

# 091301: FEIBA NF GLOBAL OUTCOME STUDY (FEIBA-GO) (091301: FEIBA-GO)

**First published:** 24/06/2014

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6691

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### Study ID

43046

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### DARWIN EU® study

No

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### Study countries

- France
- Germany
- Hungary
- Italy
- Norway
- Poland

- Portugal
  - Russian Federation
  - Spain
  - United Kingdom
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### **Study description**

The study addresses the need to measure long-term effectiveness, safety and quality of life outcome measures for haemophilia A or B patients with high-responding inhibitors treated on-demand and in prophylaxis with FEIBA NF. The purpose of the study is to document the natural history of hemophilia A or B disease in subjects with high responding inhibitors either to Factor VIII or Factor IX and to describe long-term outcomes in terms of effectiveness, safety and quality of life in subjects receiving FEIBA NF in routine clinical practice.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Shire**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

Multiple centres: 40 centres are involved in the study

## Contact details

### Study institution contact

Study Contact Shire [clinicaltransparency@shire.com](mailto:clinicaltransparency@shire.com)

Study contact

[clinicaltransparency@shire.com](mailto:clinicaltransparency@shire.com)

### Primary lead investigator

Study Contact Shire

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 30/09/2013

Actual: 30/09/2013

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### Study start date

Planned: 30/06/2014

Actual: 03/09/2014

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### Data analysis start date

Planned: 28/02/2020

Actual: 28/02/2020

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

Planned: 30/10/2020

Actual: 26/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Baxalta Innovations GmbH, now part of Shire

## Study protocol

[091301-protocol-original-redact.pdf](#) (964.17 KB)

[091301-protocol-amendment 2-redact.pdf](#) (1017.02 KB)

## 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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Pharmacodynamic study, Health-Related Quality of Life Analysis

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of the study is to describe the hemostatic effectiveness of FEIBA NF in a variety of clinical settings including on-demand therapy, prophylaxis and immune tolerance induction (ITI) in haemophilia A or B patients with high-responding inhibitors.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Post-authorization, prospective, uncontrolled, observational, non-interventional, open-label, multicenter cohort study

## Study drug and medical condition

**Medicinal product name, other**

FEIBA NF

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**Additional medical condition(s)**

Haemophilia A or B with high responding inhibitors

## Population studied

**Short description of the study population**

Patients were male hemophilia A or B patients with high-responding inhibitors who had been prescribed FEIBA for the treatment or prevention of bleeding events by a treating physician prior to the decision to enroll in the study. No additional diagnostic or monitoring procedures were applied to patients, except those that were part of normal/routine clinical practice.

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**Age groups**

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

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

Other

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### **Special population of interest, other**

Hemophilia A or B patients

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### **Estimated number of subjects**

55

## Study design details

### **Outcomes**

(A) 1) Prophylaxis: Treatment of breakthrough bleeds 2) On-demand: Treatment of BEs: -Bleed rates -Types of bleeding events -Number of BEs with corresponding hemostatic efficacy ratings(B) 1) Prophylaxis: Totals & breakthrough bleeds 2) On-demand: -Number of infusions- Weight adjusted dose- Total units of FEIBA NF infused, 1) Joint clinical outcomes in routine clinical practice setting, using any therapeutic regimen, assessed as in common practice2) Health-Related Quality of Life using standardized assessment questionnaires/ tools

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### **Data analysis plan**

Descriptive statistics will include specifically but not exclusively, arithmetic mean, standard deviations, medians, minimum, maximum, 25th and 75th

percentiles, proportions, frequency counts and 95% confidence intervals of select point estimates. Figures will be prepared to illustrate the patterns of data over time where appropriate.

## Documents

### Study results

[091301-clinical-study-report-redact.pdf](#) (812.48 KB)

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## 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 sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## 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