Brand-specific respiratory syncytial virus (RSV) vaccine effectiveness in Europe

First published: 01/03/2024

Last updated: 29/10/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000035

Study ID

1000000035

DARWIN EU® study

No

Study countries

Canada

Germany

Spain

United Kingdom

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.

- - 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

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)

Universitätsklinikum Ulm

Charité - Universitätsmedizin Berlin

Universitätsklinikum Düsseldorf

Universitätsklinikum Essen

Manchester University NHS Foundation Trust (MFT)

NHS Lothian

The Ottawa Hospital

The Toronto Invasive Bacterial Diseases Network

(TIBDN)

Calgary Corridor Hospitals

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: 15/03/2024

Study start date

Planned: 01/06/2024

Actual: 29/08/2024

Date of final study report

Planned: 01/03/2028

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)

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

RSV Vaccine Effectiveness protocol v3.0_21 Feb 2025.pdf (856.05 KB)

RSV Vaccine Effectiveness protocol v3.0_21 Feb 2025.pdf (856.05 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Link to id.DRIVE webpage

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study topic, other:

RSV vaccine effectiveness, Severe Acute Respiratory Infection (SARI), hospitalisation

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

If ‘other’, further details on the scope of the study

Vaccine effectiveness

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 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

Other

Non-interventional study design, other

Test-negative case control

Study drug and medical condition

Medicinal product name

ABRYSVO

Medicinal product name, other

Respiratory syncytial virus vaccine (bivalent, recombinant)

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

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 hospitalised "modified severe acute respiratory infection (SARI)"* ≥18 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:

• new or worsening cough,

• new or worsening shortness of breath,

• fever (≥38 C^0)

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

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

Study publications

Link to 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)

Non-interventional study

Spontaneous reports of suspected adverse drug reactions

Vaccination registry

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