SAFETY-VAC: Network of Data Sources for Vaccine Safety Evaluation

First published: 07/06/2024

Last updated: 30/10/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000193

EU PAS number

EUPAS1000000193

Study ID

1000000193

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] France

- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

This study aims to provide and describe a network of real-world data sources to evaluate vaccine safety signals and to assess its fitness for the purpose of conducting vaccine safety studies.
SAFETY-VAC will assess the capacity to conduct safety studies in a network of 10 different electronic health record data sources from the EU PE&PV and VAC4EU networks of seven EU-EEA countries.
The study will describe data quality of the included data sources, the data source population, coverage of routine immunizations of 13 different vaccines authorized in the EU-EEA, and incidence of 39 selected events that may be potentially associated with vaccination.

Study status

Finalised

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

- [ ] Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Pedianet network

Italy

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Other

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Instituto Aragonés de Ciencias de la Salud (IACS)

Spain

First published: 01/02/2024

Last updated: 02/04/2024

Institution | Educational Institution

Agenzia regionale di sanità della Toscana (ARS)

Italy

First published: 01/02/2024

Last updated: 12/03/2024

Institution | EU Institution/Body/Agency | ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

First published: 01/02/2024

Last updated: 05/11/2024

Institution

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain

First published: 01/02/2024

Last updated: 04/09/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority | ENCePP partner

University of Oslo

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Teamit Institute

Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution | Other | ENCePP partner

Utretch University (UU)

University of Eastern Finland (UEF)

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

Belgium

Denmark

Finland

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

Last updated: 22/09/2020

Network | ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

- [ ] Netherlands

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Last updated: 26/11/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Carlos Durán Salinas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2024

Actual: 06/02/2024

Study start date

Planned: 30/01/2024

Actual: 15/02/2024

Date of final study report

Planned: 30/06/2024

Actual: 17/06/2024

Sources of funding

- EMA

Study protocol

SafetyVacProtocolObj1v1.0_FINAL.pdf(1.7 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:

Feasibility analysis

Data collection methods:

Secondary use of data

Study design:

Retrospective multi-database population-based cohort study designed during the study period from January 1st, 2017, till the last data availability, with the

aim of describing and assessing the fitness for purpose of data sources to address potential future studies on vaccine safety.

Main study objective:
This study specifically aims to provide and describe a network of real-world data sources for the evaluation of vaccine safety signals, and to assess its fitness-for-purpose through the following specific objectives:
- To assess data quality for conducting safety studies on the general population, specific vaccines, and selected outcomes.
- To assess whether data are fit-for-purpose for conducting future safety studies on specific vaccines and selected outcomes in a near real-time monitoring manner.

Study Design

Non-interventional study design
Cohort

Population studied

Short description of the study population
Electronic health records or registries data of people from 10 data sources in 7 countries in Europe from January 1st, 2017, till the last data availability were selected. Persons were included in the dynamic study population when they had:
- Information on age and gender available,
- At least one day of follow in the study period (1/1/2017- latest availability).
Follow-up started at the latest date of any of the following dates: day that one

year of lookback is available during the study period, or at 1/1/2017 when the person is born in the data base.
Follow-up finished at the earliest of the following dates: death, disenrollment, end of study period, or recommended end date. For calculation of incidence rates of outcomes, occurrence of the diagnosis of interest for the selected events was an additional censoring date.

Age groups

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

In this study a multi-database cohort has been conducted using electronic health records or registries data from 10 data sources in 7 countries in Europe (UK, Spain, Denmark, Finland, Norway, Italy and France) from January 1st, 2017, till the last data availability. Persons were included in the dynamic study

population when they had:

- Information on age and gender available,
- At least one day of follow in the study period (1/1/2017- latest availability).

Outcomes

Thirty-nine events have been selected with EMA to assess data sources preparedness and estimate diseases' incidence/prevalence rates. Clinical definition forms and codes' lists including ICD9, ICD10, SNOMED, and ICPC codes have been generated using the standardized VAC4EU process for identifying the events. The list of events included:

1. Microangiopathy
2. Acute coronary artery disease
3. Arrhythmia
4. Myocarditis
5. Pericarditis
6. VTE (DVT & PE & Splanchnic)
7. Arterial thrombosis (AMI /Ischemic stroke)
8. TTS (VTE, arterial thrombosis, or CVST with thrombocytopenia in 10 days)
9. Pulmonary embolism
10. Haemorrhagic stroke
11. DIC (disseminated intravascular coagulation)
12. CVST
13. Generalised convulsion
14. Guillain Barré Syndrome
15. Diabetes (type 1)
16. Single organ cutaneous vasculitis
17. Erythema multiforme
18. Meningoencephalitis
19. Acute disseminated encephalomyelitis (ADEM)
20. Narcolepsy

21. Thrombocytopenia
22. Transverse myelitis
23. Bells’ palsy
24. Kawasaki's disease
25. Pancreatitis
26. Rhabdomyolysis
27. SCARs
28. Sensorineural hearing loss
29. Graves' disease
30. Hashimoto's thyroiditis
31. Auto-immune hepatitis
32. Polyarteritis nodosa
33. Rheumatoid arthritis
34. Psoriatic arthropathies
35. Systemic lupus erythematosus
36. Idiopathic thrombocytopenic purpura
37. Erythema nodosum
38. Multiple sclerosis
39. Ulcerative colitis

Documents

Study report

SAFETY-VAC_1-1_Report.pdf(8.53 MB)

Data management

Data sources

Data source(s)

Pedianet network

Norwegian Health Registers

The Valencia Health System Integrated Database

EpiChron Cohort

Danish Health Data Registries

Système National des Données de Santé (French national health system main database)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Clinical Practice Research Datalink (CPRD) GOLD

The Information System for Research in Primary Care (SIDIAP)

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Data sources (types)

Disease registry

Drug registry

Electronic healthcare records (EHR)

Population registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after extract-transform-load to a common data model