

# id.DRIVE study of brand-specific respiratory syncytial virus (RSV) vaccine effectiveness in Europe

**First published:** 01/03/2024

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000035

### Study ID

1000000035

### DARWIN EU® study

No

### Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain

☐ United Kingdom

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### Study description

This is a European, non-interventional study to estimate the effectiveness of vaccines against respiratory syncytial virus (RSV). Of interest is the effectiveness against hospitalisation with severe acute respiratory infection (SARI) caused by RSV.

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### 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:** 05/11/2024

**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

Hôpitaux Universitaires Henri-Mondor  
Centre Hospitalier Annecy Genevois

Manchester University NHS Foundation Trust  
(MFT)  
NHS Lothian

## 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

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Study contact

[kaatje.bollaerts@p-95.com](mailto:kaatje.bollaerts@p-95.com)

## Primary lead investigator

Kaatje Bollaerts

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/03/2024

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### Study start date

Planned: 01/06/2024

Actual: 29/08/2024

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### Date of final study report

Planned: 01/12/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[RSV\\_Master Protocol V2.0\\_07 Jun 2024.pdf](#) (994.21 KB)

[RSV Vaccine Effectiveness protocol v3.0\\_21 Feb 2025.pdf](#) (856.05 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

Other study registration identification numbers and links

<https://iddrive.eu>

## Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

**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 RSV vaccine effectiveness (VE) against hospitalisation due to laboratory-confirmed RSV infection in severe acute respiratory infection (modified SARI) older adult patients.

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Name of medicine**

ABRYSVO

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**Name of medicine, other**

Respiratory syncytial virus vaccine (bivalent, recombinant)

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BX05) respiratory syncytial virus vaccines  
respiratory syncytial virus vaccines

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## Medical condition to be studied

Severe acute respiratory syndrome

## Population studied

### Short description of the study population

The study population consists of hospitalised "modified severe acute respiratory infection (SARI)"\*  $\geq 60$  year-old patients.

A "modified SARI"\* patient is a person hospitalised primarily for a suspicion of a respiratory infection with at least one of the following symptoms:

- cough,
- shortness of breath,
- fever ( $\geq 38^{\circ}\text{C}$ )

with symptom onset within the last 10 days prior to hospital admission.

\*This SARI definition is modified from the latest European Centre for Disease Prevention and Control (ECDC) case definition [EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (2021). ECDC Technical report: Core protocol for ECDC studies of COVID-19 vaccine effectiveness against hospitalisation with Severe Acute Respiratory Infection laboratory-confirmed with SARS-CoV-2, version 1.0, 2021].

## Study design details

### Setting

Hospitals

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### Outcomes

The outcome of interest for the primary analysis will be RSV detection in patients hospitalised with symptoms consistent with the modified ECDC SARI definition.

RSV infection must be laboratory-confirmed by reverse transcription polymerase chain reaction (RT-PCR) or another ribonucleic acid (RNA) amplification system with at least the same sensitivity as RT-PCR (e.g., transcription-mediated amplification [TMA]). RT-PCR assays must be used for the detection of at least RSV, SARS-CoV-2, and influenza.

The secondary outcomes in patients hospitalised with modified SARI symptoms include:

- detection of RSV subtypes A and B
- detection of RSV genotypes
- modified SARI severity level of study participants (both cases and controls), including respiratory support severity level

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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.

## **Documents**

[Link to id.DRIVE.eu](#)

## **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.

## 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