrhosis **	❑Yes		
Date of diagnosis *			
Liver fibrosis and/or progression of liver fibrosis **	❑Yes		
Date of diagnosis *			
Liver biopsies? *	❑Yes	❑No	❑Unknown
Date of biopsy *			
Results (findings, vector integration and its relation to any liver related malignancies) *			
Have you received non-vector related immunosuppressive therapy since last follow-up? *	❑Yes	❑No	❑Unknown
Drug name *			
Dose *			
Date *			

New onset comorbidities

Onset of any other new co-morbidities *	❑Yes	❑No

Select all co-morbidities that apply

Respiratory disease **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Hypertension **	❑Yes
Date of onset *	
Date of resolution *	
Description *	

Kidney disease **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Diabetes **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Osteoarthritis **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Osteoporosis **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Rheumatoid arthritis **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Obesity **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Anxiety **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Depression **	❑Yes
Date of onset *	
Date of resolution *	
Description *	
Other **	❑Yes
Specify other *	
Date of onset *	
Date of resolution *	
Description *	

Surgeries

Date of visit *			
Surgeries *	❑Yes	❑No	❑Unknown
What was the surgery *	❑Abdominal surgery	❑Orthopedic surgery	
	❑Dental procedure	❑Central device	
	❑Neurosurgery	❑Other (please specify)	
	❑Unknown		
Specify other surgery *	❑Optieset 508	❑Moet nog gevuld worden	
	❑Met assay / reagents	❑Manufacturer / reagent	
	❑Unknown		

Surgery date

Month (1-12) *		
Year *		
Severity *	❑Major	❑Minor

Did the surgery require factor? *	❑ Yes		❑ No
Factor details *			
Total dose (IU/kg) *			
Bleeding complication *	❑ Yes		❑ No
Additional intervention *	❑ Required red cell transfusion		❑ Required additional factor
	❑ Other (please specify)		
Specify other additional intervention *			

Quality of Life

Date *	
EQ-5D-5L score *	
PROBE score *	

Mortality

Date of death

Month (1-12) **			
Year **			
Death related to gene therapy *	❑ Yes	❑ No	❑ Unknown
Primary cause of death *	❑ Intracranial hemorrhage		❑ Bleeding (excluding intracranial)
	❑ Thromboembolic event		❑ Liver disease
	❑ Cancer		❑ Cardiac
	❑ Infection (including pneumonia)		❑ HIV
	❑ Other		
Please specify cancer *	❑ Leukemia		❑ Lymphoma
	❑ Liver		❑ Lung
	❑ Prostate		❑ Colorectal
	❑ Stomach		❑ Breast
	❑ Other		
Please specify other cancer *			
Please specify liver disease *			
Please specify other *			

Medicatie uitgifte EPD koppeling

identifier.value van FHIR Medication Expence *			
Datum uitgifte *			
Uitgiftekenmerk	❑ Klinisch		❑ Poliklinisch
	❑ Thuis		
Naam product			
Dosis product			
Eenheid dosis product	❑ IE	❑ Gram	❑ Milligram
Verstrekte hoeveelheid product			
Batchnummer			

Labuitslagen EPD koppeling

Datum en tijd van bloedafname *	
Factor VIII: one-stage in IE/ml	
Factor VIII: chromogeen in IE/ml	
FVIII remmer in BU/ml	
Factor IX: one-stage in IE/ml	
FIX remmer in BU/ml	
VWF:GP1bR in IE/ml	
VWF Antigeen in IE/ml	

VWF:RCo in IE/ml	

Surgical procedure

Identificatie

Ziekenhuis *	
Unieke patiëntcode binnen kliniek *	
Type event	❑ Allergic or other acute event ❑ Inhibitor event ❑ Malignancy event ❑ Poor efficacy event ❑ Other possible adverse or unusual event ❑ Levensbedreigende bloedingen ❑ Transfusion transmitted infection event ❑ Thrombosis event ❑ Death event ❑ Neurological event ❑ Chirurgische ingreep ❑ Vaccination event
Datum ingreep (DD-MM-YYYY) *	

