

## **HEMONED VARIABLES – SHORT VERSION**

### **Registry: Baseline**

#### **Identification**

- Registration number HemoNED registry
- Date Informed Consent
- Hemophilia Treatment Center (HTC)
- Patient number HTC (*only available for health care provider*)
- ID number (*only available for health care provider*)
- Name (*only available for health care provider*)
- Date of birth (*only available for health care provider*)
- Age
- Gender
- Ethnicity
- Blood group

#### **Diagnosis**

- Diagnosis
- Severity/Type
- Laboratory values of coagulation factors; date & type of assessment
- Date of diagnosis
- Reason of diagnosis
- Gene mutation
- Family anamnesis
- Number of 'exposure days' at time of inclusion registry
- Birth: type of delivery, intracranial bleed 1<sup>st</sup> week (*inclusion newborns*)

#### **Clinical information** (*status quo*)

- Transfusion transmitted infections (HIV, Hepatitis B/C): never/ever/current
- Inhibitor: never/ever/current

### **Registry: Prospective data**

#### **Treatment plan**

- Date of (change) treatment plan
- Prophylaxis vs. on demand
- Product(s)
- Prophylaxis: dose & frequency
- Reason to start or stop using a product (*only for newest products*)

## Biometry

- Date of (change) biometry
- Weight, length, BMI

## Gene therapy

- Demographics
- Diagnosis
- Medical/Clinical history
- AAV Neutralizing Antibodies
- Pre-existing/co-morbidities
- Liver related medical history
- Concomitant medication
- Gene therapy details
- Follow-up visits:
  - o Safety data
  - o Efficacy data
  - o Surgeries
  - o Quality of Life
  - o Mortality

## Complications & Adverse events

- Date of event
- Allergic or other acute event
- Transfusion transmitted infection event
- Inhibitor event
- Thrombosis event
- Malignancy event
- Death event
- Poor efficacy event
- Neurological event
- Vaccination event
- Other possible adverse or unusual event
- Surgical procedure
- Severe bleeding

## **Digital infusion log (VastePrik app)**

### Infusions

- Date and time of infusion
- Reason of infusion: prophylaxis, risk, bleed, after care

- Product
- Dose
- Number of vials
- Batch number

### Bleeds

- Date and time of bleed
- Type of bleed: joint, muscle, mucous membranes, subcutaneous, head, other
- Location
- Severity
- Cause

### Side effects *(only for newest products)*

- Date and time of registration
- Reaction at the place of injection: redness, warmth, pain, itch, sensible skin
- Joint pain