Elafibranor Pregnancy Surveillance Program: A Study to Evaluate the Safety of Elafibranor During Pregnancy

First published: 23/04/2026

Last updated: 23/04/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000891

Study ID

1000000891

DARWIN EU® study

No

Study countries

European Union

United Kingdom

United States

Study description

The study will include participants who were exposed to at least one dose of elafibranor either within the three weeks before conception or at any time during pregnancy (based on estimated last menstrual period [LMP]).

Information will be collected from participants, their healthcare providers, published studies, and safety databases. Reports of pregnancy linked to elafibranor from clinical trials, spontaneous reports, or literature will also be included, with steps taken to avoid duplicates.

The study begins once the first participant is enrolled and ends after the last mother and child data are collected. It is planned to run for about 10 years, with infant follow-up lasting up to 2 years, for a maximum total duration of 12 years and 9 months.

The program is strictly observational. All medical care, visit schedules, and treatment decisions remain with healthcare providers. Only routine medical record data will be collected, and no extra tests or procedures are required.

Participation is voluntary, and written informed consent will be obtained before enrollment.

Study status

Planned

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Ipsen Clinical Study Enquiries clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2026

Study start date

Planned: 30/04/2026

Date of final study report

Planned: 31/01/2039

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

CLIN-60190-471_16.1.1 Protocol V3.0 23 February 2026_Redacted.pdf (8.22 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

The study begins once the first participant is enrolled and ends after the last mother and child data are collected. It is planned to run for about 10 years, with infant follow-up lasting up to 2 years, for a maximum total duration of 12 years and 9 months.

Main study objective:

To describe the occurrence of congenital malformations and developmental delays in the offspring of participants exposed to elafibranor during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Elafibranor

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

ELAFIBRANOR

Anatomical Therapeutic Chemical (ATC) code

(A05AX06) elafibranor

elafibranor

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

The participants of this study will be of any age who are exposed to at least one dose of elafibranor at any time during pregnancy, or since 3 weeks prior to the conception (based on estimated last menstrual period [LMP])

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - 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)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)

- Adults (85 years and over)

Special population of interest

Pregnant women

Special population of interest, other

infant

Estimated number of subjects

3

Study design details

Comparators

To contextualize the surveillance program data, outcomes will be compared to those of participants with primary biliary cholangitis (PBC) who became pregnant after their PBC diagnosis but were not exposed to elafibranor, using publicly available literature, as well as considering general population data.

Outcomes

Primary Safety Endpoint:

• Prevalence of congenital malformations.

Secondary Safety Endpoints:

• Prevalence of minor and major congenital malformations

• Prevalence of molar/ectopic pregnancy

• Prevalence of fetal loss, including SAB, stillbirths, and terminations (medically indicated or elective or medically indicated abortion)

• Prevalence of live births

• Prevalence of premature delivery
• Prevalence of infants born SGA
• Prevalence of neonatal/infant death
• Prevalence of postnatal growth deficiency at 4 months, 12 months and 24 months
• Prevalence of infant developmental delay at 4 months, 12 months and 24 months
• Prevalence of infant healthcare requirements and interventions not considered standard, including but not limited to:
- Infant hospitalization due to serious illness
- Emergency department visits
- Specialist or other healthcare professional consultations
- Developmental assessments and interventions
- Therapeutic services
- Educational support and adaptations
• Incidence and nature of all adverse events (AEs)
• Changes in biochemical markers of cholestasis from last available measurement before pregnancy and through pregnancy and postpartum:
- ALP
- Bilirubin
- ALT
- AST
- GGT
- Albumin
- Bile acids
- Creatine phosphokinase (CPK)
- Lipid profile (including total cholesterol, LDL-C, HDL-C, VLDL-C and triglycerides)

Data analysis plan

All the analyses will be primarily descriptive in nature. For each continuous variable, the number of observations, median, mean, standard deviation, interquartile range, minimum and maximum will be reported. For each categorical variable, the frequency and percentage in each category will be reported. The frequency and percentage of subjects with missing data for each data point will be presented. Results will be rounded off to one decimal place; therefore, percentages may not always add up to 100.

The prevalence of each outcome will be calculated by dividing the number of cases of the outcome by the appropriate denominator for that particular outcome.

The study will include planned interim clinical reports, with the first to be drafted by the end of September 2030.

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

- Prospective patient-based data collection
- Routine primary care electronic patient registry
- Spontaneous pharmacovigilance reporting

Data sources (types)

Electronic healthcare records (EHR)

Other

Patient surveys

Published literature

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

- Prospective patient-based data collection
- Routine primary care electronic patient registry

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