

# INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden

**First published:** 22/12/2020

**Last updated:** 29/11/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS38736

---

### Study ID

48665

---

### DARWIN EU® study

No

---

### Study countries

 Finland

 Sweden

---

## **Study description**

Observational data have suggested no increased risk of adverse pregnancy outcomes associated with exposure to interferon-beta (IFNB) before or during pregnancy.

After the emergence of these data, the European Medicines Agency approved a label change for IFNB in September 2019, stating that use of IFNB during pregnancy may be considered, if clinically needed.

However, limited data on pregnancies exposed in the 2nd and 3rd trimesters were observed.

INFORM is a non-interventional drug utilisation study (DUS) to determine late pregnancy exposure (i.e. during the 2nd and 3rd trimester) to IFNB in Finland and Sweden, which will inform whether the number of exposed pregnancies is adequate to conduct a cohort study on adverse pregnancy outcomes, with a focus on late pregnancy exposure.

The number of pregnancies will be initially reported three years after the revised label implementation (September 2019) and will include data on pregnancies from 1996 in Finland and from 2005 in Sweden up through 31 December 2022.

If the number of pregnancies is deemed adequate for conducting the cohort study on adverse pregnancy outcomes, this DUS will be finalised with the drug utilisation data accrued up through 31 December 2022. If the number of pregnancies until 31 December 2022 is deemed inadequate, this study may be continued and the primary and secondary objectives may be examined five years after the revised label implementation, including pregnancies until 31 December 2024.

---

## **Study status**

Ongoing

## **Research institutions and networks**

# Institutions

**IQVIA**

 United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Victoria Banks [PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

**Study contact**

[PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

### Primary lead investigator

Victoria Banks

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 25/10/2019

Actual: 25/10/2019

---

**Study start date**

Planned: 01/01/2024

Actual: 20/03/2024

---

**Data analysis start date**

Planned: 01/03/2024

Actual: 01/04/2024

---

**Date of interim report, if expected**

Planned: 31/10/2024

---

**Date of final study report**

Planned: 30/10/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG, Biogen Netherlands B.V., Merck Europe, B.V. Novartis Europharm Limited

## Study protocol

[INFORM Protocol\\_V2.1 03 November 2020\\_signed\\_redacted.pdf](#) (4.58 MB)

## 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 topic:**

Human medicinal product

---

#### **Study type:**

Non-interventional study

---

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

Drug utilisation

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

To determine the number of pregnancies exposed to IFNB during late pregnancy, the 2nd and 3rd trimesters, in Finland and Sweden.

This informs whether the number of exposed pregnancies is adequate to conduct a cohort study on adverse pregnancy outcomes, with a focus on late pregnancy exposure.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Study drug International non-proprietary name (INN) or common name**

INTERFERON BETA-1A

INTERFERON BETA-1B

---

### **Anatomical Therapeutic Chemical (ATC) code**

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b

(L03AB13) peginterferon beta-1a

peginterferon beta-1a

---

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

Multiple sclerosis

## Population studied

### **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- 

### **Special population of interest**

## **Estimated number of subjects**

100

## **Study design details**

### **Outcomes**

1. The number of pregnancies of women with MS exposed to IFNB before and during pregnancy, not allowing exposure to other MS Disease Modifying Drugs (MSDMDs)
2. The level of precision for the risk of pre-defined adverse pregnancy outcomes in late pregnancy that can be obtained with the available number of pregnancies
3. The annual number of pregnancies of women with MS in the exposure groups:
  - a) The number of pregnancies of women with MS in Finland and Sweden allowing exposure to other MSDMDs
  - b) The annual number of women with MS of childbearing age, and with dispensed IFNB in 2015-2022

---

### **Data analysis plan**

Analyses will be descriptive and exclusively categorical variables are included. The categorical variables will be summarised as numbers of women and pregnancies and as proportions of the relevant denominator.

The following will be reported:

1. The number of pregnancies by exposure status, without allowing exposure to other MS Disease Modifying Drugs (MSDMDs) than IFNB, by calendar year of last menstrual period (LMP) and during the study period.
2. The number of pregnancies in the late pregnancy only exposed group with

and without the composite adverse pregnancy outcome consisting of stillbirths, spontaneous abortions, and elective terminations.

3. The number of pregnancies by exposure status, regardless of exposure to other MSDMDs, by calendar year of LMP and during the study period.

4. The number of women dispensed IFNB who have been diagnosed with MS and are of childbearing age during the full study period (reference population).

## 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**

National Institute for Health and Welfare (THL) registers: Medical Birth Register (MBR-Fin), Care Register for Health Care, Register of Induced Abortions Finland, National Reimbursement Register National Prescription Register Finland, Medical Birth Register (MBR-Swe) Sweden, National Patient Register (NPR) Sweden, Swedish Prescribed Drug Register (SPDR) Sweden

### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

Drug dispensing/prescription data

Other

---

**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

---

**Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No