# Eptacog beta post marketing safety surveillance using aggregated data reports from the EUHASS Registry (F7TG2206-EUHASS Registry)

First published: 05/06/2023 Last updated: 23/04/2024





## Administrative details

EU PAS number	
EUPAS105020	
Study ID	
105021	
DARWIN EU® study	
No	
Study countries	
Austria	
Belgium	
France	

Germany	
Italy	
Netherlands	
Spain	
United Kingdom	

#### **Study description**

This Post Marketing safety Surveillance study is based on observational data collection from the European Hemophilia Safety Surveillance (EUHASS) cohort. EUHASS is a pharmacovigilance program to monitor the safety of treatments for people with inherited bleeding disorders in maintaining a database of all the haemophilia centres in Europe. EUHASS will transmit to the sponsor, LFB Biotechnologies 4 reports of adverse events issued at the end of each 3 month period and a detailed annual report.

#### **Study status**

Ongoing

## Research institutions and networks

### **Institutions**

# European Haemophilia Safety Surveillance System (EUHASS)

First published: 01/02/2024

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2 sites Austria, 2 sites Belgium, 6 sites France, 7sites Germany, 10 sites Italy, 4 sites Netherlands,5 sites Spain, 21 sites United Kingdom

## Contact details

**Study institution contact** 

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Study contact

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Primary lead investigator

Emmanuelle LAGRUE

Primary lead investigator

## Study timelines

Date when funding contract was signed

Actual: 25/01/2023

Study start date

Actual: 25/01/2023

Date of final study report

Planned: 30/06/2028

Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

LFB Biotechnologies

## Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

## Methodological aspects

## Study type

Study type list

#### Study type:

Not applicable

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Main study objective:

The primary objective will be to determine the number and incidence of important potential risks defined as: - Hypersensitivity reactions -

Thromboembolic events, including those due to drug-drug interactions with activated or nonactivated prothrombin complex or other haemostatic agents - Immunogenicity

## Study drug and medical condition

## Study drug International non-proprietary name (INN) or common name EPTACOG BETA (ACTIVATED)

#### Medical condition to be studied

Factor VIII deficiency

Factor IX deficiency

#### Additional medical condition(s)

with inhibitors

## Population studied

#### Age groups

- Preterm newborn infants (0 27 days)
- Term newborn infants (0 27 days)
- Infants and toddlers (28 days 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)</li>
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Special population of interest**

Renal impaired

Hepatic impaired

**Immunocompromised** 

Pregnant women

#### **Estimated number of subjects**

168

## Study design details

#### **Outcomes**

- Number of allergic or other acute event and thromboses - Incidence of allergic or other acute event and thromboses - Incidence of antidrug antibodies

#### Data analysis plan

Data management including data collection is under the responsibility of the EUHASS registry, in accordance with the current version of the EUHASS working protocol. At the end of each 3-month period, participating centres have 3 weeks to report their data, so the three-monthly report can be produced within four weeks of the end of each surveillance period. Every 12 months, a more detailed analysis is provided. The number and incidence of subjects with treatment-emergent AEs (TEAEs), specifically allergic or other acute events, thrombosis will be assessed and presented in a final report.

## Data management

## **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

#### Data sources

Data source(s), other

**EUHASS** - Blood disorders

**Data sources (types)** 

Other

Data sources (types), other

Case-control surveillance database

Use of a Common Data Model (CDM)

**CDM** mapping

No

Data quality specifications

**Check conformance** 

Unknown

**Check completeness** 

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No