# ACCESS template protocol for safety of COVID-19 vaccines

**First published:** 19/02/2021

**Last updated:** 01/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS39361

**Study ID**

50436

**DARWIN EU® study**

No

**Study countries**

- Belgium
- Denmark
- France
- Italy
- Netherlands
- Norway

Spain

United Kingdom

**Study description**

This listing includes the four different safety protocol templates to monitor COVID-19 vaccine safety. These protocols were prepared on request of EMA and have been reviewed by EMA and stakeholders. Protocols require finalization by the final users and are not conducted as such. This registration includes the following protocols: 1. Cohort event monitoring to assess safety of COVID-19 vaccines using patient reported events, a protocol template from the ACCESS project 2. Rapid assessment of COVID-19 vaccines safety concerns through electronic health records: a protocol template from the ACCESS project 3. Safety evaluation of COVID-19 vaccines through electronic health records: a protocol template from the ACCESS project 4. Safety Protocol for Hospital Case–Based Monitoring of Specific Adverse Events Following COVID-19 Vaccines: A Protocol Template from the ACCESS project Section 19 includes the template protocols. Word documents can be retrieved from study authors or PI. Section 19 includes the final ACCESS report with feasibility assessment

**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

## Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

**First published:** 01/03/2010

**Last updated:** 23/05/2024

Institution | Educational Institution | ENCePP partner

## Health Search, Italian College of General Practicioners

Italy

**First published:** 02/03/2010

**Last updated:** 20/08/2024

Institution | Educational Institution | Other

## Unit of Clinical Psychopharmacology and Drug Epidemiology, University of Verona

Italy

**First published:** 17/07/2012

**Last updated:** 03/07/2014

Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

## Netherlands Pharmacovigilance Centre Lareb

Netherlands

**First published:** 05/02/2010

**Last updated:** 19/07/2016

Institution | Outdated | Not-for-profit | ENCePP partner

## PharmacoEpidemiology Unit (PELyon), Claude Bernard Lyon 1 University

France

**First published:** 27/04/2010

**Last updated:** 21/09/2016

Institution | Outdated | Educational Institution | ENCePP partner

## Department of Epidemiology of the Regional Health Service - Lazio

Italy

**First published:** 23/03/2010

**Last updated:** 22/06/2018

Institution | Outdated | EU Institution/Body/Agency | ENCePP partner

## Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

**First published:** 29/03/2010

**Last updated:** 30/03/2026

Institution | Not-for-profit | 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

## Drug Safety Research Unit (DSRU)

United Kingdom

**First published:** 10/11/2021

**Last updated:** 09/01/2026

Institution | Not-for-profit | 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

## Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

Italy

**First published:** 29/11/2021

**Last updated:** 20/08/2024

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

## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

**First published:** 07/01/2022

**Last updated:** 19/12/2025

Institution | Non-Pharmaceutical company | ENCePP partner

## RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

Institution | Not-for-profit | ENCePP partner

## Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

**First published:** 25/10/2022

**Last updated:** 13/03/2025

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:** 08/12/2025

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

## 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**

## Multiple centres: 20 centres are involved in the study

# 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


**Study institution contact**

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Study contact

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**Primary lead investigator**

Miriam Sturkenboom

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 21/05/2020

Actual: 21/05/2020

**Study start date**
Planned: 21/05/2020

Actual: 21/05/2020

**Date of final study report**
Planned: 15/12/2020

Actual: 30/06/2021

## Sources of funding

- EMA

## Study protocol

3c.Protocol_ACCESS_Safety-Evaluation-EHR.pdf (1.27 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:**

Other

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**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Assess the safety of COVID-19 vaccines

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective multi-database dynamic study

## Population studied

**Short description of the study population**

The study included general population to determine safety of covid-19 vaccines.

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**Age groups**

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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)

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**Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

**Estimated number of subjects**

1000000

## Study design details

**Outcomes**

All AESI

**Data analysis plan**

Depends on the study protocol template and study implementation

## Documents

**Study report**

EUPAS39361-39356.pdf (1.92 MB)

**Study, other information**

3a.Cohort-event-monitoring-to-assess-safety-of-COVID-19-vaccines-using-patient-reported-events-a-protocol-template-from-the-ACCESS-project.pdf (1.37 MB)

3b.Rapid-assessment-of-COVID-19-vaccines-safety-concerns-through-electronic-health-records-a-protocol-template-from-the-ACCESS-project-.pdf (1.2 MB)

3d.Safety-Protocol-for-Hospital-Case–Based-Monitoring-of-Specific-Adverse-Events-Following-COVID-19-Vaccines-A-Protocol-Template-from-the-ACCESS-project.pdf (1.21 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 sources (types)**

Other

**Data sources (types), other**

Choice of data sources depends on the protocol template and the study implementation

# 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