

# NN7999-4413: Adverse Event Data Collection from External Registries on Nonacog Beta Pegol

**First published:** 28/09/2018

**Last updated:** 14/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS25696

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### Study ID

27138

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### DARWIN EU® study

No

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### Study countries

 Netherlands

 United Kingdom

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### Study description

The purpose of this study is to collect data on adverse events from third party registries that include information about adverse events from patients with haemophilia B treated with nonacog beta pegol. The third party registries include PedNet Haemophilia Registry (PedNet) and the European Haemophilia Safety Surveillance System (EUHASS). Data from national and international registries in countries where nonacog beta pegol has been approved and marketed could be included in the data collection.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

[Novo Nordisk](#)

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Institution

## Contact details

### Study institution contact

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S [pactadmin@novonordisk.com](mailto:pactadmin@novonordisk.com)

Study contact

[pactadmin@novonordisk.com](mailto:pactadmin@novonordisk.com)

### **Primary lead investigator**

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 31/08/2017

Actual: 14/09/2018

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### **Study start date**

Planned: 01/10/2018

Actual: 01/10/2018

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### **Date of final study report**

Planned: 01/10/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novo Nordisk A/S

## Study protocol

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Other study registration identification numbers and links

UTN:U1111-1212-4050NCT:NCT03690336

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

The purpose of this study is to collect data on adverse events from third party registries that include information about adverse events from patients with haemophilia B treated with nonacog beta pegol.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

[REFIXIA](#)

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### **Medical condition to be studied**

Haemophilia B with anti factor IX

Haemophilia B without inhibitors

## Population studied

### **Age groups**

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

- Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

10

## Study design details

### **Outcomes**

Adverse Drug Reactions (ADRs) reported to the registries with suspected relation to nonacog beta pegol in patients with haemophilia B, Other ADRs reported to the registries during the study period with suspected relation to nonacog beta pegol in patients with haemophilia B

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### **Data analysis plan**

This is a purely descriptive study and the statistical analyses and presentations do not include any testing of pre-specified hypotheses. Novo Nordisk will be responsible for all statistical analyses.

## 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)

PedNet Haemophilia registry

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### Data source(s), other

EUHASS - Blood disorders

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### Data sources (types)

[Disease registry](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No