

DARWIN EU® - Pregnancies amongst statin users with familial hypercholesterolaemia

First published: 27/08/2026

Last updated: 27/08/2026

Study

Planned

Administrative details

EU PAS number

EUPAS1000001100

Study ID

1000001100

DARWIN EU® study

Yes

Study countries

 Finland

 Spain

 United Kingdom

 United States

Study status

Planned

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

 Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution

Educational Institution

ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

 Belgium

 Croatia

 Denmark

 Estonia

 Finland

 France

 Germany

 Greece

 Hungary

 Italy

 Netherlands

 Norway

 Portugal

 Spain

 Sweden

 United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Guido van Leeuwen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/07/2026

Actual: 06/07/2026

Study start date

Planned: 15/09/2026

Date of final study report

Planned: 29/01/2027

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

Data collection methods:

Secondary use of data

Population studied

Special population of interest

Pregnant women

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

<https://www.ohdsi.org/Data-standardization/>

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No