DARWIN EU® - Pregnancies amongst statin users with familial hypercholesterolaemia

First published: 27/08/2026

Last updated: 30/09/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001100

Study ID

1000001100

DARWIN EU® study

Yes

Study countries

Finland

Spain

United Kingdom

United States

Study status

Ongoing

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
- Lithuania
- Netherlands

Norway
Poland
Portugal
Spain
Sweden
United Kingdom
United States

First published: 01/02/2024

Last updated: 05/11/2026

Network

Contact details

Study institution contact

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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

Actual: 07/09/2026

Date of final study report

Planned: 29/01/2027

Study protocol

DARWIN EU_Protocol_P5-C1-015_C2-012_Statins_and_Pregnancy_V2.0.pdf (1.31 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

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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