EUMAEUS: Evaluating Use of Methods for Adverse Event Under Surveillance (for vaccines)

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Study Planned

Administrative details

EU PAS number

EUPAS40259

Study ID

43745

DARWIN EU® study

No

Study countries

- ☐ Netherlands
- ☐ United States

Study status

Planned

Research institutions and networks

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

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Network

Contact details

Study institution contact

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Study contact

schuemie@ohdsi.org

Primary lead investigator

Martijn J Schuemie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2021

Study start date
Planned: 01/03/2021

Date of final study report
Planned: 01/09/2021

Sources of funding

- Other

More details on funding

This is an open science study with collaborators from multiple institutions across academia, regulators, and industry

Study protocol

Protocol_1_0_0 (002).pdf (210.04 KB)

EUMAEUS_protocol updated.pdf (198.12 KB)

Regulatory

Was the study required by a regulatory body?
No

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:

The overarching aim is to identify the best methods for the generation of evidence of vaccine safety in observational, real-world data

Study Design

Non-interventional study design

Cohort

Case-control

Other

Non-interventional study design, other

Self-controlled case series, Historical rate comparison

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07B) VIRAL VACCINES

VIRAL VACCINES

Population studied

Age groups

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

2000000

Study design details

Data analysis plan

• Design: Cohort, self-controlled, and case-control studies • Exposures: previous viral vaccines including 2017-2018 flu, H1N1 flu, Human Papillomavirus (HPV), and Varicella-Zoster. • Outcomes: selected adverse events of special interest, negative control outcomes, synthetic positive control outcomes • Analyses: 1. Historical rate comparisons. 2. Cohort analyses using a contemporary non-user comparator, with large-scale propensity score matching 3. Self-controlled case series with variations 4. Case-control analyses

Documents

Study publications

Schuemie MJ, Arshad F, Pratt N, Nyberg F, Alshammari TM, Hripcsak G, Ryan P, Pr...

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)

Clinical Practice Research Datalink

Data source(s), other

CPRD

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No