# 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

**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

**First published:** 01/02/2024

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Network

## Contact details

**Study institution contact**

Martijn J Schuemie schuemie@ohdsi.org

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

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**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

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**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**

2.000.000

## 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