DARWIN EU - Background incidence rates of selected vaccine adverse events of special interest (AESIs) in Europe – supporting international preparedness

First published: 04/05/2026

Last updated: 04/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000969

Study ID

1000000969

DARWIN EU® study

Yes

Study countries

Denmark

Finland

Germany

Netherlands

Norway

Spain

Sweden

United Kingdom

Study description

The Coronavirus disease 2019 (COVID-19) pandemic highlighted the regulatory and public health need for timely post-authorisation safety monitoring of vaccines based on novel platforms (such as mRNA technology), but also for continuous monitoring throughout the lifecycle of established vaccines. Rapid regulatory response to vaccine safety concerns is crucial for maintaining public confidence. Information on background incidence rates of adverse events of special interest (AESIs) can support this response when used for rapid assessment via observed-to-expected analyses, an essential first step to inform further signal management. While evidence from real-world data (RWD) studies has been published during and after the pandemic, background rates vary across countries, data sources, with variable granularity/stratification in terms of population groups and important factors such as seasonality, therefore, updated evidence is needed to support preparedness and regulatory decision-making.

The International Coalition of Medicines Regulatory Authorities (ICMRA) Working Group on Real-World Evidence for Public Health Emergencies was established to provide a collaborative forum for international regulatory agencies to proactively enhance the efficiency and coordination of critical responses to emerging public health emergencies (PHEs) through joint evidence generation. This study aims to support a proof-of-concept within the Working Group, with the goal to generate evidence on background rates of eight vaccine AESIs selected based on capacity and interest at national level. Parallel studies will be conducted by other jurisdictions in collaboration with local research teams.

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

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Ivan Lam

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 27/11/2025

Actual: 27/11/2025

Study start date
Planned: 09/02/2026

Actual: 09/02/2026

Date of final study report
Planned: 15/06/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C2-018_Background incidence of AESI_V3.pdf (1.96 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 topic, other:

Vaccines

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

The study population will include all individuals observed in one of the participating data sources during the study period. We will require individuals to have at least 365 days of data availability before entering the cohort.

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)

Danish Health Data Registries

InGef Research Database

Integrated Primary Care Information (IPCI)

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

Data source(s), other

FinOMOP-THL

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/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No