

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

First published: 23/03/2021

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Study

Planned

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/43745>

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

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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:

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

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