DARWIN EU® - Background incidence rates of selected vaccine adverse events of special interest (AESIs) in Europe

First published: 10/07/2024

Last updated: 26/02/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000254

EU PAS number

EUPAS1000000254

Study ID

1000000254

DARWIN EU® study

Yes

Study countries

☐ Germany

- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

Vaccines are approved for immunisation against various infectious diseases, with an increasing number based on novel platforms like mRNA technology. Safety information for these new platforms was limited to pre-licensure clinical trials until the COVID-19 pandemic. The pandemic highlighted the need for timely post-authorisation vaccine safety surveillance for new vaccines and continuous monitoring throughout the lifecycle for established vaccines. Rapid regulatory responses to vaccine safety concerns are crucial for maintaining public confidence. Background incidence rates of adverse events of special interest (AESIs) can support these responses, with observed-to-expected analyses being essential for informing further signal evaluation.

The 2020 EMA-funded ACCESS project aimed to estimate the background rates of AESIs for monitoring COVID-19 vaccines. Several publications have contributed to global knowledge on background incidence rates, but regular updates are needed to remain prepared for new safety concerns.

Granularity in estimates, particularly regarding risk groups and factors like seasonality, is important. Background rates vary across age groups, sex, regions, and data sources, influenced by different clinical coding systems and healthcare practices. Understanding patient demographics and clinical characteristics aids in evaluating potential safety signals.

While some AESIs are specific to certain vaccines, others like Guillain-Barre syndrome are associated with various vaccines.

This study aims to expand previous research on AESIs to support safety monitoring for both approved and newly developed vaccines. This study will support vaccine safety monitoring endeavors as part of the Vaccine Monitoring

platform.

Study status

Finalised

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium

☐ Croatia

☐ Denmark

☐ Estonia

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/02/2024

Actual: 20/02/2024

Study start date
Planned: 10/07/2024

Actual: 10/07/2024

Date of final study report
Planned: 07/02/2025

Actual: 29/01/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P3_C3_001_AESI_V3.pdf(724.8 KB)

DARWIN EU_Protocol_P3_C3_001_AESI_V4.pdf(725.73 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study design:

This is a population-level retrospective, multi-database cohort study using electronic health record data from Europe.
The incidence rates of AESIs will be assessed using Population Level Disease Epidemiology.

Main study objective:

Main objectives
1. To estimate population level incidence rates of selected adverse events of special interest (AESIs) in the general population during 2010 and until the latest data availability, stratified by calendar year, month, sex, age groups, and data source.
2. To estimate age and sex standardised incidence rates (to the European population) of selected adverse events of special interest (AESIs) in the general population during 2010 and until the latest data availability, stratified by calendar year.

Secondary objective
3. To describe demographic and clinical characteristics of individuals with incident AESIs and comparing the characteristics with individuals of similar age and sex but without the AESI.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

Vaccine adverse events of special interest

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.
The index date of cohort entry will be 1st January 2010 or the date that individual fulfil the data availability and outcome ‘clean window’ requirement.

Documents

Study report

DARWIN EU_Report_P3-C3-001 Vaccines AESIs rates_V3.pdf(3.78 MB)

P3-C3-001 supplementary materials cohort code use.pdf(12 MB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Norwegian Health Registers

IQVIA Disease Analyzer Germany

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

Unknown