Orthopedische ingreep/port-a-cath

Type orthopedische ingreep/port-a-cath	❑ Yttrium synoviorthese ❑ Synovectomie ❑ Arthroplastiek ❑ Wedge- Osteotomie ❑ Verwijdering Orthopedisch materiaal ❑ Fractuur ❑ Anders, namelijk ❑ arthrosc. Synoviorthese ❑ Artrodese ❑ Tenotomie ❑ Verwijdering van cysten ❑ Behandeling van complicatie ❑ Porth-a-cath plaatsen/verwijderen
Toelichting keuze 'Anders namelijk'	

Locatie orthopedische chirurgie

Locatie	❑ Rechter elleboog ❑ Rechter knie ❑ Rechter enkel ❑ Rechter heup ❑ Elleboog ❑ Enkel ❑ Anders namelijk ❑ Linker elleboog ❑ Linker knie ❑ Linker enkel ❑ Linker heup ❑ Knie ❑ Heup ❑ Niet van toepassing
Toelichting keuze 'Anders namelijk'	

Overige ingrepen

Type ingreep	
Indicatie	
Hemostatische uitkomst	❑ Goed ❑ Matig ❑ Slecht
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord ❑ Akkoord

Allergic or other acute event

Identification

Ziekenhuis *	
Unieke patiëntcode binnen kliniek *	
Type of event *	❑ Allergic or other acute event ❑ Inhibitor event ❑ Malignancy event ❑ Poor efficacy event ❑ Other possible adverse or unusual event ❑ Levensbedreigende bloedingen ❑ Transfusion transmitted infection event ❑ Thrombosis event ❑ Death event ❑ Neurological event ❑ Chirurgische ingreep ❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *	

Type of acute event(s)

Anaphylaxis *	❑ Yes ❑ No

Shortness of breath *	❑ Yes	❑ No
Rash *	❑ Yes	❑ No
Rigors (shivering) *	❑ Yes	❑ No
Other *	❑ Yes	❑ No
Explain other: *		

Algemeen

Product *		
Explain 'Other, namely' *		
Batchnumbers *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		
Batchnumbers *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		
Batchnumbers *		
Additional blood products? *	❑ Yes	❑ No
Blood	❑ Yes	
FFP	❑ Yes	
Cryoprecipitate	❑ Yes	

Time between dose and event

Number *			
Unit *	❑ Minutes	❑ Hours	❑ Days
Lifetime exposure days *	❑ < 10	❑ 10-50	❑ > 50

Has this happened previously?

Has this happend previously? *	❑ Yes	❑ No
Details *		
Outcome *	❑ Resolved	❑ Alive with long term disability
	❑ Death	
Do you consider this relationship to the concentrate to be *	❑ Definite (the adverse event is clearly related to the drug)	❑ Probable (the adverse event is likely related to the drug)
	❑ Possible (the adverse event may be related to the drug)	❑ Unlikely (the adverse event is doubtfully related to the drug)
	❑ Unrelated (the adverse event is clearly NOT related to the drug)	
Comment		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Transfusion transmitted infection event

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event

Date of occurrence of event (DD-MM-YYYY) *		

Infection

Infection *	❑HIV	❑Hepatitis A
	❑Hepatitis B	❑Hepatitis C
	❑Parvovirus B19	❑vCJD
	❑Other,	
Explain other: *		

Product(s)

