SAFETY-VAC: a framework for the post-authorisation safety monitoring and evaluation of vaccines in the European Union (SAFETY-VAC)

First published: 07/06/2024
Last updated: 01/07/2024

Study | Ongoing

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
Ongoing

Research institution and networks

Institutions

University Medical Center Utrecht (UMCU)
Netherlands
First published: 24/11/2021
Last updated 22/02/2024

Pedianet network
Italy
First published: 01/02/2024
Last updated 01/02/2024

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 01/02/2024

Institution

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

Spain
First published: 01/02/2024
Last updated 01/07/2024

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

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
First published: 01/02/2024
Last updated 22/07/2024
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

Sources of funding

- EMA

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 data collection

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?

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)

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)

Data source(s), other
Finnish national data registers

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