DARWIN EU® - Burden of meningococcal and gonococcal disease in the general population in European countries

First published: 20/07/2026

Last updated: 16/10/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001066

Study ID

1000001066

DARWIN EU® study

Yes

Study countries

- Belgium
- Croatia
- Denmark
- Finland

Germany
Lithuania
Norway
Spain
Sweden
United Kingdom

Study description

There is a need to assess the availability, completeness, and suitability of real-world data (RWD) within the DARWIN EU® network to support future meningococcal vaccine effectiveness studies. In particular, the identification of invasive meningococcal disease (IMD), gonorrhoea, IMD-related mortality, and meningococcal carriage in RWD presents methodological challenges due to variability in coding practices, laboratory data capture, and the limited capture of asymptomatic conditions, such as carriage.

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
- Netherlands
- Norway
- Portugal
- Spain
- Sweden
- United Kingdom

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anna Saura Lazaro

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/03/2026

Actual: 26/03/2026

Study start date

Planned: 01/07/2026

Actual: 01/07/2026

Date of final study report

Planned: 21/12/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P5-C3-004_P5-C2-002_V5.0.pdf (3.87 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:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 11 data sources from 10 countries across Europe and in 8 EU member states.

Main study objective:

1. To estimate incidence rates of IMD in the general population, overall and stratified by calendar year, sex, and age.
2. To estimate mortality rates due to IMD in the general population, overall and stratified by calendar year, sex, and age.
3. To estimate incidence rates of gonorrhoea in the general population, overall and stratified by calendar year, sex, and age.
4. To describe the demographic characteristics and clinical profile of individuals with IMD or gonorrhoea, including treatment with antibiotics.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Gonorrhoea

Additional medical condition(s)

invasive meningococcal disease, IMD-related mortality

Population studied

Short description of the study population

Objectives 1–3: Descriptive epidemiology of IMD, gonorrhoea, and mortality due to IMD

Inclusion criteria

• Present in the study period of 01/01/2017 until the end of available data in the selected data sources.

• Minimum 30 days of available history before index date.

Objective 4: Characterisation of individuals with IMD or gonorrhoea

Inclusion criteria

• At least one record of IMD or gonorrhoea during the study period (01/01/2017) until the end of available data in the selected data sources).

• Minimum 365 days of available history before index date (except for children <1 year during the study period).

Objective 5: Characterisation of meningococcal serogroup or carriage

Inclusion criteria

• At least one record of IMD or meningococcal carriage-related record during the study period (01/01/2017) until the end of available data in the selected data sources)

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)

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)

IQVIA Longitudinal Patient Data - Belgium

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

Danish Health Data Registries

InGef Research Database

Norwegian Linked Health registry at University of Oslo

The Information System for Research in Primary Care (SIDIAP)

The Valencia Health System Integrated Database

Health Impact - Swedish Population Evidence Enabling Data-linkage

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Data source(s), other

FinOMOP-THL, LDH, CPRD Aurum Linked

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://ohdsi.github.io/CommonDataModel/cdm54.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No