Product 1 *		
Explain 'Other, namely' *		
Batchnumber(s) 1 *		
Add another batch or product? *	❑Yes	❑No
Product 2 *		
Explain 'Other, namely' *		
Batchnumber(s) 2 *		
Add another batch or product? *	❑Yes	❑No
Product 3 *		
Explain 'Other, namely' *		
Batchnumber(s) 3 *		
Add another batch or product? *	❑Yes	❑No
Product 4 *		
Explain 'Other, namely' *		
Batchnumber(s) 4 *		
Add another batch or product? *	❑Yes	❑No
Write down any more productname(s) and batchnumbers. *		
Additional blood products? *	❑Yes	❑No
Blood	❑Yes	
FFP	❑Yes	
Cryoprecipitate	❑Yes	
Last negative test date (DD-MM-YYYY) *	❑.....	
	❑Datum onbekend	
First positive test date (DD-MM-YYYY) *		
Last exposure date (DD-MM-YYYY) *	❑.....	
	❑Datum onbekend	
Do you consider this relationship to the concentrate to be *	❑Definite (the adverse event is clearly related to the drug)	❑Probable (the adverse event is likely related to the drug)
	❑Possible (the adverse event may be related to the drug)	❑Unlikely (the adverse event is doubtfully related to the drug)
	❑Unrelated (the adverse event is clearly NOT related to the drug)	
Comment		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑Niet akkoord	❑Akkoord

Inhibitor event

Identification

Ziekenhuis *	
Unieke patiëntcode binnen kliniek *	

Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *		
Is this the first ever inhibitor? *	❑ Yes	❑ No, reappearance of a previous inhibitor
Has the inhibitor reappeared after immune tolerance induction (IT)? *	❑ Yes	❑ No
Previous inhibitor information: *		

Product(s)

Products used in 3 months prior to inhibitor, start with the most recently used product. *		
Explain 'Other, namely' *		
Batchnumber *		
Add another batch or product? *	❑ Yes	❑ No
Other product used in 3 months prior to inhibitor. *		
Explain 'Other, namely' *		
Batchnumber *		
Add another batch or product? *	❑ Yes	❑ No
Other product used in 3 months prior to inhibitor. *		
Explain 'Other, namely' *		
Batchnumber *		
Add another batch or product? *	❑ Yes	❑ No
Other product used in 3 months prior to inhibitor. *		
Explain 'Other, namely' *		
Batchnumber *		
Add another batch or product? *	❑ Yes	❑ No
Write down any more productname(s) and batchnumbers. *		
Confirm last product used before inhibitor detection *		
Additional blood products? *	❑ Yes	❑ No
Blood	❑ Yes	
FFP	❑ Yes	
Cryoprecipitate	❑ Yes	
Total lifetime exposure days *		

Inhibitor test

Date of last negative inhibitor test (DD-MM-YYYY) *	❑	
	❑ Date unknown	❑ Not applicable (no previous tests)
First positive level (BU/ml) *		
Date of first positive level (DD-MM-YYYY) *		
Second positive level (BU/ml)		
Date of second positive level (DD-MM-YYYY)	❑	
	❑ Datum onbekend	

Assay

Assay used *	❑ Bethesda	❑ Nijmegen modified
	❑ Other	
Explain other: *		

Positive Test cut-off *			
Has this inhibitor been reported to any other studies/schemes/registries *	❑ Yes	❑ No	❑ Unknown
Please give the name of the studies/schemes/registries you have also reported this inhibitor to: *			
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord	

Thrombosis event

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *		

Type thrombosis

Thrombotic event *	❑ Angina (first occurrence only)	❑ Arterial thromboembolism
	❑ Deep Vein Thrombosis (DVT)	❑ Myocardial infarction
	❑ Pulmonary Embolism (PE)	❑ Thrombotic microangiopathy
	❑ Thrombotic Stroke	❑ Transient Ischemic Attack (TIA) (first occurrence only)
	❑ Other	
Explain other *		
Patient received concentrate/Emicizumab/DDAVP/FFP/Platelets in previous 30 days? *	❑ Yes	❑ No ❑ Unknown
Is the patient on prophylaxis treatment? *	❑ Yes	❑ No

Time between dose and event

Time between last dose and thrombosis event: Number *			
Time between last dose and thrombosis event: Unit *	❑ Minutes	❑ Hours	❑ Days

Product(s)

Product *		
Explain 'Other, namely' *		
Batchnumber(s) *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		
Batchnumber(s) *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		
Batchnumber(s) *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		

Batchnumber(s) *		
Add another batch or product? *	❑Yes	❑No
Write down any more productname(s) and batchnumbers. *		
Additional blood products? *	❑Yes	❑No
Blood	❑Yes	
FFP	❑Yes	
Cryoprecipitate	❑Yes	

Was thrombosis associated with a central venous catheter

Was thrombosis associated with a central venous catheter? *	❑Yes	❑No
Catheter type? *	❑Broviac Line	❑Hickman Line
	❑Jugular/Subclavian central line	❑Portacath
	❑Other	
Explain other: *		

Did the patient have surgery in the last 3 months?

