# Coverage of COVID-19 vaccines in electronic healthcare databases: a protocol template from the ACCESS project

First published: 19/02/2021

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





## Administrative details

EU PAS number	
UPAS39370	EUPAS393
tudy ID	Study ID
0439	50439
ARWIN EU® study	DARWIN I
0	No
tudy countries	Study cou
Italy	Italy
Netherlands	Nether
Spain	Spain
United Kingdom	United

#### **Study description**

As part of the preparedness activities for surveillance of COVID-19 vaccines, this template protocol provides a template for quickly developing a full study protocol to perform vaccine coverage studies through the secondary use of electronic healthcare data bases and/or immunization registers. This protocol has been accepted by EMA as a deliverable of the framework contract No EMA/2018/28/PE.

#### **Study status**

**Finalised** 

### Research institutions and networks

#### **Institutions**



#### **Networks**

Vaccine monitoring Collaboration for Europe (VAC4EU)

☐ Belgium
☐ Denmark
Finland
France
Germany
Italy
☐ Netherlands
── Norway
Spain
United Kingdom
First published: 22/09/2020
<b>Last updated:</b> 22/09/2020
Network Outdated ENCePP partner
EU Pharmacoepidemiology and Pharmacovigilance
(PE&PV) Research Network
☐ Netherlands
Eirat published: 01/02/2024
First published: 01/02/2024
<b>Last updated:</b> 24/09/2025

# 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: 19/05/2020

Actual: 19/05/2020

#### Study start date

Planned: 19/05/2020

Actual: 19/05/2020

#### **Date of final study report**

Planned: 15/12/2020

Actual: 08/01/2021

## Sources of funding

EMA

# Study protocol

# 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:

Drug utilisation

Other

#### If 'other', further details on the scope of the study

Coverage evaluation

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

This is a template protocol to determine exposure and coverage to COVID-19 vaccines and to determine exposure and coverage to COVID-19 vaccines in specific subgroups that are targeted for vaccination.

# Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Retrospective (multi)-database study

## Population studied

#### Short description of the study population

The study included all patients registered in the electronic medical record databases, claims databases or population-based immunizations registers that capture electronic information on the covid-19 vaccine.

#### 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

#### Data analysis plan

This protocol template includes a section describing descriptive analysis, measures of coverage, data integration, subroup analysis and sensitivity analysis as well as quality control.

## **Documents**

#### **Study report**

## 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)**

Administrative healthcare records (e.g., claims)
Electronic healthcare records (EHR)

## 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