SAFETY-VAC: Phenotype proposal and rates of immunocompromised populations in real-world data sources.

First published: 24/02/2025

Last updated: 24/02/2025

Study **Planned**

Administrative details

EU PAS number

EUPAS1000000288

Study ID

1000000288

DARWIN EU® study

No

Study countries

☐ Denmark

☐ Finland

☐ France

☐ Italy

☐ Norway

☐ Spain

☐ United Kingdom

Study description

This SAFETY-VAC project aims to provide a consolidated approach to identify and characterise immunocompromised populations in real-world data sources and to produce incidence and prevalence rates for these populations using electronic healthcare records databases.

Study status

Planned

Research institutions and networks

Institutions

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**

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

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: 23/05/2025

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

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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: 15/05/2024

Date of final study report

Planned: 16/09/2024

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Method development or testing

Data collection methods:

Secondary use of data

Study design:

- Scoping review aimed at describing and identifying immunocompromised populations in epidemiological studies using EHRs.
- Retrospective cohort study from January 1, 2017, to the last available data aimed at identifying and characterizing these populations using RWD.

Main study objective:

- To describe what operational definitions are used to identify immunocompromised populations when conducting epidemiological research in EHR databases and propose a phenotype to identify immunocompromised individuals in database studies correctly.
- To estimate the incidence and one-year prevalence rates of immunocompromised status based on the agreed phenotype and different durations of episodes.
- To assess the contribution of different provenances of data and durations to the prevalence of the immunocompromised status.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Electronic health records of people from 10 data sources in 7 countries in Europe from January 1st, 2017, until the last data availability were selected.
Persons were included in the 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.

Age groups

Paediatric Population (< 18 years)

Adult and elderly population (≥18 years)

Study design details

Setting

The study will use data from 10 secondary electronic health record databases that are population-based in 7 countries in Europe (UK, Spain, Denmark, Finland, Norway, Italy and France).
The study will be conducted during the period from January 1st, 2017, to the last data availability, specific for each data source.

The source population comprises all persons in the data sources who can be potentially included in the study.

Documents

Study report

SAFETY-VAC_Immunocompromised_population_D4_Report.pdf(1009.31 KB)

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)

Data source(s), other

Finnish national data registers

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