Did the patient have surgery in the last 3 months? *	❑Yes	❑No
Surgery type? *		
Was thromboprophylaxis given? *	❑Yes	❑No

Where there any risk factors for thrombosis?

Riskfactors for thrombosis: Thrombophilia (AT/PC/PS/FVL/PT20210A) *	❑Yes	❑No
Riskfactors for thrombosis: Pregnancy *	❑Yes	❑No
Riskfactors for thrombosis: Oral contraceptive pill *	❑Yes	❑No
Riskfactors for thrombosis: Hormone Replacement Therapy *	❑Yes	❑No
Riskfactors for thrombosis: Diabetes *	❑Yes	❑No
Riskfactors for thrombosis: Smoking - Current *	❑Yes	❑No
Riskfactors for thrombosis: Smoking - Former *	❑Yes	❑No
Riskfactors for thrombosis: Smoking - Never *	❑Yes	❑No
Riskfactors for thrombosis: Hyperlipidemia *	❑Yes	❑No
Riskfactors for thrombosis: BMI>30 *	❑Yes	❑No
Riskfactors for thrombosis: Any personal past history of MI/Stroke/DVT/PE *	❑Yes	❑No
Riskfactors for thrombosis: Any first degree relative with MI or Stroke *	❑Yes	❑No
Riskfactors for thrombosis: Any first degree relative with DVT or PE *	❑Yes	❑No
Riskfactors for thrombosis: HIV positive *	❑Yes	❑No
Riskfactors for thrombosis: On HAART *	❑Yes	❑No
Riskfactors for thrombosis: Hypertension *	❑Yes	❑No
Riskfactors for thrombosis: Atrial fibrillation *	❑Yes	❑No
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑Niet akkoord	❑Akkoord

Malignancy event

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *		

Malignancy diagnosis

Diagnosis *	❑ Hepatocellular carcinoma	❑ Gastrointestinal
	❑ Lung	❑ Lymphoma
	❑ Prostate	❑ Bladder
	❑ Pancreas	❑ Breast
	❑ Testis	❑ Leukaemia
	❑ Skin	❑ Kidney
	❑ Thyroid	❑ Other Genitourinary
	❑ Melanoma	❑ Pituitary
	❑ Other	
Explain other: *		
Did the patient ever undergo radioactive synovectomy? *	❑ Yes ❑ No	❑ Unknown
In the last 10 years did the patient receive *	❑ Plasma derived concentrate or FFP or Cryoprecipitate	❑ Recombinant concentrate
	❑ Both of the above	❑ None of the above

Infections

Is/Was the patient?

HIV positive *	❑ Yes	❑ No	❑ Unknown
Hepatitis B positive (HBsAg or HBV DNA +ve) *	❑ Yes	❑ No	❑ Unknown
Hepatitis C positive (Current or past PCR +ve) *	❑ Yes	❑ No	❑ Unknown
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord		❑ Akkoord

Death event

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *		

Cause of death

Cause of death *	❑ Intracranial Haemorrhage	❑ Bleeding (Excluding Intracranial)
	❑ Hepatocellular Carcinoma	❑ Liver Failure (Excluding Hepatocellular Carcinoma)
	❑ Cancer (Excluding Hepatocellular Carcinoma)	❑ Cardiac
	❑ Infection	❑ Unknown
	❑ Other	
Specify Cause of Death *		
Specify Liver disease: *		
Specify bleeding location **		
Specify type **		
Specify event type **		
Specify type **		
Confirmed by autopsy? *	❑ Yes	❑ No
Inhibitor present at time of death? *	❑ Yes	❑ No

Infections

Is/Was the patient?

