Benefit Risk contextualisation of COVID-19 vaccines in the EU

First published: 24/11/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS44229

Study ID

47485

DARWIN EU® study

No

Study countries

Belgium

Study description

The Belgian CenStat/I-BioStat team is delighted to contribute to EMA’s important task to monitor important benefits and safety signals of COVID-19 vaccines by addressing three specific objectives. The first objective is to

propose a valid method to quantify both the benefits and the risks related to COVID-19 vaccines given potential data limitations and reflecting uncertainty with regard to the various ingredients of the proposed risk-benefit measure. The second objective is to explore the possibility of developing composite measure The third objective is to provide a toolkit to support the calculations and interpretation of the various outcomes.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Geert Molenberghs

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/07/2021

Actual: 27/07/2021

Study start date

Planned: 04/08/2021

Actual: 04/08/2021

Date of final study report

Planned: 25/04/2022

Actual: 25/05/2022

Sources of funding

- EMA

Study protocol

COVID 19 risk benefit analysis for EMA- study protocol .pdf (484.14 KB)

Study protocol EUPAS44229.pdf (486.36 KB)

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

1) to propose a valid method to quantify both the benefits and the risks related to COVID-19 vaccines given potential data limitations and reflecting uncertainty with regard to the various ingredients of the proposed risk-benefit measure. 2) to explore the possibility of developing composite measures. 3) to provide a toolkit to support the calculations and interpretation of the various outcomes.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BN) Covid-19 vaccines

Covid-19 vaccines

Medical condition to be studied

COVID-19 immunisation

Additional medical condition(s)

Adverse events likely to associated to COVID-19 vaccines as reported to EudraVigialance (e.g. myocarditis, TTS)

Population studied

Short description of the study population

Individuals who have received COVID-19 vaccines.

Age groups

- 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)

Estimated number of subjects

44800000

Study design details

Data analysis plan

For the benefit of COVID-19 vaccines assessment: Dynamic disease transmission models will be used to study multiple benefits and take into account uncertainty about parameter estimates. Both the societal perspective, via compartmental models, and the individual perspective, via individual-based models, belong to this family of dynamic transmission models. For the risk assessment: The ratio of the observed events and patients exposed to vaccine results in an estimate for the probability of the risk after vaccination. The probability of risk in the unvaccinated population or background risk can be retrieved through background rates provided (or estimated) by EMA. Additional benefits and risks can be added to the model, as well as additional covariates such as comorbidities and additional compartments for vaccines or mixed vaccines.Uncertainty of input variables can be incorporated into priors into the Bayesian analysis. Alternatively, sensitivity analysis can be performed.

Documents

Study results

EMA_COVID19_vaccines_final_report_20042022.pdf (5.55 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 source(s), other

EudraVigilance

Data sources (types)

Other

Data sources (types), other

Case-control surveillance database, ECDC data: The European Surveillance System (TESSy) (europa.eu). Eurostat data: Population data for all EU/EEA Member States Eu data: Effectiveness of COVID-19 vaccines Eu data: Data on COVID-19 vaccination in the EU/EEA (europa.eu) Dashboard Background rates of Adverse Events of Special Interest for COVID-19 vaccines - VAC4EU

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