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

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

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: 16/02/2024

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: 24/07/2024

Institution | Laboratory/Research/Testing facility | 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: 08/02/2023

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 | ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

☐ Netherlands

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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

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Assess the safety of COVID-19 vaccines

Study Design

Non-interventional study design

Cohort

Other

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.

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)

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