HIV positive *	❑ Yes	❑ No	❑ Unknown
Hepatitis B positive (HBsAg or HBV DNA +ve) *	❑ Yes	❑ No	❑ Unknown
Hepatitis C positive (Current or past PCR +ve) *	❑ Yes	❑ No	❑ Unknown
Any evidence of cirrhosis (fibroscan > 13) or liver failure (hepatic decompensation)? **	❑ Yes	❑ No	❑ Unknown
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord	

Poor efficacy event

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *		
Please describe what happened and why you think this was an unexpectedly poor efficacy. Please state the name of the concentrate. *		
Name concentrate *		
Explain 'Other, namely' **		
Batchnumber *		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Neurological event

Identification

Ziekenhuis *	

Unieke patiëntcode binnen kliniek *			
Type of event *	❑ Allergic or other acute event		❑ Transfusion transmitted infection event
	❑ Inhibitor event		❑ Thrombosis event
	❑ Malignancy event		❑ Death event
	❑ Poor efficacy event		❑ Neurological event
	❑ Other possible adverse or unusual event		❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen		❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *			
Neurological Event *	❑ Motor Neurone Disease (Amyotrophic Lateral Sclerosis)		❑ Other Neurological Event
	❑ Sporadic CJD		❑ Variant CJD
Please state *			
Patient received concentrate/Emicizumab/DDAVP/FFP/Platelets in previous 3 months? *	❑ Yes	❑ No	❑ Unknown
Comment			
Is the patient on prophylaxis treatment? *	❑ Yes		❑ No

Time between dose and event

Time between last dose and neurological event: Number *			
Time between last dose and neurological event: Unit *	❑ Minutes	❑ Hours	❑ Days

Infusion Information

Product *		
Explain 'Other, namely' *		
Batchnumber(s) *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		
Batchnumber(s) *		
Add another batch or product? *	❑ Yes	❑ No
Product *		
Explain 'Other, namely' *		
Batchnumber(s) *		
Additional Blood Products *	❑ Yes	❑ No
Blood	❑ Yes	
FFP	❑ Yes	
Cryoprecipitate	❑ Yes	
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Other possible adverse or unusual event

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (DD-MM-YYYY) *		

Please describe any events that you wish to report even if the relationship to concentrate is unclear. Briefly describe the patient's previous treatment history. *		
Name concentrate *		
Explain 'Other, namely' **		
Batchnumber *		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Severe bleeding

Identification

Ziekenhuis *		
Unieke patiëntcode binnen kliniek *		
Type event	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Datum bloeding (DD-MM-YYYY) *		

Type bloeding

Waar vond de bloeding plaats	❑ Intracraniaal	❑ Gastro-intestinaal
	❑ Anders, namelijk	
Toelichting keuze 'Anders namelijk'		

Locatie

Locatie	❑ Subduraal	❑ Cerebraal
	❑ Epiduraal	❑ Anders, namelijk
Toelichting keuze 'Anders namelijk'		
De arts/behandelaar kan hier aanvinken dat de gegevens van de patiënt compleet en correct zijn. *	❑ Niet akkoord	❑ Akkoord

Vaccination event

Type of event *	❑ Allergic or other acute event	❑ Transfusion transmitted infection event
	❑ Inhibitor event	❑ Thrombosis event
	❑ Malignancy event	❑ Death event
	❑ Poor efficacy event	❑ Neurological event
	❑ Other possible adverse or unusual event	❑ Chirurgische ingreep
	❑ Levensbedreigende bloedingen	❑ Vaccination event
Date of occurrence of event (dd-mm-yyyy) *		
Date of vaccination (dd-mm-yyyy) *		
Vaccine involved *	❑ Corona BioNTech/Pfizer	❑ Corona Moderna
	❑ Corona Janssen	❑ Corona AstraZeneca
	❑ Corona Sanofi/GSK	❑ Corona Curevac
	❑ Other vaccine	
Explain other *		
Type of side effect *	❑ Bleed	❑ Other
Severity of bleed *	❑ Light	❑ Moderate ❑ Severe
Explain Other *		