# id.DRIVE (former COVIDRIVE) study of brand-specific COVID-19 vaccine effectiveness against severe COVID-19 disease in Europe

**First published:** 02/08/2021

**Last updated:** 01/10/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS42328

**Study ID**

49374

**DARWIN EU® study**

No

**Study countries**

- ☐ France
- ☐ Germany
- ☐ Italy

- [ ] 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.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### P95 Clinical and Epidemiology Services

- [ ] Belgium
- [ ] Colombia

- [ ] Netherlands
- [ ] South Africa
- [ ] Thailand
- [ ] United States

**First published:** 07/11/2022

**Last updated:** 21/02/2025

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

## Centro Interuniversitario per la Ricerca sull'Influenza e le altre Infezioni (CIRI-IT)

## Universitätsklinikum Ulm

## Charité - Universitätsmedizin Berlin

Manchester University NHS Foundation Trust (MFT)

NHS Lothian

Hôpitaux Universitaires Henri-Mondor

Centre Hospitalier Annecy Genevois

## Networks

### id.DRIVE (former COVIDRIVE)

- [ ] Austria
- [ ] Belgium
- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Iceland
- [ ] Italy
- [ ] Poland
- [ ] Romania
- [ ] Spain

**First published:** 06/09/2021

**Last updated:** 29/02/2024

Network ENCePP partner

## Contact details

**Study institution contact**

Kaatje Bollaerts kaatje.bollaerts@p-95.com

Study contact

kaatje.bollaerts@p-95.com

**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: 01/12/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca, Johnson & Johnson, Novavax, Valneva, Pfizer

## Study protocol

COVIDRIVE_TND-VE_MasterProtocol_v3.1.pdf (3.85 MB)

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

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**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)

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

# Methodological aspects

## Study type

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**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**

Case-control

## Study drug and medical condition

**Medicinal product name**

COMIRNATY

COVID-19 VACCINE (INACTIVATED, ADJUVANTED)

JCOVDEN

NUVAXOVID

VAXZEVRIA

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**Medicinal product name, other**

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

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

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**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

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BN) Covid-19 vaccines

Covid-19 vaccines

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**Medical condition to be studied**

Respiratory tract infection

# 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**

15000

## 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.

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**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.

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**Summary results**

See interim analyses by AstraZeneca and Pfizer (Study publications section)

See final analyses by AstraZeneca and Janssen (Study publications section)

# Documents

**Study results**

COVIDRIVE_Pfizer interim.pdf (878.86 KB)

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# 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

Other

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**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

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes

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**Data characterisation moment**

after data extraction