DARWIN EU® - Characterisation of pregnancies identified through the PeriNet pregnancy algorithm

First published: 18/11/2026

Last updated: 19/11/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001218

Study ID

1000001218

DARWIN EU® study

Yes

Study countries

- Croatia
- Denmark
- Finland
- Germany

Netherlands

Norway

Spain

Study status

Planned

Research institutions and networks

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

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Cindy Porras

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/08/2026

Actual: 04/08/2026

Study start date

Planned: 17/11/2026

Date of final study report
Planned: 23/04/2027

Study protocol

DARWIN EU_Protocol_P5-C3-011.pdf (2.78 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 type:

Non-interventional study

Main study objective:

1. To describe pregnancy episodes in terms of gestational length, pregnancy outcome, mode of delivery, and number of pregnancy episodes with mother-child linkage.
2. To describe time trends in the number of pregnancy episodes, pregnancy outcomes, mode of delivery, and number of pregnancy episodes with mother-child linkage.
3. To characterise individuals with a pregnancy episode in terms of demographics, baseline comorbidities, health-related behaviours, medication use, pregnancy complications, and pregnancy outcomes.
4. To characterise infants with mother-child linkage in terms of birth-related characteristics, early-life factors, and duration of follow-up, restricted to those linked to a pregnancy episode identified using the pregnancy algorithm.

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No