

# An Observational Pregnancy Safety Study in Women with Neuromyelitis Optica Spectrum Disorder (NMOSD) Exposed to UPLIZNA® (inebilizumab-cdon) during Pregnancy (VIB0551.P4.S4 /20230064)

**First published:** 29/06/2023

**Last updated:** 02/04/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS105613

### Study ID

105845

### DARWIN EU® study

No

### Study countries

- Canada
- Denmark

- Finland
- France
- Germany
- Norway
- Sweden
- United States

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### **Study description**

This global observational pregnancy safety study is conducted to better characterize how inebilizumab commercial product (UPLIZNA) may affect pregnancy and infant outcomes.

The study is a post-marketing commitment that aims to monitor female patients who were exposed to UPLIZNA during pregnancy, as defined by receipt of any dose during pregnancy or within 6 months preceding conception. The primary objectives are: (1) to assess pregnancy and birth outcomes in female patients with neuromyelitis optica spectrum disorder (NMOSD), exposed to inebilizumab commercial product (UPLIZNA) during pregnancy as defined by receipt of any dose during pregnancy or within 6 months preceding conception, (2) to describe major congenital malformations, minor congenital malformations, spontaneous abortions, stillbirths, preterm births, and small-for-gestational-age births, if they occur, in women with gestational exposure to UPLIZNA.

The study period is a minimum 10 years.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

Amgen

United States

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

**Last updated:** 21/02/2024

**Institution**

## Contact details

### **Study institution contact**

Global Development Leader Amgen Inc.

[medinfo@amgen.com](mailto:medinfo@amgen.com)

**Study contact**

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### **Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator**

## Study timelines

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

Actual: 11/11/2022

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### **Study start date**

Planned: 01/07/2023

Actual: 10/07/2023

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### **Data analysis start date**

Planned: 16/02/2033

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### **Date of interim report, if expected**

Planned: 31/07/2026

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

Planned: 31/07/2033

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Horizon Therapeutics

## Study protocol

[Protocol-Published Original inebilizumab-cdon 20230064 .pdf \(452.31 KB\)](#)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

VIB0551.P4.S4

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

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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

**Main study objective:**

To assess pregnancy and birth outcomes in female patients with neuromyelitis optica spectrum disorder (NMOSD), exposed to UPLIZNA during pregnancy as defined by receipt of any dose during pregnancy or within 6 months preceding conception.

## Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Observational Pregnancy Safety Study

# Study drug and medical condition

## **Medicinal product name**

UPLIZNA

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

INEBILIZUMAB

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## **Medical condition to be studied**

Neuromyelitis optica spectrum disorder

# Population studied

## **Short description of the study population**

Study is recruiting participants ages 15 years and older.

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## **Age groups**

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

- Adults (46 to < 65 years)

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## **Special population of interest**

Pregnant women

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## **Estimated number of subjects**

60

# Study design details

## **Outcomes**

- Major congenital malformation (MCM): Any major structural or chromosomal defect, or a combination of 2 or more conditional defects in live-born infants, stillbirths, or fetal losses of any gestational age (including outcomes prior to 20 weeks' gestation or weighing < 500 g)
- Preterm birth: An infant born at gestational age < 37 weeks
- Low birth weight: An infant whose birth weight < 2500 g.
- Minor congenital malformation: congenital anomalies that do not require major medical or surgical treatment, do not seriously affect health and development, and do not have significant cosmetic impact, in live-born infants, stillbirths, or fetal losses of any gestational age.
- Developmental milestones or neurologic abnormalities in offspring of exposed mothers.
- Abnormalities of immune system development in offspring of exposed mothers.

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## **Data analysis plan**

Pregnancy outcomes will be summarized by the trimester of exposure and by preconception exposure.

The number of infants with congenital malformations will be summarized

descriptively.

In addition, the risk of infants with congenital malformations, defined as the percentage of infants with congenital malformations among total number of infants, will be reported.

If data permit, analyses will also be presented by the subgroups of maternal age, race/ethnicity, prior history of elective or therapeutic pregnancy termination status, prospective cases vs. retrospective cases, and other important risk factors.

## 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, Data will also be collected on retrospective cases as well (among patients whose pregnancy outcome has been identified). The data will be collected at enrollment, and if the infant is less than 12 month-old, the infant will be followed up to 12 months after

delivery

## 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