

# Monitoring of pregnancy outcomes in women treated with inclisiran: a non-interventional study

**First published:** 07/10/2021

**Last updated:** 31/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS42905

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### Study ID

50706

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### DARWIN EU® study

No

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### Study countries

Switzerland

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### Study description

This post-authorisation safety study is a worldwide, single-arm descriptive non-interventional study that collects prospective and retrospective data in women exposed to inclisiran during pregnancy. It uses an enhanced pharmacovigilance data collection and processing system via a set of targeted checklists, structured follow-up, rigorous process of data entry and data quality control, and programmed aggregate analysis. The overall objective of the study is to collect data on pregnancy outcomes in patients treated with inclisiran during or prior to pregnancy. Although pharmacovigilance data may be collected from any country in the world where the product is approved, the anonymized patient level data will be analyzed at a global level in Switzerland.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

**Novartis Pharmaceuticals**

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

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

**Institution**

## Contact details

### **Study institution contact**

Novartis Clinical Disclosure Officer  
Trialandresults.registries@novartis.com

Study contact

[Trialandresults.registries@novartis.com](mailto:Trialandresults.registries@novartis.com)

**Primary lead investigator**  
Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

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

Planned: 09/12/2020

Actual: 09/12/2020

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### **Study start date**

Planned: 31/12/2021

Actual: 31/12/2021

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### **Data analysis start date**

Planned: 31/01/2031

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

Planned: 31/07/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharma AG

## Study protocol

[CKJX839A12011-v00--protocol\\_Redacted.pdf](#) (726.72 KB)

[CKJX839A12011\\_Protocol V2\\_Redacted.pdf](#) (593.52 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

CKJX839A12011

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Main study objective:**

To estimate the proportion of major congenital malformations among pregnancies exposed to inclisiran during pregnancy prospectively reported to Novartis amongst (i) live births and (ii) live births plus still births plus termination of pregnancy for fetal anomaly (TOPFA).

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Intensive monitoring schemes

## Study drug and medical condition

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

INCLISIRAN

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**Anatomical Therapeutic Chemical (ATC) code**

(C10AX16) inclisiran

inclisiran

## Population studied

## **Age groups**

- 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**

500

# Study design details

## **Outcomes**

Major congenital malformations (MCM) among pregnancies exposed to inclisiran during pregnancy, • To estimate the proportion of MCM among pregnancies exposed to inclisiran prior to the last menstrual period (LMP) • To compare the frequency of MCM among pregnancies exposed to inclisiran with the background frequencies • To estimate the proportion of other secondary outcomes in pregnancies exposed to inclisiran prior to LMP and during pregnancy

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## **Data analysis plan**

Data analysis will focus on the prospectively reported pregnancy cases. Retrospective pregnancy cases will also be analyzed and presented separately from the prospective cases. Data analysis will include the estimation of proportion (and 95% confidence interval) of malformations (major, minor, and overall), and of specific pregnancy outcomes such as live births, stillbirths, spontaneous abortions and elective terminations. Proportions will be estimated

by timing of drug exposure in pregnancy (during pregnancy and prior to LMP, as well as by trimester if sample size allows). Descriptive analysis will be performed for all prospective pregnancy cases including case disposition (outcome known, pending, and lost to follow-up) and maternal characteristics (i.e. age, ethnicity, region) by providing the number and percentage of pregnancies in each category. Further stratified analyses may be undertaken if sample size allows.

## 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

[Spontaneous reports of suspected adverse drug reactions](#)

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### Data sources (types), other

targeted follow-up questionnaires for reported pregnancy cases

## 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**

Not applicable