Study of brand-specific COVID-19 vaccine effectiveness against severe COVID-19 disease in Europe (former COVIDRIVE)

First published: 02/08/2021

Last updated: 25/09/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS42328

Study ID

49374

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Finland
- France

Germany
Iceland
Italy
Luxembourg
Poland
Romania
Spain
United Kingdom

Study description

This Master Protocol describes a non-interventional study to estimate the effectiveness of coronavirus disease 2019 (COVID-19) vaccines against severe COVID-19 in Europe.
The study is a multi-country, hospital-based, case-control study with test-negative controls (test-negative case-control design, TNCC).

This Master Protocol will be used to create Study Requestor-specific protocols that meet the requirements of the Study Requestors (Pharmaceutical Company Partners) and to create site-specific protocols that reflect the data collection and requirements at the specific study sites (Study Contributors).

This Master Protocol is set up to harmonise study methods (e.g., study objectives, subject inclusion/exclusion criteria, case definitions, exposures, outcomes, and data collection) and to mutualise healthcare providers/study site resources.

- - Update 01 Sep 2026- -
From 01 Sep 2026 (start of the id.DRIVE epidemiological year 2026-2027), the three id.DRIVE master study protocols (EUPAS1000000012, EUPAS42328, and EUPAS1000000035) are merged into one common master protocol

(EUPAS1000000012; V3.0 02 Mar 2026).

New, common study title:
Surveillance of Respiratory Pathogens and Brand-Specific Vaccine Effectiveness in Adults Hospitalised with SARI: An Observational Study
This means that the respiratory pathogen surveillance protocol (EUPAS1000000012; ongoing) now also incorporates the RSV vaccine effectiveness (EUPAS1000000035; ongoing; RSV VE module) and COVID-19 vaccine effectiveness (EUPAS42328; paused; CVE module) studies. EUPAS42328 and EUPAS1000000035 are updated accordingly in this register (the reader of those two is now referred to EUPAS1000000012).

Study status

Ongoing

Research institutions and networks

Institutions

P95 Julius Clinical (former P95 Clinical and Epidemiology Services)

- Belgium
- Colombia
- Netherlands
- South Africa
- Thailand
- United States

First published: 07/11/2022

Last updated: 24/09/2026

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

First published: 01/02/2024

Last updated: 31/10/2025

Institution

University Hospital Vall d'Hebron (HUVH)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

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

Imperial College London

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Valencia Hospital Network for the Study of Influenza and Other Respiratory Viruses (VAHNSI)

Germans Trias i Pujol University Hospital

Hospital Clínico Universitario de Santiago de Compostela

Hospital Universitario La Paz

Hospital Clínic Universitari Barcelona

Grand Hôpital de Charleroi

UZA University Hospital Antwerp

CHU Saint-Pierre Hospital Brussels

Klinik Favoriten Hospital

Centro Interuniversitario per la Ricerca

sull’Influenza e le altre Infezioni (CIRI-IT)

Ospedale Luigi Sacco

Universitätsklinikum Freiburg

Universitätsklinikum Ulm

Universitätsklinikum Frankfurt

Charité - Universitätsmedizin Berlin

Manchester University NHS Foundation Trust (MFT)

NHS Lothian

Hôpitaux Universitaires Henri-Mondor

Centre Hospitalier Annecy Genevois and St Julien

Networks

id.DRIVE (former COVIDRIVE)

- Austria
- Belgium
- Canada

Croatia
Czechia
Denmark
France
Germany
Iceland
Italy
Poland
Romania
Spain
United Kingdom

First published: 06/09/2021

Last updated: 04/05/2026

Network **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kaatje Bollaerts

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/08/2021

Study start date
Planned: 15/08/2021

Actual: 08/09/2021

Date of final study report
Planned: 01/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Current and former partners of COVIDRIVE and id.DRIVE:

AstraZeneca, Bavarian Nordic, CureVac, GSK, Johnson & Johnson, Moderna, Novavax, Pfizer, Sanofi, and Valneva

Study protocol

COVIDRIVE_TND-VE_MasterProtocol_v3.1.pdf (3.85 MB)

