

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

First published: 06/11/2025

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Study

Planned

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
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Study status

Planned

Research institutions and networks

Institutions

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

☐ Netherlands

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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

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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

Talita Duarte-Salles

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/08/2025

Study start date

Planned: 31/10/2025

Date of final study report

Planned: 27/02/2026

Sources of funding

- EMA

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 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.

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