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

First published: 07/06/2024

Last updated: 23/10/2025





Administrative details

EU PAS number	
EUPAS100000193	
Study ID	
1000000193	
DARWIN EU® study	
No	
Study countries	
Denmark	
Finland	
France	
☐ Italy	
Norway	
Spain	

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	

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





Institution
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
The Foundation for the Promotion of Health and
Biomedical Research of Valencia Region (FISABIO)
Spain
First published: 01/02/2024
Last updated: 31/10/2025



First published: 01/02/2024

Last updated: 04/09/2024

Institution (EU Institution

ig(EU Institution/Body/Agency ig) ig(

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

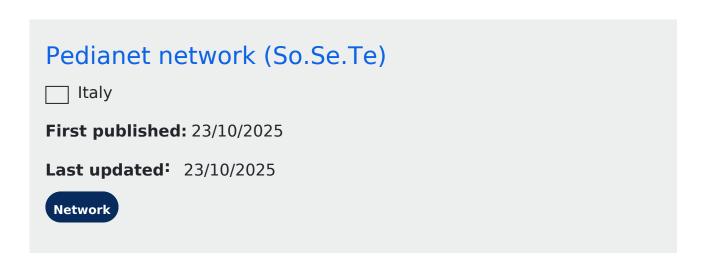
Last updated: 12/03/2024

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 Outdated ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network Netherlands First published: 01/02/2024 Last updated: 24/09/2025 Network



Contact details

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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 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

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)

Pedianet

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

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after extract-transform-load to a common data model