DARWIN EU® - Enabling pregnancy and mother-child research in DARWIN EU® Data Network - PeriNet

First published: 06/11/2025

Last updated: 04/09/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000812

Study ID

1000000812

DARWIN EU® study

Yes

Study countries

Croatia

Denmark

Finland

France

Germany
Hungary
Netherlands
Norway
Portugal
Spain
Sweden
United Kingdom

Study description

Pregnant individuals are often excluded from clinical trials due to ethical reasons, and are, therefore, an important population to be included in post-approval risk management plans. Many observational healthcare databases contain detailed data related to the perinatal period. However, the use of the OMOP common data model (CDM) for perinatal research has been relatively limited.

Different algorithms to identify pregnancy episodes from claims and electronic health records (EHR) in native data format have been developed. However, their implementation in OMOP CDM data has been limited to databases in the US. Therefore, these algorithms can potentially be optimised and require validation prior to their implementation in different data sources.

This study will serve as a foundational step in determining the DARWIN EU® Data network's capacity to support high-quality, population-based research in pregnancy and mother-child health, including regulatory, clinical, and epidemiological studies.

Study status

Finalised

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

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Talita Duarte-Salles

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/08/2025

Actual: 29/08/2025

Study start date
Planned: 31/10/2025

Actual: 31/10/2025

Date of final study report
Planned: 30/04/2026

Actual: 13/08/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C4-001_Pregnancy_All Objectives.pdf (4.27 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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Feasibility analysis

Method development or testing

Validation of study variables (exposure outcome covariate)

Data collection methods:

Secondary use of data

Main study objective:

1. To identify data partners in the DARWIN EU® Data Network with available data on pregnancy, pregnancy start and end dates, pregnancy outcomes and mother and child linkage.
2. To optimise and validate OMOP pregnancy algorithms for Darwin EU® databases with pregnancy-related data.
3. To establish a convention for the mapping of pregnancy-related data and mother and child linkage data to the OMOP CDM, exploring the use of the Perinatal Extension Table (PET).
4. To characterise pregnancies and mother-child linkage over time for Darwin EU® databases with pregnancy-related data.
5. To create a database with aggregate counts related to pregnancy and mother-child linkage to support feasibility assessment.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

The study population included all individuals registered as female sex (at data source entry) present in the data source during the study period.

Inclusion criteria

• All individuals who were present in the period from 01/01/2010 to 31/12/2024 (or the latest date

of data availability)

• Participants were female sex (at data source entry)

• Aged 15 to 55 years

• Minimum 365 days of continuous data source history were available

• At least one record indicative of a pregnancy episode occurred up to 31/12/2023 (or one year before the data source end date), to ensure full-term pregnancies could be identified.

Special population of interest

Pregnant women

Documents

Study report

DARWIN EU_Report_P4-C4-001_PeriNet_All Objectives.pdf (8.14 MB)

Shiny App - Objective 2: PregnancyIdentifier

Shiny App - Objective 3: PeriNet Mapping Guidance

Shiny App - Objective 4

Data management

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)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Danish Health Data Registries

Auria Clinical Informatics (FinOMOP)

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

TaUH patient cohort (FinOMOP)

Clinical Data Warehouse of the Bordeaux University Hospital

InGef Research Database

Semmelweis University Clinical Data

Integrated Primary Care Information (IPCI)

Norwegian Linked Health registry at University of Oslo

Egas Moniz Database

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

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/

CDM version

https://github.com/OHDSI/CommonDataModel/releases

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No