

# Evolocumab Pregnancy Exposure Registry: An OTIS Pregnancy Surveillance Study (20150338)

**First published:** 01/12/2016

**Last updated:** 30/10/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS16049

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### Study ID

38953

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### DARWIN EU® study

No

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### Study countries

Canada

United States

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### Study description

This study was terminated prematurely and there were 0 exposed subjects and therefore no results to report.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Amgen

United States

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

**Last updated:** 27/03/2026

Institution

### Networks

#### Organization of Teratology Information Specialists (OTIS) Network

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

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

Network

### Contact details

**Study institution contact**

Global Development Leader Amgen Inc.  
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**

Planned: 01/10/2016

Actual: 20/10/2016

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**Study start date**

Planned: 22/12/2016

Actual: 22/12/2016

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**Data analysis start date**

Planned: 08/06/2032

Actual: 22/07/2020

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**Date of final study report**

Planned: 14/02/2033

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc.

## Study protocol

[Protocol-Published Original evolocumab 20150338 .pdf](#) (1.55 MB)

## 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)

## 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:**

Safety study (incl. comparative)

**Main study objective:**

Primary scope is to evaluate the safety of Repatha in pregnant women and their pregnancy outcomes.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

REPATHA

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

EVOLOCUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(C10AX13) evolocumab

evolocumab

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**Medical condition to be studied**

Hypercholesterolaemia

Pregnancy

## Population studied

### Age groups

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

375

## Study design details

### Setting

A prospective observational study of pregnant women exposed to evolocumab to evaluate fetal, infant & childhood outcomes of these women & their live born offspring through the first 5 years of life to estimate incidence rates for potential safety signals of adverse pregnancy outcomes, embryo-fetal growth and development, & adverse infant and childhood outcomes related to humoral immune suppression.

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## Outcomes

To estimate the overall combined rate of major structural defects in infants of women with ASCVD and/or familial hypercholesterolemia (FH) exposed to evolocumab during pregnancy. Any major structural defects will be classified by a study investigator according to the Centers for Disease Control (CDC) Coding Manual: Abortion (spontaneous and elective), stillbirth, premature delivery, minor structural defects, size at gestational age, postnatal growth deficiency, postnatal serious infections, infant vaccination reactions, IgG-tetanus antibody response, adverse neurodevelopmental outcomes, breastfeeding outcomes

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## Data analysis plan

All statistical analyses will be performed at the 0.05 significance level using 2-sided tests or 2-sided 95% confidence intervals (CIs) unless otherwise specified. Demographics and baseline characteristics will be summarized. All continuous variables will be summarized using the following statistics: Number of non-missing data, Mean, Standard Deviation, Median, Minimum, Maximum, 1st quartile, 3rd quartile. All categorical variables will be summarized using counts and percentages. Missing data or unknown responses will not be counted in the percentages. e.g. risk estimation, measures of risk, internal/external validity.

## 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