DARWIN EU® - Prescription of Common Drugs Before and During Pregnancy in Europe

First published: 27/08/2026

Last updated: 19/10/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001101

Study ID

1000001101

DARWIN EU® study

Yes

Study countries

- Norway
- Spain
- Sweden
- United Kingdom

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
Lithuania
Netherlands
Norway
Poland
Portugal
Spain
Sweden
United Kingdom
United States

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Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Nicholas Hunt

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

Study protocol

DARWIN EU_Protocol_P5-C3-009_V3.0.pdf (1.33 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

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort study

Main study objective:

The specific objectives of this study are:

1. To estimate the proportion of individuals prescribed commonly prescribed drugs, overall and by pregnancy trimester.
2. To estimate the proportion of individuals prescribed commonly prescribed drugs before pregnancy which:

a) are discontinued before pregnancy start;

b) continued into the first trimester of pregnancy but not into the second trimester;

c) continued into the first and second trimesters but not into the third trimester; or

d) continued into the first, second, and third trimesters of pregnancy.

3. To estimate the proportion of individuals prescribed commonly prescribed drugs initiated during pregnancy, overall and by pregnancy trimester.
4. To describe the dose and treatment duration during pregnancy for the most

commonly prescribed drugs ongoing at pregnancy start.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

The study population will consist of individuals with a recorded pregnancy.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)

- Adults (85 years and over)

Study design details

Setting

4 primary care data sources in the DARWIN EU® Network of Data Partners from 4 European countries

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 source(s)

Norwegian Linked Health registry at University of Oslo

The Information System for Research in Primary Care (SIDIAP)

Health Impact - Swedish Population Evidence Enabling Data-linkage

Clinical Practice Research Datalink (CPRD) GOLD

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