DARWIN EU® – Proof-of-concept: Preparedness for annual seasonal influenza vaccine effectiveness studies - Vaccine coverage and incidence of influenza-related outcomes

First published: 05/11/2025

Last updated: 18/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000803

Study ID

1000000803

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark

- [ ] Finland
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

During the revision of the European Medicines Agency (EMA) Guideline on Influenza Vaccines, it was agreed that the optimal way to monitor the performance of influenza vaccines was to generate high-quality vaccine effectiveness data. However, there are identified challenges to generating annual influenza vaccine effectiveness (IVE) evidence from previous European initiatives. With the need for real-world evidence on influenza vaccines, the current study will contribute to informing EMA on the opportunities and challenges of conducting IVE studies within the DARWIN EU® network. Such IVE studies aim to provide robust evidence to support decision-making by EMA.

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

First published: 01/02/2024

Last updated: 30/04/2025

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: 26/06/2025

Actual: 26/06/2025

Study start date

Planned: 08/09/2025

Actual: 08/09/2025

Date of final study report

Planned: 27/02/2026

Actual: 10/02/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-016_Flu vaccines_V3.0.pdf (5.9 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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Validation of study variables (exposure outcome covariate)

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from six databases from six countries across Europe and in five EU member states

Main study objective:

1. To estimate the period prevalence of influenza vaccination in the general population for each influenza season from 2015/16 to 2023/24, overall and stratified by age group and sex.
2. To characterise influenza vaccine use within each influenza season by month of vaccination, vaccine brand, and route of administration, stratified by age group and sex.
3. To describe the baseline demographic characteristics, comorbidities, immunocompromised status, and receipt of other vaccinations of individuals receiving any influenza vaccine in each influenza season.
4. To describe the background incidence rates of influenza-related clinical outcomes, hospitalisations, and deaths in the general population, and crude incidence rates of influenza-related clinical outcomes, hospitalisations, and deaths in the vaccinated and unvaccinated populations, overall and stratified by age group and sex in each influenza season.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

INFLUENZA VACCINE

Anatomical Therapeutic Chemical (ATC) code

(J07BB) Influenza vaccines

Influenza vaccines

Population studied

Short description of the study population

Objective 1: Population-level drug utilisation on influenza vaccine

Inclusion criteria

• All individuals present in each influenza season (1st October-30th April) during the study period of 01/10/2015 to 30/04/2024 (or the latest available date)

Exclusion criteria

• Individuals with missing information on sex and age

Objective 2: Patient-level characterisation on use and type of influenza vaccine

Inclusion criteria

• All individuals receiving influenza vaccine in each influenza season during the period of 01/10/2015 to 30/04/2024 (or the latest available date)

Exclusion criteria

• Individuals with missing information on sex and age

Objective 3: Patient-level characterisation of influenza vaccine recipients

Inclusion criteria

• All individuals receiving influenza vaccine in each influenza season during the

period of 01/10/2015 to 30/04/2024 (or the latest available date)

• Minimum 365 days of available history before index date

Exclusion criteria

• Individuals with missing information in sex and age

Objective 4: Population-level descriptive epidemiology of influenza-related outcomes

Inclusion criteria

• All individuals with at least one of the defined influenza-related outcomes in each influenza season during the period of 01/10/2015 to 30/04/2024 (or the latest available date)

Exclusion criteria

• Individuals with missing information in sex and age

Study design details

Data analysis plan

Period prevalence of influenza vaccines will be estimated in the general population for each influenza season from October to April, overall and stratified by age group and sex. The statistical analyses will be performed based on OMOP CDM mapped data using IncidencePrevalence R package. A minimum cell counts of 5 will be used when reporting results, with any smaller count reported as “<5”.

Documents

Study report

DARWIN EU_Report_P4-C1-016_Flu Vaccine_V3.pdf (7.83 MB)

Shiny App

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)

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

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Norwegian Linked Health registry at University of Oslo

The Information System for Research in Primary Care (SIDIAP)

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://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