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

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50439

EU PAS number

EUPAS39370

Study ID

50439

DARWIN EU® study

No

Study countries

☐ Italy

☐ Netherlands

☐ Spain

☐ United Kingdom

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

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**

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

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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: 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

3g.Protocol_ACCESS_CoverageEvaluation.pdf(1.33 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:

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

EUPAS39370-39369.pdf(1.92 MB)

Data management

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