Master Protocol Surveillance + VE_V3.0_02 Mar 2026.pdf (830.1 KB)

COVID-19 Vaccine Effectiveness protocol v7.0_21 Feb 2025.pdf (727.1 KB)

COVID-19 Vaccine Effectiveness protocol v7.0_21 Feb 2025.pdf (727.1 KB)

COVID-19 Vaccine Effectiveness protocol v7.0_21 Feb 2025.pdf (727.1 KB)

CVE_Master Protocol v6.0_21 Mar 2024.pdf (883.8 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

Link to id.DRIVE.eu

Interim analysis AstraZeneca (AZD1222, ChAdOx1 nCoV-19)

Final analysis AstraZeneca (AZD1222, ChAdOx1 nCoV-19)

Final analysis Janssen (JCOVDEN, Ad26.COV2.S)

Interim analysis Pfizer (BNT162b2 XBB.1.5-adapted vaccine)

Final analysis Pfizer (BNT162b2 XBB.1.5-adapted vaccine)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This study is a multi-country, multi-centre, hospital-based case-control study with test-negative controls (TNCC design).
A combination of primary and secondary data collection will be used to obtain the relevant data.

Main study objective:

To estimate brand-specific COVID-19 vaccine effectiveness (CVE) against hospitalisation due to laboratory-confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in SARI patients who have received [vaccine dose of interest], compared to [selected comparator group].

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Test-negative case-control

Study drug and medical condition

Medicinal product name

COMIRNATY

COVID-19 VACCINE (INACTIVATED, ADJUVANTED)

JCOVDEN

NUVAXOVID

VAXZEVRIA

Medicinal product name, other

COVID-19 vaccine (Ad26.COV2-S [recombinant])

COVID-19 vaccine (ChAdOx1-S [recombinant])

Study drug International non-proprietary name (INN) or common name

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)

FAMTOZINAMERAN

RAXTOZINAMERAN

RILTOZINAMERAN

TOZINAMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN) Covid-19 vaccines

Covid-19 vaccines

Medical condition to be studied

Respiratory tract infection

Severe acute respiratory syndrome

Additional medical condition(s)

Severe Acute Respiratory Infection (SARI)

Population studied

Short description of the study population

The study population consists of individuals (patients), presenting at the participating hospitals during the study period, who were ever eligible for COVID-19 vaccination following the national/regional immunisation recommendations prior to hospital admission AND from whom informed consent is obtained (alternative: informed consent from legally acceptable representative) AND are hospitalised (=person admitted to the hospital with overnight stay) AND meet the severe acute respiratory infection (SARI) case definition but HAVE NOT BEEN hospitalised with COVID-19 within 3 months prior to the current admission and DO NOT HAVE any contraindication for swabbing and DID NOT receive their last vaccine dose with any other than EMA-approved COVID-19 vaccine brand (EMA approval status at time of hospitalisation).

Age groups

- 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

15.000

Study design details

Setting

Hospitals

Comparators

Unvaccinated or not recently vaccinated patients

Outcomes

The outcome of interest for the primary analysis will be SARS-CoV-2 detection in patients hospitalised with SARI symptoms.
SARS-CoV-2 infection should be laboratory-confirmed by reverse transcription polymerase chain reaction (RT-PCR) or another RNA amplification system with at least the same sensitivity as RT-PCR (e.g., transcription-mediated amplification (TMA)).
As the SARS-CoV-2 testing practices might change over time, the test requirement for confirmation of COVID-19 disease might be revisited. The impact of such revisions on the potential for disease misclassification will be considered.

Data analysis plan

A SAP is developed prior to the conduct of the analysis.
The SAP specifies all statistical analyses conducted, and includes tables shells and mock figures.

Summary results

See https://iddrive.eu/deliverables/

Documents

Study publications

id.DRIVE publications list

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)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Non-interventional study

Other

Spontaneous reports of suspected adverse drug reactions

Vaccination registry

Data sources (types), other

Vaccination registries, vaccination cards, medical records, laboratory data (RT-PCR and genetic variants).

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction